RECORD NO: 2012/12009P

THE HIGH COURT

BETWEEN:

AOIFE BENNETT

PLAINTIFF

AND

THE MINISTER FOR HEALTH AND CHILDREN, THE HEALTH SERVICE EXECUTIVE, AND GLAXOSMITHKLINE BIOLOGICALS S.A.

DEFENDANTS

AFFIDAVIT OF GILLIAN O'CONNOR

1. I, Gillian O'Connor, Partner in Augustus Cullen Law, aged 18 years and upwards, MAKE OATH and say as follows:

2. I am a Solicitor in the firm of Augustus Cullen Law, who are acting for and on behalf of the Plaintiff in the above-entitled proceedings. I am duly authorised by the Plaintiff to make this Affidavit for and on behalf and I do so from facts within my own knowledge, save where otherwise appears and where so otherwise appears I believe the same to be true.

3. I beg to refer to the pleadings had herein when produced.

4. I say that the within is an Application to join the Health Products Regulatory Authority as a Defendant in the within proceedings. I say that the Health Products Regulatory Authority (HPRA) is a State agency whose role is to protect and enhance public and animal health by regulating medicines, medical devices and other health products and monitoring the safety of cosmetics. The HPRA was formerly the Irish Medicines Board. It changed its name to the Health Products Regulatory Authority on 1 July 2014.

5. I further say that your Deponent first wrote to the First and Second named Defendants in relation to this matter on 9 November 2012. The Personal Injuries Summons for Plaintiff, was served upon the Chief State Solicitor's Office on behalf of the First and Second Named Defendants on 15 November 2013 together with the Affidavit of Verification on 2 December 2013. It was served upon McCann Fitzgerald, Solicitors, on behalf of the Third Named Defendant on 15th of November 2013 together with the Affidavit of Verification on 26th of November 2013. I beg to refer to a copy of said letters and pleadings, upon which, marked with the letters and number **"GOC1"** I have endorsed my name prior to the swearing hereof.

6. I say that a Defence on behalf of the Third Named Defendant was delivered on 30 April 2015 and that a Defence on behalf of the First and Second Named Defendants was delivered on 19 May 2015. I say further that the Plaintiff's Reply to the Defence of the First and Second Named Defendants was delivered on 23 September 2015 and that the Plaintiff's Reply to the Defence of the Third Named Defendant was delivered on the same date.

7. I say that the within proceedings are for serious personal injuries alleged to have been caused to the Plaintiff by the wrongful acts of the Defendants relating to the administration to her of the Pandemrix vaccine, produced by the Third Named Defendant. I say that the Plaintiff was born on 21 December 1992. I say further that the First Named Defendant is responsible for the governance, operation and management of the public health and medical system in Ireland, and is entrusted with a duty to take all reasonable steps to ensure the safe administration of public health and medical services in the State and that the Second Named Defendant is responsible for the provision of public health and medical services in the State, as well as the provision of appropriate advice and the promotion of health.

8. I say that, in the Personal Injuries Summons, the Plaintiff alleges that the First and Second Named Defendants owed the Plaintiff duties of care in and around their decision to recommend and administer the Pandemrix vaccine in this jurisdiction; that they owed the Plaintiff further duties in and around the advice they gave and caused to be given with respect to the Pandemrix vaccine and its potential effects and risks of injury, in and around administration of the vaccine through their servants or agents, and in and around their response to health complications and injuries suffered in consequence of having received the said vaccine.

9. I say and am advised that the Third Named Defendant is the producer of the Pandemrix vaccine, that the said vaccine was a product and the Defendant was its producer for the purposes of the Liability for Defective Products Act, 1991 I say and am advised further that, in the Personal Injuries Summons, the Plaintiff alleges that the Third Named Defendant owed her additional duties of care, to take all reasonable steps to ensure the safety of its product, and to investigate sufficiently, the associated risks of

injury, and to warn purchasers and users of the vaccine as to the risks of injury, known and unknown.

10. I say that, in the midst of concern as to the health risks posed by 'human swine influenza' in 2009 and 2010, the First and Second Named Defendants purchased, approved and administered in the State a form of the Pandemrix vaccine manufactured and produced by the Third Named Defendant in Dresden. I say further that the Second Named Defendant thereupon adopted and ran a Pandemrix vaccine programme in the State, administering the vaccine through its servants or agents in local hospitals, clinics and schools.

11. I say that, following warnings by the HSE on the risks associated with human swine flu, the Plaintiff was administered the Pandemrix vaccine at a HSE clinic in St Mary's College, Naas, Co. Kildare, on 8 December 2009.

12. I say that in the Personal Injuries Summons, the Plaintiff alleges that in consequence of receiving the Pandemrix vaccine, the Plaintiff proceeded to suffer a narcolepsy and cataplexy disorder, involving severe personal injuries, damages and loss, which has required her to attend doctors regularly for investigation and management of the condition, with highly disruptive ongoing effects for every activity of her daily life. In the months following vaccination, the Plaintiff developed excessive daytime sleepiness, disruption to nocturnal sleep, and episodes of sudden weakness and cataplexy. She fell spontaneously in the shower, chipping her teeth, and thereafter had recurrent falls and collapses. She also had fainting fits. After a range of medical interventions, the Plaintiff underwent a nocturnal polysomnogram and multiple sleep latency test in April 2011, which yielded highly abnormal findings, indicative of narcolepsy.

13. I say that the Plaintiff's quality of life has been very seriously curtailed as a result of her condition. I say that she has suffered significant mental distress, anxiety and worry arising from the condition, its diagnosis, and the potential implications into the future, personally, socially and occupationally.

14. I say that the Plaintiff had always been a high achiever in school. After these injuries developed, however, she routinely suffered morning fatigue, significant drops in her concentration and energy levels, which hindered her abilities at college. Throughout 2010, she was observed by her teachers to "zone out" in class and she was required to miss five or six weeks of school as well as shorten her class times. The medication contributed to her drowsiness. She was obliged to repeat fifth year. She postponed sitting her Leaving Certificate in 2011.

15. I say that the Plaintiff had previously been excellent at sports and had represented her school in athletics, cross country running and volleyball. She had represented her county for the All Irelands in cross country running. Following her profound tiredness and regular cataplectic episodes, she was required to discontinue these activities. This resulted in a substantial increase in her weight.

16. I say that despite her disability, the Plaintiff completed a three year Primary Degree in English and Irish in 2015 and this was not without serious difficulty. She completed her course at St Patrick's College in Drumcondra over a three year period and had to frequently return home, coming home every weekend and was frequently ill during term time. This resulted in increased financial costs. She was unable to work during the summer months or travel due to the severity of her illness. She is dependent on her parents for all physical, psychological and economic support. During exam times, she sought support from the HSE but was told there was nothing available as there was no precedent in providing this care because of the uniqueness of her situation. Throughout her college years, she struggled to complete her course and was unable to sit her second year exam because of a severe cataplexy attack. This attack was so severe, the College contacted her parents and requested that they come and collect her. Despite all of this, the Plaintiff managed to get her degree in the required three year period.

    The Plaintiff had aspirations to train as a primary school teacher and this required a further two years Masters in Education. In between, she tried to obtain part time work with children to gain some experience. She commenced her Masters Degree in September 2016. This is an online based course with Hibernia College. She attends one day a week for a full day and has 20 hours tutorials on line, as well as Webinars per week as a thesis and assignments to complete. She also has had to complete 24 weeks of teaching practice over a 2 year period. Because of the Plaintiff's disability, the cost of the Masters and her study commitments have escalated. The Plaintiff has had to return to live with her parents resulting in a loss of independence for her. It is only through her parents' financial, psychological and physical support that she has struggled through the second course of the Master Degree. The Plaintiff has been unable to work at any part time jobs which would be the norm for students like her at her age but because of her health, this has not been feasible and so, the full cost of the Master's Degree of €14,000 has fallen upon her parents and proved to be a further financial burden for the family. Furthermore, the Plaintiff has continued to have other repeated illnesses such as glandular fever and sinus problems as verified by her Consultant Dr Catherine Crowe. Because of her narcolepsy and cataplexy, the Plaintiff has been unable to complete assignments on time, needs extra time during the day to sleep and eat during exam periods. In all, the Plaintiff's life as a College student was very seriously compromised by her condition of Narcolepsy with Cataplexy. She suffered nightmares and hallucinatory dreams on a regular basis. The medication she has been prescribed has reduced this effect over time but she remains constantly tired. Even now, she can only sleep for approximately 2 ½ hours in between doses of Xyrem and can still remain drowsy and tired on waking. As a result of all these difficulties, the Plaintiff suffers from anxiety and has had severe difficulty in completing her Master's Degree.

17. I say that the Plaintiff did not begin to acquire knowledge of a possible association between her personal injuries and the Pandemrix vaccine for the purposes of the

Statute of Limitations Acts, 1957-1991, until after it began to be discussed in the media and magazine publications from about March 2011.

18. I say that, in her Personal Injuries Summons, the Plaintiff alleges that negligence and breaches of duty (including breaches of statutory duty) on the part of the Defendants and their servants or agents caused the Plaintiff to suffer her severe personal injuries, damage and loss, and/or that they caused the Plaintiff to lose a material chance of avoiding some or all of the said personal injuries, damage and loss. The Plaintiff alleges that the First and Second Named Defendants and/or their servants or agents were guilty of negligence and breach of duty by:

a) Approving and/or adopting the Pandemrix vaccine for a national vaccination programme;
b) Recommending the Pandemrix vaccine;
c) Administering the Pandemrix vaccine;
d) Failing to satisfy themselves, sufficiently or at all, as to the risks of injury known to be associated with the Pandemrix vaccine;
e) Failing to satisfy themselves, sufficiently or at all, as to the unknown risks of injury potentially associated with the Pandemrix vaccine;
f) Failing to seek further information on all the potential risks posed by administration of the vaccine in this jurisdiction;
g) Failing to warn, sufficiently or at all, as to the known risks and/or the unknown risks and/or the uncertainties and/or the potential consequences of receiving the vaccine;
h) Failing to approve or recommend alternative vaccines about which more was known at the time;
i) Failing to have regard, sufficiently or at all, to the incidences of genetic predisposition to narcolepsy;
j) Failing to provide and/or delaying in the provision of adequate treatment to ameliorate the physical effects of the disorder;
k) Failing to provide and/or delaying in the provision of adequate treatment to ameliorate the effects of the disorder for education;
l) Failing to provide and/or delaying in the provision of adequate treatment to ameliorate the effects of the disorder for mental welfare;
m) Failing to advise the public at an earlier date of the association between the Pandemrix vaccine and narcolepsy and cataplexy.
n) Failing to offer the Plaintiff an alternative choice of vaccine including the Celvapan vaccine (non-adjuvanated) and manufactured by Baxter and/or alternatively, offering the Plaintiff the right to refuse the vaccine with a choice to do so given the risks involving Pandemrix and in compliance with the Plaintiff's right to bodily integrity under Article 3 (Right to Integrity of the Person) as per the European Convention of Human Rights;

19. I say that the Plaintiff alleges that the Third Named Defendant is liable to her under the Liability for Defective Products Act 1991 and that the Third Named Defendant and/or its servants or agents was and/or were guilty of negligence and breach of duty by:

a) Failing to exercise reasonable care when manufacturing and producing the Pandemrix vaccine in this jurisdiction;
b) Failing to exercise reasonable care in and around its distribution and supply of the Pandemrix vaccination in this jurisdiction;
c) Failing sufficiently to investigate the risks potentially associated with the form of Pandemrix vaccine with Squalene adjuvant which was administered in this jurisdiction;
d) Failing to test the Pandemrix vaccine, adequately or at all;
e) Failing to test the effects of the vaccine adjuvant, namely Squalene;
f) Failing to warn, sufficiently or at all, as to the associated risks of injury, known and unknown;
g) Manufacturing the Pandemrix vaccine to include a Squalene adjuvant;
h) Recommending distribution in this jurisdiction of the Pandemrix vaccine with Squalene adjuvant;
i) Supplying the Pandemrix vaccine with Squalene adjuvant in this jurisdiction;
j) Failing to have any or adequate regard to the risk that the Pandemrix vaccine and/or the Squalene adjuvant might engender narcolepsy and/or cataplexy;
k) Failing to have regard to demographic incidences of genetic predisposition to narcolepsy;
l) Failing to advise, caution or warn as to the risk that the said Pandemrix vaccine might engender narcolepsy and/or cataplexy.

20. I say that Orders for discovery have been obtained against GSK on 14 July 2016 and a further Order against the First and Second Named Defendants on 28 November 2016 with a further Order by the Honourable Ms Justice Baker on 28th March 2017 regarding the modus operandi for e-discovery to be made by the First and Second Named Defendants.

21. I say that the within application to join HPRA arises from the initial discovery of 4,500 documents received from the Third Named Defendants by the solicitors for the Plaintiff on 30 January 2017. I say that this has revealed information of a serious nature which makes it necessary for the Plaintiff to seek to join HPRA as a Defendant in the within proceedings. In summary, over several weeks, the Irish Medicines Board (now known as HPRA) became party to crucial information regarding the respective safety records of the Pandemrix vaccine and the Arepanrix version of the vaccine, of such striking difference that any person contemplating taking the Pandemrix vaccine would be likely, if in receipt of this information, not to choose to have the Pandemrix vaccination.

22. I say, by way of preliminary explanation, that there were two vaccines available for use in Ireland at the relevant time Pandemrix, manufactured by the Third Named Defendant, and Celvapan, manufactured by Baxter. The vaccine known as Pandemrix was manufactured in the Third Named Defendant's premises at Dresden. The same vaccine, known as Arepanrix, was manufactured in the Third Named Defendant's premises in Quebec. There were some differences in the manufacturing process as between Dresden and Quebec.

23. I say that the discovered documents include an email sent by Louise B. Mannion, Scientific Advisor at GlaxoSmithKline Ireland to Niamh McArdle, Pharmacovigilance Executive of GlaxoSmithKline and others, dated 30th October 2009 at 12:40, highlighting Adverse Events in relation to Pandemrix in Sweden. I beg to refer to a copy of said email, upon which, marked with the letters and number "**GOC2**" I have endorsed my name prior to the swearing hereof.

24. I say that the discovered documents also include an email sent from Martijn L Akveld, Scientific Affairs Manager of GlaxoSmithKline to Brenda Corcorcan of the HSE dated the 29th of October 2009 (Brenda Corcoran being one and the same Dr. Brenda Corcoran, Consultant in Public Health Medicine for the HSE and the signatory on the Purchase Agreement between GlaxosmithKline and the Department of Health dated the 18th of May 2009) furnishing the English Translation for Adverse Events in relation to Pandemrix in Sweden with "summary of the information published on the MPA website (29th October 2009) regarding adverse drug reaction reports in Sweden with Pandemrix – influenza A (H1N1) vaccine published 29th October 2009. I beg to refer to the said email upon which marked with the letters and number **"GOC3"** I have endorsed my name prior to the swearing hereof.

25. I say that the discovered documents also include an email sent Richard T. Kenney of GlaxoSmithKline dated 12 November 2009 to Carlos A. Leandro (and others) containing the contents of a communication from Thomas Verstraeten, Managing Director and Vice President and Head of Biological Clinical Safety and Pharmacovigilance, GlaxoSmithKline regarding Adverse Events relating to Pandemrix vs. Arepanrix vs. non-adjuvanted vaccines. I beg to refer to a copy of said email, upon which, marked with the letters and number "**GOC4**" I have endorsed my name prior to the swearing hereof. The said email states:

> "It is our understanding that GSK's H1N1 pandemic vaccines are now being administered in at least 19 countries ....The total number of doses of Pandemrix distributed cumulatively as on 9 Nov is 30.5 million doses to 34 countries. For Arepanrix, the total number delivered is 6.5 million doses to 1 country (Canada). Current estimates are that a total of 6.4 million doses have been administered to date, including 37,300 doses to children and 15,000 doses in (sic) pregnant women...
>
> The total number of adverse events that have been reported spontaneously during this review period is 469, mostly from Finland, Germany, Ireland, Norway, Sweden, UK, and Belgium,

reflecting the known usage patterns. The total number of adverse events that have been reported spontaneously during this review period for Arepanrix (antigen source Quebec) is 21, and all are from Canada, reflecting the known usage pattern."

26. I say and am advised that the difference in Adverse Events reported in this email, as between Pandemrix and Arepanrix is striking: 469 to 21. When one takes into account the respective distributions and administrations of the two vaccines, the difference remains striking.

27. I say that discovery has produced a document headed "H1N1 Enhanced Safety Review Team (Team 1) Communication on Safety Review for 24th – 30th November 2009", sent from Thomas M. Verstraeten, Vice President and Head of Biological Clinical Safety and Pharmacovigilance, GSK to Carlos A. Leandro and others, dated 2 December 2009, enclosing specific data regarding Adverse Events relating to Pandemrix, Arepanrix and a non-adjuvanted vaccine supplied by GlaxoSmithKline. I beg to refer to a copy of said document, upon which, marked with the letters and number "**GOC5**" I have endorsed my name prior to the swearing hereof.

The said document records up to that date, doses administered in total of 27 million including 15 million doses of Pandemrix, 12 million doses of Arepanrix plus adjuvanted H1N1 vaccine including 840,000 to children and 110,000 to pregnant women.

The document goes on to state:

> "The total number of A[dverse] E[vents] reports that have been reported spontaneously during this review period for Pandemrix is 1276, mostly from UK, Germany, France, Denmark, Switzerland and Sweden. The total number of AE reports that have been reported spontaneously during this review period for Arepanrix (antigen source Quebec) is 84, and all are from Canada. Two reports have been received for the unadjuvanted vaccine.
>
> As of data lock point 30 November 2009, a search of the OCEANS safety database identified a total of 4319 AE reports (3807 Pandemrix, 510 Arepanrix and 2 for the unadjuvanted vaccine), compared with 2957 reports received by the week before." The equivalent figures for SAE are 1,233 (1138 for Pandmerix, 95 for Arepanrix and 53 reported fatalities. This records a Serious Adverse Event rate of 75.8 per million for Pandemrix compared to 7.9 per million for Arepanrix. Despite such differences, the report concludes that "the risk / benefit profile of GSK's H1N1 Pandemic vaccines has not changed and remains favourable".

28. I say that the document goes on to record that there were 1138 serious adverse events reported for Pandemrix, 95 for Arepanrix and none for the unajuvanted vaccine. There were 47 fatal outcomes for Pandemrix, 6 for Arepanrix and none for the unadjuvanted vaccine. All of the remaining categories are recorded as involving significantly higher reports for Pandemrix over Arepanrix and the unadjuvanted vaccine as can be seen by the graph set out hereunder from the said email.

Event	Pandemrix	Arepanrix	Swine flu split Quebec without AS03	Total
All adverse events	3807	510	2	4319
Serious adverse events	1138	95	0	1233
Fatal outcomes	47	6	0	53
AESIs				
Anaphylaxis	141	43	0	184
Facial palsy	12	2	0	14
Guillain-Barré syndrome	3	1	0	4
Encephalitis	2	0	0	2
Demyelinating disorders	3	0	0	3
Convulsions	51	6	0	57
Neuritis	6	0	0	0
Vasculitis	10	0	0	10

Anaphylaxis: 141 for Pandemrix, 43 for Arepanrix and 0 for the unadjuvanted vaccine.

Facial palsy: 12 for Pandemrix, 2 for Arepanrix and 0 for the unadjuvanted vaccine.

Guillain-Barre syndrome: 3 for Pandemrix, 1 for Arepanrix and 0 for the unadjuvanted vaccine.

Encephalitis: 2 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine.

Demyelinating disorders: 3 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine.

Convulsions: 51 for Pandemrix, 6 for Arepanrix and 0 for the unadjuvanted vaccine.

Neuritis: 6 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine.

Vasculitis: 10 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine.

29. I say and am advised by epidemiological experts, that the difference in Adverse Events reported in this document, as between Pandemrix and Arepanrix and the unadjuvanated vaccine is striking. When one takes into account the respective distributions and administrations of the two vaccines, the difference remains striking. I say further that the difference in Adverse Events between Pandemrix and non-adjuvanted vaccine is also particularly striking. I say further that the difference between

reports of Serious Adverse Events for Pandemrix (1138) and Arepanrix (95) is also striking and that the same is true for the 47 deaths recorded for Pandemrix, in contrast to the six deaths recorded for Arepanrix and no deaths for the unadjuvanted vaccine.

30. I say and believe that any person invited to be vaccinated for the H1N1 virus, aware of these facts, would regard them as material and, if he or she decided to be vaccinated, would not have elected to have the Pandemrix vaccine, would have exercised their constitutional right not to have any vaccine or alternatively, would have opted for a non-adjuvanted vaccine such as Celvapan which is available and manufactured by Baxter. I say and I believe that, a fortiori, parents would not have permitted their children to receive the Pandemrix vaccine had they been aware of these facts and would have exercised their Constitutional Right to refuse the vaccine and/or alternatively requested the non-adjvanated vaccine Celvapan manufactured by Baxter.

31. I say that discovery has further revealed that an email was sent from Jean O'Connor dated 18 Dec 2009, International Communications Business Partner, Global Clinical R&D, GSK Biologicals addressed to wav_globalsafetycomms network list 1 of 2, subject "H1N1 vaccines newsflash" with H1N1 communications availability PDF communicating public and worldwide information and publicity regarding Pandemrix and Arepanrix. I beg to refer to a copy of said document, upon which, marked with the letters and number "**GOC6**" I have endorsed my name prior to the swearing hereof. The said document states that it is currently estimated that a minimum of 44.8 million doses have been administered to date – 31.3 million doses of Pandemrix and 13.5 million doses of Arepanrix and non-adjuvenated H1N1 vaccine, including at least 1.2 million doses to children and 132,000 doses to pregnant women. The document goes on to state:

> "The total number of A[dverse] E[vents] that have been recorded to GSK spontaneously during this review period for Pandemrix (antigen source Dresden) is 1,880, mostly from Germany, the UK, Greece and France, reflecting the known usage patterns. The total number for Arepanrix (antigen source Quebec) is 22 from Canada. No reports have been received for unadjuvanted vaccine."

32. I say and am advised that parents, on being informed of this vast difference in adverse events as between those persons to whom Pandemrix had been given and those persons to whom Arepanrix had been given, or alternatively the persons to whom Celvapan had been given with due regard to the total numbers of doses respectively administered, would not have given their consent to the administration of Pandemrix to their children.

33. I say that the discovered material includes an email sent from Maeveanne McHugh, Pharmacovigilance, Quality and Compliance Manager with GlaxoSmithKline Ireland addressed to Kevin O'Donnell, Aoife Farrell, Joan Gilvarry, Almath Spooner, Niamh

Arthur and Nigel Fox all of the Irish Medicines Board dated 30 December 2009 at 11:02. I beg to refer to a copy of said document, upon which, marked with the letters and number "**GOC7**" I have endorsed my name prior to the swearing hereof. The document comprises GSK's Enhanced Safety Review Team's Report for week 53 (22 to 28 December 2009). It states that GSK estimates that 48 million doses of Pandemrix and 13.8 million doses of Arepanrix plus unadjuvanted H1N1 vaccine have been administered to date. It goes on to state that, as of data lock point 14 December 2009, a search of the OCEANS safety database identified total of 12766 Adverse Events reports: 12180 for Pandemrix, 584 for Arepanrix and 2 for the unadjuvanted vaccine. It goes on to set out a Summary of Spontaneous Adverse Event Reports: Data Lock Point 28 December 2009. In every one of the fifteen categories it lists, the incidents of Adverse Events for Pandemrix is far greater than that for Arepanrix, taking account the respective volumes of administration of each vaccine. The list includes the following data in its first six categories as depicted in the graph set out hereunder:

Summary of Spontaneous Adverse Event Reports: Data Lock Point 28 December 2009.

Event	Pandemrix	Arepanrix	Swine flu split Quebec without AS03	Total
All adverse events	12180	584	2	12766
Serious adverse events	3280	108	0	3388
Fatal outcomes	107	6	0	113
Drug exposure during pregnancy	214	27	0	241
Stillbirth	8 (+1)	0	0	8
Abortion spontaneous	30 (+2)	0	0	30
AESIs				
Anaphylaxis	284 (+25)	47	0	311
Facial palsy	35 (+6)	2	0	37
Guillain-Barré syndrome	28 (+7)	4	0	32
Encephalitis	7 (+2)	0	0	7
Demyelination	18 (+2)	0	0	18
Convulsions	214 (+43)	7	0	221
Neuritis	11 (+1)	0	0	11
Vasculitis	21 (+2)	0	0	
Vaccination failure	18 (+5)	0	0	18

All Adverse Events: 12180 for Pandemrix, 584 for Arepanrix and 2 for the unadjuvanted vaccine.

Serious Adverse Events: 3280 for Pandemrix, 108 for Arepanrix and 0 for the unadjuvanted vaccine.

Fatal outcomes: 107 for Pandemrix, 6 for Arepanrix and 0 for the unadjuvanted vaccine

Drug exposure during pregnancy: 214 for Pandemrix, 27 for Arepanrix and 0 for the unadjuvanted vaccine

Stillbirth: 8 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine

Spontaneous abortion:	30 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine

The list proceeds to list nine categories under the heading "AESIs" (Adverse Events of Special Interest):

Anaphylaxis:	264 for Pandemrix, 47 for Arepanrix and 0 for the unadjuvanted vaccine
Facial palsy:	35 for Pandemrix, 2 for Arepanrix and 0 for the unadjuvanted vaccine
Guillain-Barre syndrome:	28 for Pandemrix, 4 for Arepanrix and 0 for the unadjuvanted vaccine
Encephalitis:	7 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine
Demyelination:	18 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine
Convulsions:	214 for Pandemrix, 7 for Arepanrix and 0 for the unadjuvanted vaccine
Neuritis:	11 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine
Vasculitis:	21 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine
Vaccination failure:	18 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine

34. I say that these consistent huge disparities as between the safety of Pandemrix and Arepanrix, if known to parents, would have encouraged parents not to consent to have their children vaccinated with Pandemrix. What is clear is that is ratio of reporting of harms in the two different vaccines is strikingly different, and even more so when including the non-adjuvanted vaccine. For example, using doses administered as at the 30th of November 2009 (email 2nd of December 2009) and numbers reported in the email of the 30th of December 2009, the figures show that Serious Adverse Events for Pandemrix in the 2nd of December 2009 stood at 1138 with 95 for Arepanrix and Zero for the non-aduvuanted vaccine. By the 30th of December 2009 Serious Adverse Events for Pandemrix had escalated to 3280 and only an additional 13 Serious Adverse Events for Arepanrix (previous figure being 95) and again zero for the non adjuvanted vaccine.

35. I say that the discovered material includes an email from Niamh McArdle, Pharmacovigilance Executive of GlaxoSmithKline to Kevin O'Donnell, Aoife Farrell, Joan Gilvarry, Almath Spooner, Niamh Arthur and Nigel Fox of the Irish Medicines Board dated 27 January 2010. I beg to refer to a copy of said document, upon which, marked with the letters and number "**GOC8**" I have endorsed my name prior to the swearing hereof. The document comprises GSK's Enhanced Safety Review Team's Report for19 to 25 January 2010. It states that GSK estimates that a minimum of 61 million doses of Pandemrix, 14 million doses of Arepanrix plus unadjuvanted H1N1 vaccine have been administered to date. It states further that the total number of Adverse Events reported spontaneously during the review period for Pandemrix is 652, mostly from the UK, Ireland and the Netherlands. The total number of Adverse Events reported spontaneously during the period for Arepanrix is 4. No report has been received for the unadjuvanted vaccine. It goes on to state that, as of data lock point 25 January 2010, a search of the OCEANS safety database identified total of 16170 Adverse Events reports: 15552 for Pandemrix, 615 for Arepanrix and 3 for the unadjuvanted vaccine. It goes on to set out what constitutes a summary of spontaneous Adverse Event reports. In every one of the fifteen categories it lists, the incidence of adverse events for Pandemrix is far greater than that for Arepanrix, taking account the respective volumes of administration of each vaccine. The list includes the following data in its first six categories as depicted in the graph set out hereunder:

Event	Pandemrix	Arepanrix	Swine flu split Quebec without ASO3	Total
All adverse events	15552 (652)	615 (4)	3(0)	16170
Serious adverse events	4094 (203)	116 (3)	0	4210
Fatal outcomes	132 (7)	7 (0)	0	139
Drug exposure during pregnancy	262 (6)	28 (1)	0	290
Stillbirth	18 (-1)	71	0	19
Abortion spontaneous	43 (2)	0	0	43
AESIs				
Anaphylaxis	287 (8)	48 (1)	0	335
Facial palsy	43 (3)(-1)	2 (0)	0	45
Guillain-Barré syndrome	62 (5)	4 (0)	0	66
Encephalitis	9 (0)	0	0	9
Demyelination	31 (7)	0	0	31
Convulsions	256 (15)	7 (0)	0	263
Neuritis	12 (0)	0	0	12
Vasculitis	28 (1)	1 (0)	0	29
Vaccination failure	27 (2)	0	0	27

( ) : Number of new cases since last week.

All Adverse Events: 15552 for Pandemrix, 615 for Arepanrix and 3 for unadjuvanted vaccine

Serious Adverse Events: 4094 for Pandemrix, 116 for Arepanrix and 0 for unadjuvanted vaccine

Fatal Outcomes: 132 for Pandemrix, 7 for Arepanrix and 0 for the unadjuvated vaccine.

Drug Exposure During Pregnancy:	262 for Pandemrix, 28 for Arepanrix and 0 for the unadjuvanted vaccine.
Still Birth:	18 for Pandemrix, 1 for Arepanrix and 0 for the unadjuvanted vaccine.
Spontaneous Abortion:	43 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine.

The list proceeds to list nine categories under the heading "AESIs" (Adverse Events of Special Interest):

Anaphylaxis:	287 for Pandemrix, 48 for Arepanrix and 0 for the unadjuvanted vaccine.
Facial Palsy:	43 for Pandemrix, 2 for Arepanrix and 0 for the unadjuvanted vaccine.
Guillain-Barre syndrome:	52 for Pandemrix, 4 for Arepanrix and 0 for the unadjuvanted vaccine.
Encephalitis:	9 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine.
Demyelination:	31 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine.
Convulsions:	256 for Pandemrix, 7 for Arepanrix and 0 for the unadjuvanted vaccine.
Neuritis:	12 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine.
Vasculitis:	28 for Pandemrix, 1 for Arepanrix and 0 for the unadjuvanted vaccine
Vaccination Failure:	27 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine.

36. I say and am advised that any person, on being informed of these facts, would not have chosen to be vaccinated with Pandemrix; I am advised that parents in particular would not have consented to have their children vaccinated with Pandemrix.

37. I say that discovery disclosed an email from Aurélie Delaigle (Biological, BE) dated 3 February 2010 to Carlos Arturo Leandro – Calderon and others subject "H1N1

Enhanced Safety Review Team". I beg to refer to a copy of said document, upon which, marked with the letters and number "**GOC9**" I have endorsed my name prior to the swearing hereof. The document comprises a summary of the H1N1 pandemic vaccines safety review for Week 5 2010 and covers cumulative safety data reported to GSK up to 27 January 2010. It states that GSK estimates that about 62 million doses of Pandemrix, 14 million doses of Arepanrix plus unadjuvanted H1N1 vaccine have been administered to date. It goes on to state that, as of data lock point 27 January 2010, a search of the OCEANS safety database identified total of 16280 Adverse Events reports: 15662 for Pandemrix, 615 for Arepanrix and 3 for the unadjuvanted vaccine. It goes on to set out what constitutes a summary of Spontaneous Adverse Event reports. In every one of the twelve categories it lists, the incidence of adverse events for Pandemrix is far greater than that for Arepanrix, taking account the respective volumes of administration of each vaccine. The list includes the following data in its first three categories as depicted in the graph also set out hereunder:

Event	Pandemrix	Arepanrix	Swine flu split Quebec without AS03	Total
All adverse events	15662 (110)	615 (0)	3 (0)	16280
Serious adverse events	4156 (62)	116 (0)	0	4272
Fatal outcomes	136 (4)	7 (0)	0	143
AESIs				
Anaphylaxis	210 (1)	48 (0)	0	258
Facial palsy	60 (2)	2 (0)	0	62
Guillain-Barré syndrome	55 (1)	4 (0)	0	59
Encephalitis	11 (0)	0	0	11
Demyelination	40 (0)	0	0	40
Convulsions	299 (2)	7 (0)	0	306
Neuritis	12 (0)	0	0	12
Vasculitis	30 (0)	1 (0)	0	31
Vaccination failure	27 (0)	0	0	27

( ) : Number of new cases since last update.

All Adverse Events: 15662 for Pandemrix, 615 for Arepanrix and 3 for the unadjuvanted vaccine.

Serious Adverse Events: 4156 for Pandemrix, 116 for Arepanrix and 0 for the unadjuvanted vaccine.

Fatal Outcomes: 136 for Pandemrix, 7 for Arepanrix and 0 for the unadjuvanted vaccine.

The list proceeds to list nine categories under the heading "AESIs" (Adverse Events of Special Interest):

Anaphylaxis:	210 for Pandemrix, 48 for Arepanrix and 0 for t the unadjuvanted vaccine.
Facial palsy:	50 for Pandemrix, 2 for Arepanrix and 0 for the unadjuvanted vaccine.
Guillain-Barre syndrome:	55 for Pandemrix, 4 for Arepanrix and 0 for t the unadjuvanted vaccine.
Encephalitis:	11 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine.
Demyelination:	40 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine.
Convulsions:	299 for Pandemrix, 7 for Arepanrix and 0 for the unadjuvanted vaccine.
Neuritis:	12 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine.
Vasculatis:	30 for Pandemrix, 1 for Arepanrix and 0 for the unadjuvanted vaccine
Vaccination Failure:	27 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine.

38. I say further that discovery disclosed an email from Niamh McArdle, Pharmacovigilance Executive of GlaxoSmithKline to Kevin O'Donnell, Aoife Farrell, Joan Gilvarry, Almath Spooner, Niamh Arthur and Nigel Fox, all of the Irish Medicines Board, dated 10 February 2010. I beg to refer to a copy of said document, upon which, marked with the letters and number "**GOC10**" I have endorsed my name prior to the swearing hereof. The document comprises a summary of the H1N1 pandemic vaccines safety review for Week 6 2010 and covers cumulative safety data reported to GSK up to 3 February 2010. It states that GSK estimates that 64 million doses of Pandemrix, 15 million doses of Arepanrix plus unadjuvanted H1N1 vaccine have been administered to date. It goes on to state that, as of data lock point 3 February 2010, a search of the OCEANS safety database identified total of 16578 Adverse Events reports: 15933 for Pandemrix, 642 for Arepanrix and 3 for the unadjuvanted vaccine. It goes on to set out what constitutes a summary of spontaneous Adverse Event reports. In every one of the twelve categories it lists, the incidence of adverse events for Pandemrix is far greater than that for Arepanrix, taking account the respective volumes of administration of each vaccine. The list includes the following data in its first three categories as depicted in the graph set out hereunder:

Event	Pandemrix	Arepanrix	Swine-flu split Quebec without ASO3	Total
All adverse events	15933	642	3 (0)	16578
Serious adverse events	4291	140	0	4431
Fatal outcomes	142	7	0	149
AESIs				
Anaphylaxis	300	61	0	361
Facial palsy	46	3	0	49
Guillain-Barré syndrome	57	26	0	83
Encephalitis	10	0	0	10
Demyelination	32	0	0	32
Convulsions	277	7	0	284
Neuritis	12	1	0	13
Vasculitis	30	1	0	31
Vaccination failure	28	0	0	28

All Adverse Events: 15933 for Pandemrix, 642 for Arepanrix and 3 for the unadjuvanted vaccine.

Serious Adverse Events: 4291 for Pandemrix, 140 for Arepanrix and 0 for the unadjuvanted vaccine.

Fatal Outcomes: 142 for Pandemrix, 7 for Arepanrix and 0 for the unadjuvanted vaccine.

The list proceeds to list nine categories under the heading "AESIs" (Adverse Events of Special Interest):

Anaphylaxis: 300 for Pandemrix, 61 for Arepanrix and 0 for the unadjuvanted vaccine.

Facial palsy: 46 for Pandemrix, 3 for Arepanrix and 0 for the unadjuvanted vaccine.

Guillain-Barre Syndrome: 57 for Pandemrix, 26 for Arepanrix and 0 for the unadjuvanted vaccine.

Encephalitis: 10 for Pandemrix, 0 for Arepanrix and 0 for t the unadjuvanted vaccine.

Demyelination: 32 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine.

Convulsions: 277 for Pandemrix, 7 for Arepanrix and 0 for the unadjuvanted vaccine.

Neuritis: 12 for Pandemrix, 1 for Arepanrix and 0 for the unadjuvanted vaccine.

Vasculitis: 30 for Pandemrix, 1 for Arepanrix and 0 for the unadjuvanted vaccine

Vaccination Failure: 28 for Pandemrix, 0 for Arepanrix and 0 for the unadjuvanted vaccine.

39. I say and am advised that it is clear from the foregoing emails and the data on Adverse Events collated by the Third Named Defendant, that the instances of Serious Adverse Events arising from the use of the Pandemrix Vaccine were several times more frequent than those with the Arepanrix/Quebec version of the vaccine.

40. I say further that discovery disclosed an email dated 24th of February 2010 from Ciara Rafferty Quality and Pharmacovigilance officer of GlaxoSmithKline to Kevin O'Donnell at Irish Medicines Board, Aoife Farrell, Joan Galvary, Almath Spooner, Niamh Arthur and Nigel Foxx all of Irish Medicines Board and I beg to refer to a copy of the said document from which marked with the letters and number "**GOC11".** I have endorsed my name prior to swearing hereof. The email confirms that "GSK estimates that approximately 81 million doses have been administered – 66 million doses of Pandemrix, 15 million doses of Arepanrix plus unadjuvanted H1N1 vaccine including at least 4.2 million doses to children and 390,000 doses to pregnant women". It goes on to give a summary of that as of the 17th of February 2010, a search of the OCEANS safety data base identified a total of 17,446 Adverse Event Reports (16,772 Pandemrix, 671 Arepanrix and 3 for the unadjuvanted vaccine). This shows the instance of Adverse Events for Pandemrix is far greater than that of Arepanrix taking into account the respective volumes of administration of each vaccine but in particular, the non adjuvanted vaccine. The list includes the following data in the first three categories as depicted in the graph set out hereunder:

Event	Pandemrix	Arepanrix	Swine flu split Quebec without AS03	Total
All adverse events	16772 (839)	671 (29)	3 (0)	17446
Serious adverse events	4619 (328)	159 (19)	0	4778
Fatal outcomes	156 (14)	10 (3)	0	166
AESIs				
Anaphylaxis	308 (8)	61 (0)	0	369
Facial palsy	62 (6)	3 (0)	0	65
Guillain-Barré syndrome	68 (11)	28 (2)	0	96
Encephalitis	11 (1)	0	0	11
Demyelination	40 (8)	0	0	40
Convulsions	287 (10)	7 (0)	0	294
Neuritis	13 (1)	1 (1)	0	13
Vasculitis	32 (2)	1 (0)	0	33
Vaccination failure	29 (1)	0	0	29

() Number of new reports in the last 2 weeks

All Adverse Events: Pandemrix- 16,772 (839 reported in the previous two weeks), Arepanrix- 671 with (29 reporting the previous two weeks) and 3 for the unadjuvanted swine flu vaccine with (zero) reported in the previous two weeks.

Serious Adverse Events: Pandemrix - 4,619 (328 in the previous two weeks) Arepanrix – 159 (19 in the previous two weeks) and zero for the unadjuvanted swine flu vaccine.

In the remaining categories including fatal outcomes, we have the following figures.

Fatal outcomes:

Pandemrix -	156 (14 in the previous two weeks)
Arepanrix -	10 (3 in the previous two weeks)
Swine flu non adjuvanted -	zero

AESIS

Anaphylaxis: Pandemrix 308 (with 8 in the previous two weeks) Arepanrix 61 (with zero in the previous two weeks) and zero for the unadjuvanted swine flu vaccine.

Facial Palsy: Pandemrix 52 (6 in the previous two weeks) Arepanrix 3 (zero instance in the previous two weeks) and non adjuvanted swine flu zero.

Guillain-Barre syndrome: Pandemrix 62 (with 11 in the previous two weeks), Arepanrix 28 (with 2 instances in the previous two weeks) and zero for the non adjuvanted swine flu vaccine.

Encephalitis: Pandemrix 11 (with 1 instance in the previous two weeks) and zero for both Arepanrix and the non-adjuvanted swine flu vaccine.

Demylination: Pandemrix 40 cases (with 8 occurring in the previous two weeks) and zero for both Arepanrix and non-adjuvanted swine flu vaccine.

Convulsions: Pandemrix 287 (with 10 in the previous two weeks), Arepanrix 7 (with zero in the previous two weeks) and zero for the non-adjuvanted swine flu vaccine.

Neuritis: Pandemrix 13 (with 1 instance in the previous two weeks) and 1 instance for Arepanrix (with further 1 instance in the previous two weeks) and zero for the non-adjuvanted swine flu vaccine.

Vasculitis: Pandemrix 32 (with 2 instances in the previous two weeks), 1 for Arepanrix (with 1 further instance in the previous two weeks) and zero for the non-adjuvanted swine flu vaccine.

Vaccination failure: Pandemrix 29 (with 1 instance in the previous two weeks) and zero for both Arepanrix and the non-adjuvanted swine flu vaccine.

41. I say and I am advised that it is clear from the foregoing email and the data on Adverse Events collated by the Third Named Defendant that the instances of Serious Adverse Events arising from the use of Pandemrix were several times more frequent than those with the Arepanrix/ Quebec version and the non-adjuvanted swine flu vaccine manufactured by GSK also.

42. I say further that discovery disclosed an email from Ciara Rafferty Quality and Pharmacovigilance officer of GlaxoSmithKline Ireland dated the 3rd of March 2010 to

Kevin O'Donnell, Aoife Farrell, Joan Galvary, Almath Spooner, Niamh Arthur, and Nigel Fox all of the Irish Medicines Board. I beg to refer to a copy of the said documents upon which marked with the letter **"GOC12".** I have endorsed my name prior to swearing hereof.

Again, the document comprises a summary of the H1N1 Pandemic vaccine safety review for week 8 of 2010. It states that of all the vaccines delivered worldwide by GlaxoSmithKline, 82 million doses had been administered up to that date namely 67 million doses of Pandemrix, 15 million doses of Arepanrix plus non-adjuvanted H1N1 vaccine including 4.2 million doses to children and 400,000 doses to pregnant women. Reviewing a search of the OCEANS safety data base identified 17,083 Adverse Event reports for Pandemrix, 702 Adverse Event reports for Arepanrix and 3 for the non-adjuvanted vaccine. A copy of the graph of Adverse Events to include Serious Adverse Events in relation to this safety data base for week 10 of 2010 is set out below setting out the categories as referred to in previous paragraphs hereof:

Event	Pandemrix	Arepanrix	Swine flu split Quebec without AS03	Total
All adverse events	17083 (311)	702 (31)	3 (0)	17788
Serious adverse events	4748 (129)	162 (3)	0	4910
Fatal outcomes	158 (2)	10 (0)	0	168
AESIs				
Anaphylaxis	312 (4)	62 (1)	0	374
Facial palsy	54 (2)	3 (0)	0	57
Guillain-Barré syndrome	70 (3) (-1)	28 (0)	0	98
Encephalitis	11 (0)	0	0	11
Demyelination	42 (2)	0	0	42
Convulsions	288 (1)	7 (0)	0	295
Neuritis	13 (0)	1 (0)	0	14
Vasculitis	34 (2)	1 (0)	0	35
Vaccination failure	29 (0)	0	0	29

() Number of new reports in the last week

What is clear from the data on Adverse Events collated by the Third Named Defendant at this stage, is that the instance of Serious Adverse Events arising from the use of the Pandemrix vaccine were several times higher than the Arepanrix/ Quebec version and the non-adjuvanted vaccine also manufactured by GlaxoSmithKline as the graph for the said email depicts above.

43. I further say that had any person on being informed of the above data would not have chosen to be vaccinated with Pandemrix and also that parents in particular, would not have consented to have their children vaccinated with Pandemrix.

44. I say that the discovered material also includes an email from Maeveann McHugh dated 17th of March 2010 addressed to Kevin O'Donnell, Aoife Farrell, Joan Gilvary, Almath Spooner, Niamh Arthur and Nigel Fox all of the Irish Medicines Board. I beg to refer to a copy of the said document upon which marked with the letter "**GOC13**". I have endorsed my name prior to swearing hereof.

The document comprises GSK's enhanced safety review team's report for week 11 of 2010. At that time, GSK estimated that 69 million doses of Pandemrix had been administered, 16 million doses of Arepanrix plus non-adjuvanted swine flu vaccine including 4.2 million doses to children and 410,000 doses to pregnant women. As of the data lock point 10th of March 2010, it reveals that a search of the OCEANS safety data base identified a total of 18,156 Adverse Events including 17,431 Pandemrix, 725 Arepanrix and 3 for the non-adjuvanted swine flu vaccine. A graph depicted in the email as set out below sets out all Adverse Events and Serious Adverse Events but in particular Adverse Events under particular categories as per previous emails. However, what is clear is that the graph below also sets out the instances of related Adverse Events in the particular category for each vaccine in the previous two weeks. It is clear that Pandemrix with Serious Adverse Events of 4,903 with 155 reported in the previous two weeks, as against 166 with Arepanrix with only 4 instances reported in the previous two weeks, and zero Adverse Events in every category with the non-adjuvanted swine flu shows, that the disparities between Pandemrix, Arepanrix but in particular the non-adjuvanted swine flu vaccine is dramatic. If such safety concerns regarding Pandemrix had been known to the general populous but in particular parents, they would not have consented to having their children vaccinated with Pandemrix.

Event	Pandemrix	Arepanrix	Swine flu split Quebec without AS03	Total
All adverse events	17431 (348)	725 (23)	3 (0)	18156
Serious adverse events	4903 (155)	166 (4)	0	5069
Fatal outcomes	164 (6)	10 (0)	0	174
AESIs				
Anaphylaxis	316 (4)	62 (0)	0	378
Facial palsy	55 (1)	3 (0)	0	58
Guillain-Barré syndrome	74 (4)	29 (1)	0	103
Encephalitis	13 (2)	0	0	13
Demyelination	39 (-3)	0	0	39
Convulsions	301 (13)	7 (0)	0	308
Neuritis	16 (3)	2 (1)	0	18
Vasculitis	37 (3)	1 (0)	0	38
Vaccination failure	29 (0)	0	0	29

() Number of new reports in the last 2 weeks

45. Finally I say that a further email was discovered from Ciara Rafferty dated 31st of March 2010 addressed to Kevin O'Donnell, Aoife Farrell, Joan Gilvarry, Almath Spooner, Niamh Arthur and Nigel Fox all of the Irish Medicines Board and I beg to refer to a copy of the said document upon which marked with the letter **"GOC14".** I have endorsed my name prior to swearing hereof.

This document reveals GSK's enhanced safety review team report for week 13 in 2010. According to a search of the OCEANS safety data base but in particular, 87 million doses of the vaccine manufactured by GSK was administered but in particular, 70 million doses of Pandemrix, 17 million doses of Arepanrix plus the non-adjuvanted vaccine including 4.4 million doses to children and 420,000 doses to pregnant women.

As per the graph below, exhibited in the email, it's clear that Serious Adverse Events per Pandemrix numbers are considerably higher than those of Arepanrix and the non-adjuvanted swine flu vaccine. According to the data lock point for the 24th of March 2010, a search of the OCEANS database identified a total of 17,840 Adverse Event reports for Pandemrix, 808 for Arepanrix and 3 for non-adjuvanted swine flu vaccine. It is clear from the graph attached below (including the number of new reports in each category of the previous two weeks), that Serious Adverse Events for Pandemrix at 5,069 (with 166 Events occurring in the previous two weeks) is extraordinarily high compared with 170 Serious Adverse Events for Arepanrix (with a mere 4 in the previous two weeks) and a consistent zero for the non-adjuvanted swine flu vaccine in every category.

Event	Pandemrix	Arepanrix	Swine flu split Quebec without AS03	Total
All adverse events	17840 (409)	808 (83)	3 (0)	18651
Serious adverse events	5069 (166)	170 (4)	0	5239
Fatal outcomes	169 (5)	11 (0)	0	180
AESIs				
Anaphylaxis	318 (2)	62 (0)	0	380
Facial palsy	56 (1)	3 (0)	0	59
Guillain-Barré syndrome	80 (6)	29 (0)	0	109
Encephalitis	13 (0)	0	0	13
Demyelination	49 (10)	0	0	49
Convulsions	310 (9)	8 (1)	0	318
Neuritis	19 (3)	2 (0)	0	21
Vasculitis	41 (4)	1 (0)	0	42
Vaccination failure	31 (2)	0	0	29

() Number of new reports in the last 2 weeks

46. Again, there's huge disparities between safety for Pandemrix and Arepanrix and if known to parents, they would not have encouraged their children to be vaccinated with Pandemrix.

In conclusion, the data furnished in the above emails from the 29th of October 2009 and in particular up to and including 30th of December 2009 to the Irish Medicines Board and thereafter, shows a startlingly different reporting gradient for serious harm for the two vaccines. In particular, for example, although not reported throughout, the

risk of Spontaneous Abortion occurring in a pregnant recipient of Pandemrix was a nearly 50 fold higher, than in the Arepanrix recipients.

47. I say and believe that the discovered material does not indicate that the Irish Medicines Board made the information contained in the aforesaid emails and documents available to the First and Second Named Defendants immediately it was in receipt of the said information, in compliance with their statutory obligations, or at all. The National Public Health Emergency Team (NPHET) was set up by the Department of Health to oversee the issue and administration of the pandemic vaccines. A representative of the Irish Medicines Board attended all of the meetings of the NPHET and the Plaintiff is awaiting discovery of reports submitted at each meeting. It appears clear, however, from documents already discovered that no minutes were recorded regarding Adverse Events regarding Pandemrix at these meetings which were set up to monitor and oversee the issue and administration of the swine flu vaccine.

48. I say further that, although Dr. Joan Gilvarry of the Irish Medicines Board attended all HSE meetings relating to the swine flu vaccine from 22 October 2009 onwards, there is no record in the minutes of her having referred to the contents of these emails and data. In this regard, I would refer to the minutes of the meetings of the NPHET meetings of the 7th and 21st of January 2010 upon which marked with the letters **"GOC15"** I have endorsed my name prior to the swearing hereof.

49. I say that the legislation establishing the Irish Medicines Board, the Irish Medicines Board Act 1995, prescribed a range of functions for the Board in section 4, which include:

> Licensing the manufacture, preparation, importation, distribution and sale of medicinal products,
>
> Exercising certain powers under Council Directive No. 65/65/EEC as amended,
>
> Establishing and administering a service for obtaining and assessing information as regards the safety, quality and efficacy of medicinal products,
>
> Establishing and administering a service for obtaining and assessing reports of any adverse effects of medicinal products in use in the State,
>
> Advising the Minister for Health and others concerned as to the precautions and restrictions, if any, subject to which medicinal products may be marketed or continued in use in the State,
>
> Arranging for the collection and dissemination of information relating to medicinal products, including, in particular, information concerning the pharmacological classification and therapeutic efficacy of such products,

Furnishing, whenever requested by the Minister, advice to the Minister in relation to the licensing of the manufacture, importation, distribution and sale of medicinal products and in relation to the standards of manufacturing practice (including quality control) of medicinal products, and

Furnishing, whenever it so thinks fit or is requested by the Minister, advice to the Minister in relation to any matter connected with the functions or activities of, or the services provided by, the Board.

50. I say that I am advised, and so believe, that the Irish Medicines Board (now the HPRA), at all relevant times, in the discharge of its functions, owed the Plaintiff a duty of care and a statutory duty in respect of her health and bodily integrity and her constitutional rights thereto.

51. I say and believe that the Irish Medicines Board, in the discharge of its statutory functions and of its duty of care to the Plaintiff, as a person to whom the Pandemrix vaccine was administered with the approval of the Irish Medicines Board, owed duties to monitor and advise upon (i) the safety and appropriateness for use of the vaccine by the Plaintiff, and (ii) the activities of the First and Second Named Defendants in respect of the administration of the said vaccine, so far as such activities might impact on the health or bodily integrity of the Plaintiff and (iii) that HPRA, as an organ of the State, owed the Plaintiff the duty to respect and protect her constitutional rights, in particular her rights to health, bodily integrity, autonomy and dignity under Article 40.3.1 of the Constitution and her right to the person under Article 40.3.2, and a duty to perform its functions in a manner compatible with the State's obligations to respect and protect her rights under the European Convention on Human Rights, in particular her rights under Articles 3 and 8 thereof. I say and am advised further that the manner in which HPRA performed its functions breached the said duties.

52. I say and believe that weekly assessments were carried out by the Second Named Defendant regarding the incidence of swine flu vaccines in Ireland from week 42/October 2009 onwards. I say and believe that, during the relevant period, when Pandemrix was being administered throughout the Country on the prompting of the Second Named Defendant, the incidents of confirmed new cases of H1N1 was falling away. Indeed, the week after the vaccination programme began in week 42 of 2009, the swine flu incidents began to fall and flat lined by the end of December 2009. In that regard I beg to refer to the 2009 HPSE Annual Report upon which marked with the letter and number **"GOC16"** I have endorsed my name prior to the swearing hereof.

53. I say and believe that the Second Named Defendant prepared, produced and distributed two pamphlets, designed to encourage resort to the Pandemrix vaccine on a massive scale. I say and believe that the Irish Medicines Board had a duty to apprise itself of the contents of these brochures, to advise on their accuracy and on their compliance, or otherwise, with the duty on the part of the Second Named Defendants to ensure that those receiving the Pandemrix vaccine would be in a position to give their informed consent thereto, and to ensure that parents would be in the position to provide a properly informed consent to have the vaccine administered to their children.

54. I say that the first brochure, a four-page document, was distributed in October 2009 and that the second, a more in-depth, eight-page document, was distributed in November 2009. The second pamphlet, entitled, "Swine Flu: It Stops with You", contains material relating to the HSE's vaccination programme. It includes the following passages:

> *"Do I need one or two doses of vaccine?*
>
> There are two different makes of vaccine being used in Ireland; Pandemrix (manufactured by GSK) and Celvapan (manufactured by Baxter). The National Immunisation Advisory Committee has confirmed that for the Pandemrix vaccine, one dose of the vaccine will be enough to protect most people from Swine Flu. Both vaccines are considered to be equally effective and have the same safety profile."
>
> *"Does everyone need to get the vaccine?*
>
> We intend to offer the vaccine to everyone in Ireland. If you have had flu since April, you should still get the vaccine, as it may not have been the Pandemic H1N1 2009 or Swine Flu virus. If you have had a confirmed positive lab test for Swine Flu or Pandemic H1N1 2009, you do not need the vaccine."
>
> *"Are the Swine Flu vaccines safe?*
>
> Yes, the two Swine Flu vaccines being used in Ireland, Pandemrix and Celvapan, are both licensed by the Irish Medicines Board and have been given to millions of people across Europe already this year.
>
> Reactions have been as expected and similar to seasonal flu vaccines, which have been used for more than 60 years. Serious side effects or allergic reactions are very rare and the Swine Flu vaccine cannot give you Swine Flu."
>
> *"What can I expect after vaccination?*
>
> The most common side effects being seen are mild and may include soreness, redness or swelling where the injection was given. Headache, fever, aches, a mild rash and tiredness may occur. Some people may have mild sweating and shivering as their immune system responds to the vaccine, but this is not Swine Flu and will pass after a day or so. Severe or life threatening allergic reactions to vaccines are very rare.
>
> *What if I don't feel well after vaccination?*
>
> Take paracetamol if you or your child has a fever or any pain where the injection was given. Avoid clothes rubbing against the injection area and drink plenty of fluids. Remember, if you or your child is unwell after getting a vaccine, don't assume the vaccine is the cause – it could be for some other reason, and take medical advice if needed."

In that regard I beg to refer to the HSE pamphlets of October and November 2009 upon which marked with the letters **"GOC 17"** I have endorsed my name prior to the swearing hereof.

55. I am advised and believe that most people reading the brochure, including those intended by the First and Second Named Defendants to take the Pandemrix vaccine or to provide their consent, as parents, to their children taking it, would believe:

    (i) that everyone except those with a confirmed lab test for Swine Flu or Pandemic H1N1 2009 needed to get the vaccine;
    (ii) that it was safe to use Pandemrix;
    (iii) that Pandemrix had been appropriately tested and had passed the test of safety;
    (iv) that Pandemrix and Celvapan were equally safe;
    (v) that the National Immunisation Advisory Committee had confirmed that, for the Pandemrix vaccine, one dose of the vaccine would be enough to protect most people from Swine Flu, whereas Celvapan required two doses.;
    (vi) that it had been established that serious side effects or allergic reactions to using Pandemrix were very rare;
    (vii) That parents, finding their child to be unwell after getting a vaccine, should not assume that the vaccine was the cause.

56. I say and am advised that the reality, known to the Irish Medicines Board, was that not all of these conclusions were warranted and that the Pandemrix vaccine had been inadequately tested on children and had not been tested on adolescents at all prior to its being licensed. I say and am advised further that the Irish Medicines Board knew or ought to have known that parents, if they had been informed of the facts regarding the lack of prior tests on children and adolescents, would be likely to have refused the administration of Pandemrix to their children. I say and am advised further that the Irish Medicines Board was or became aware of the huge disparities in Adverse Events as between Pandemrix and Arepanrix and as between Pandemrix and the unadjuvanted vaccine. I say and believe that the discovered documentation to date, while indicating that the Irish Medicines Board had the relevant information, contains no indication that it advised the First Named Defendant or the Second Named Defendant of these facts, or of the safety significance thereof or of the implications for parents and other in respect of the Pandemrix vaccination.

57. I say and believe, and am so advised, that, by virtue of the information that has only now become available to the Plaintiff through Discovery, set out above, and in the light of the statutory and common law obligations of HPRA (formerly the Irish Medicines Board), it is necessary that HPRA be joined as a Defendant in the within proceedings.

    I say that I have engaged in preliminary correspondence with the Solicitors for HPRA regarding their liability in the matter, but it is fair to say, that the said correspondence indicates that HPRA will not be admitting that they have any culpability in the matter.

58. Accordingly, I pray this Honourable Court for an Order in terms of the Notice of Motion herein.

SWORN by Gillian O'Connor this 28th day of June 2017 at 2 Mountbrone Aquare, Smithfield, Dublin 7 before me a ~~Commissioner for Oaths~~/Practising Solicitor and I know the Deponent.

Gillian O'Connor

~~**COMMISSIONER FOR OATHS**~~/**PRACTISING SOLICITOR**

This Affidavit is filed by Augustus Cullen Law, Solicitors, 7 Wentworth Place, Wicklow on behalf of the Plaintiff.

RECORD NO: 2012/12009P

THE HIGH COURT

BETWEEN:

AOIFE BENNETT

PLAINTIFF

AND

THE MINISTER FOR HEALTH AND CHILDREN, THE HEALTH SERVICE EXECUTIVE, AND GLAXOSMITHKLINE BIOLOGICALS S.A.

DEFENDANTS

AFFIDAVIT OF GILLIAN O'CONNOR

Exhibit "**GOC 1**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 28th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

~~**Commissioner for Oaths/**~~**Practising Solicitor**

RECORD NO:

THE HIGH COURT

2012 12009P

BETWEEN:

AOIFE BENNETT

PLAINTIFF

AND

THE MINISTER FOR HEALTH AND CHILDREN, THE HEALTH SERVICE EXECUTIVE, AND GLAXOSMITHKLINE BIOLOGICALS S.A.

DEFENDANTS

PERSONAL INJURIES SUMMONS

To: the Defendant
GlaxoSmithKline Biologicals S.A.,
having its registered office at
Rue de L'Institut 89,
B-1330 Rixensart,
Belgium

This Personal Injuries Summons requires you to enter an Appearance in person or by Solicitor in the Central Office, Four Courts, Dublin 7, Ireland in the above action within five weeks after this Notice of Summons / Summons has been served on you (exclusive of the day of such service).

AND TAKE NOTICE that if you do not enter an Appearance the Plaintiff may proceed in this action and Judgment may be given in your absence.

BY ORDER
The Honourable Susan Denham, Chief Justice of Ireland
The 27th day of November Two Thousand and Twelve

NB This Summons is to be served within twelve calendar months from the date hereof unless the time for service has been extended by the Court. The Defendant may appear to this Summons by entering an Appearance either personally or by Solicitor at the Central Office, Four Courts, Dublin 7.

INDORSEMENT OF CLAIM

1. The Plaintiff ordinarily resides at 165 Lakelands, Naas, Co. Kildare. She brings these proceedings seeking damages for serious personal injuries, damage, and loss suffered by her in consequence of having received the Pandemrix vaccine produced by the Third Named Defendant and purchased, approved, and administered in this jurisdiction by the First and Second Named Defendants and its servants or agents.

2. The First Named Defendant is a Minister sole, having his registered office at Hawkins House, Hawkins Street, Dublin 2. The First Named Defendant is responsible for the governance, operation, and management of the public health and medical system in Ireland, and he is entrusted with a duty to take all reasonable steps to ensure the safe administration of public health and medical services in the State.

3. The Second Named Defendant is a statutory health authority, established within the State by Section 6 of the Health Act, 2004, whose duty, under and by virtue of the Health Acts, 1947-2004, as amended, is to provide and administer health services within the State. At all the material times herein, the Second Named Defendant was *inter alia* responsible for the provision of public health and medical services in the State, as well as the provision of appropriate advice and the promotion of health.

4. The First and Second Named Defendants owed the Plaintiff duties of care in and around their decision to recommend and administer the Pandemrix vaccine in this jurisdiction. They owed the Plaintiff further duties in and around the advice they gave and caused to be given with respect to the Pandemrix vaccine and its potential effects and risks of injury. They owed the Plaintiff further duties in and around administration of the vaccine through their servants or agents. They owed the Plaintiff further duties in and around their response to health complications and injuries suffered in consequence of having received the said vaccine.

5. The Third Named Defendant is the producer of the Pandemrix vaccine administered in this jurisdiction in the circumstances particularised herein. At all the material times, the said vaccine was a product and the Defendant was its producer for the purposes of the Liability for Defective Products Act, 1991. The Third Named Defendant owed the Plaintiff additional duties of care to take all reasonable steps to ensure the safety of its product, and to investigate sufficiently the associated risks of injury, and to warn purchasers and users of the vaccine as to the risks of injury, known and unknown.

6. The Defendants are directly and/or vicariously liable to compensate the Plaintiff for her severe personal injuries, damage, and loss in the circumstances herein particularised.

7. In the midst of concern as to the health risks posed by 'human swine influenza' in 2009 and 2010, the First and Second Named Defendants purchased, approved, and administered in the State a form of the Pandemrix vaccine manufactured and produced by the Third Named Defendant. The Second Named Defendant thereupon adopted and ran a Pandemrix vaccine programme in the State, administering the vaccine through its servants or agents in local hospitals, clinics, and schools.

8. Following warnings by the HSE on the risks associated with swine 'flu, the Plaintiff was vaccinated with the said Pandemrix on or about the 8th day of December 2009 at a HSE clinic in St. Mary's College, Naas, County Kildare.

9. In consequence of receiving the Pandemrix vaccine, the Plaintiff proceeded to suffer a narcolepsy and cataplexy disorder and the severe personal injuries, damage, and loss herein particularised. The Plaintiff has since been required to attend doctors regularly for investigation and management of the condition, with highly disruptive on-going effects for her daily life.

10. The Plaintiff did not begin to acquire knowledge of a possible association between her personal injuries and the Pandemrix vaccine for the purposes of the Statute of Limitations Acts, 1957-1991, until after it began to be discussed in the media from about March 2011.

11. A report was published by the Department for Health and Children on the 19th day of April 2012 called "Investigation of an Increase in the Incidence of Narcolepsy in Children and Adolescents in 2009 and 2010". Based on the information yet to hand, the Report found a 13-fold increase in the incidence of narcolepsy in children and adolescents who received the Pandemrix vaccine in Ireland, when contrasted with children and adolescents who did not receive the vaccine. This was observed to be remarkably similar to findings in a retrospective population-based cohort study published in Finland (as an Interim Report on the 31st day of January 2011 and as a Final Report on the 1st day of September 2011) and to other such studies in Scandinavia. The Report also acknowledged the higher incidence in Northern Europe of genetic material predisposing its carriers to narcolepsy, namely the DQB1*-0602 human leukocyte antigen. It cited evidence which could be construed to suggest a 35 % incidence of the said antigen in Ireland.

12. Negligence and breaches of duty (including breaches of statutory duty) on the part of the Defendants and their servants or agents caused the Plaintiff to suffer her severe personal injuries, damage, and loss, and/or they materially contributed to all or some of the said personal injuries, damage, and loss, and/or they caused the Plaintiff to lose a material chance of avoiding some or all of the said personal injuries, damage, and loss.

PARTICULARS OF LIABILITY UNDER THE LIABILITY FOR DEFECTIVE PRODUCTS ACT, 1991

The Third Named Defendant is liable to the Plaintiff under the Liability for Defective Products Act, 1991 for all the personal injuries, damage, and loss which she was caused to suffer due to defects in the design, manufacture, and/or production of the Pandemrix vaccine distributed in this jurisdiction which created or enhanced the risk of narcolepsy related injuries in patients who received it and which caused the Plaintiff to suffer narcolepsy related injuries in the circumstances herein particularised.

PARTICULARS OF NEGLIGENCE AND BREACH OF DUTY BY THE FIRST AND SECOND NAMED DEFENDANTS

The First and Second Named Defendants and/or their servants or agents were guilty of negligence and breach of duty by:

a) Approving and/or adopting the Pandemrix vaccine for a national vaccination programme;
b) Recommending the Pandemrix vaccine;
c) Administering the Pandemrix vaccine;
d) Failing to satisfy themselves, sufficiently or at all, as to the risks of injury known to be associated with the Pandemrix vaccine;
e) Failing to satisfy themselves, sufficiently or at all, as to the unknown risks of injury potentially associated with the Pandemrix vaccine;
f) Failing to seek further information on all the potential risks posed by administration of the vaccine in this jurisdiction;
g) Failing to warn, sufficiently or at all, as to the known risks and/or the unknown risks and/or the uncertainties and/or the potential consequences of receiving the vaccine;
h) Failing to approve or recommend alternative vaccines about which more was known at the time;
i) Failing to have regard, sufficiently or at all, to the incidences of genetic predisposition to narcolepsy;
j) Failing to provide and/or delaying in the provision of adequate treatment to ameliorate the physical effects of the disorder;
k) Failing to provide and/or delaying in the provision of adequate treatment to ameliorate the effects of the disorder for education;
l) Failing to provide and/or delaying in the provision of adequate treatment to ameliorate the effects of the disorder for mental welfare;
m) Failing to advise the public at an earlier date of the association between the Pandemrix vaccine and narcolepsy and cataplexy.

PARTICULARS OF NEGLIGENCE AND BREACH OF DUTY BY THE THIRD NAMED DEFENDANT

The Third Named Defendant and/or its servants or agents was guilty of negligence and breach of duty by:

a) Failing to exercise reasonable care when manufacturing and producing the Pandemrix vaccine received by the Plaintiff;
b) Failing to exercise reasonable care in and around its distribution and supply of the Pandemrix vaccine in this jurisdiction;
c) Failing sufficiently to investigate the risks potentially associated with the form of Pandemrix vaccine with Squalene adjuvant which was administered in this jurisdiction;
d) Failing to test the Pandemrix vaccine, adequately or at all;
e) Failing to test the effects of the vaccine adjuvant, namely Squalene;
f) Failing to warn, sufficiently or at all, as to the associated risks of injury, known and unknown;
g) Manufacturing the Pandemrix vaccine to include a Squalene adjuvant;
h) Recommending distribution in this jurisdiction of the Pandemrix vaccine with Squalene adjuvant;
i) Supplying the Pandemrix vaccine with Squalene adjuvant in this jurisdiction;
j) Failing to have any or adequate regard to the risk that the Pandemrix vaccine and/or the Squalene adjuvant might engender narcolepsy and/or cataplexy;

k) Failing to have regard to demographic incidences of genetic predisposition to narcolepsy;

l) Failing to advise, caution, or warn as the risk that the said Pandemrix vaccine might engender narcolepsy and/or cataplexy.

The Plaintiff expressly reserves the right to furnish the Defendants with further particulars of negligence, breach of duty, breach of statutory duty, or other wrong, where to hand.

BY REASON of the aforesaid negligence, breach of duty, breach of statutory duty, and wrong on the part of the Defendants and/or their servants or agents, the Plaintiff has suffered the following severe personal injuries, damage and loss.

PERSONAL INJURIES, DAMAGE AND LOSS

Following vaccination with Pandemrix, the Plaintiff developed excessive daytime sleepiness, disruption to nocturnal sleep, and episodes of sudden weakness and cataplexy, with highly disruptive effects for her daily life and for her physical, mental, and emotional welfare.

The Plaintiff has consequently been required to attend doctors regularly for investigation and management of her condition. From about April 2010, she was required to attend her GPs regularly at their medical centre at 1 Friary Road, Naas, County Kildare for advice, examination, and treatment to address her recurrent fatigue and sleep disruption. On or about the 22nd day of April 2010, she was required to attend her GP, Dr. Alison McDonald, after falling spontaneously in the shower and chipping her teeth. She reported a worsening of her tendency to fall asleep as well as early morning fatigue.

A conservative attitude was initially taken to the Plaintiff's profound tiredness, and she was advised to rest and to avoid exercise, as well as to keep a sleep diary. By the time of her consultation with Dr. McDonald on or about the 11th day of May 2010, she had reported three fainting episodes. She attended The National Children's Hospital, Tallaght on 17 May 2010 where she underwent an ECG exam and following concerns raised by the doctors in The National Children's Hospital, Tallaght she was admitted to Naas General Hospital for 2-3 days under the care of Dr. Michael Durrity, a consultant physician, in or about May 2010 for further investigation. She was required to undergo blooding testing for count levels, biochemistry, glucose, cortisol, and haematemics, as well as tests for thyroid function, a chest x-ray, and CT and MRI brain scans, which all reported as normal. The Plaintiff was also referred by Dr. McDonald to Dr. Siobhan Hutchinson, a consultant neurologist, at the Blackrock Clinic, where she presented in or about May 2010.

Following a finding of moderate depression by her GP Dr. McDonald, the Plaintiff was also referred urgently to Ms. Tonya Madden, a psychologist with the HSE, and she was initially placed on a waiting list on or about the 29th day of June 2010. Between August and September 2010, she attended Ms. Madden for four or so sessions of counseling, but did not feel she gained any improvement. She was also referred by Dr. McDonald to Dr. Alyson Lee, a consultant psychiatrist, at Naas, County Kildare on or about the 24th day of June 2010. It was noted by Dr. McDonald

that during a routine ECG examination the Plaintiff had become unresponsive with eye fluttering, which episode had been preceded by recurrent falls and collapses at home. Her mood was found to be very low and irritable throughout her numerous medical attendances.

The Plaintiff was referred by her GP, Dr. McDonald, to Dr. Grzegorz Wisniewski, a consultant psychiatrist, who examined her on or about the 11th day of November 2010 and the 14th day of December 2010. On or about the 17th day of January 2011, Dr. Wisniewski advised that the Plaintiff was suffering atypical depressive symptoms stemming from sleep disruption with neurotic dissociative disorder and mixed depressive anxiety symptoms..

The Plaintiff was prescribed numerous different medical drugs to address her condition as it manifested itself at various times to her doctors. She was prescribed (*inter alia*): on or about the 9th day of September 2010, a low dose of Fluoxetine, an anti-depressant; on or about the 16th day of September 2010, Zopitan tablets for sedation; on or about the 28th day of September 2010, Prozac; on or about the 2nd day of November 2010 Stilnocht tablets; on or about the 17th day of November 2010, Nitrazapam; on or about the 21st day of December 2010, Clonamox; on or about the 17th day of January 2011, Zopiclone. She reported serious deterioration over the Christmas of 2010. Laughter or excitement often caused her to fall to the ground. She was required to attend a day clinic at St. Mary's Hospital, a Mental Health Clinic in Naas on a weekly basis. The Plaintiff's mood fluctuated and she continued to report severe disruption to sleeping patterns, though improvement in her sleeping pattern was observed by Dr. Wisniewski, on or about the 17th day of January 2011, after receiving hypnotic Nitrazapam treatment. On or about the 8th day of March 2011, Dr. McDonald reported that she retained irritability and poor eye contact, failing to respond to treatment for depression.

In or about April 2011, the Plaintiff attended Dr. Catherine Crowe, a specialist in sleep disorder medicine, at 71 Eccles Street, Dublin 7. On or about the 18th day of April 2011, Dr. Crowe observed that the Plaintiff's cataplectic symptoms persisted but had become better controlled by the Plaintiff. It was also recorded that the Plaintiff frequently suffered nightmares along with tactile and auditory hallucinations at different times during the night including sleep onset hypnogogic hallucinations possibly associated with sleep paralysis described by the Plaintiff as akin to out of body experiences. She was reported to continue to suffer mild and moderate cataplectic episodes on a daily basis (around 10 a day) causing her speech to become blurred and her head and jaw to drop with tiredness if she laughed or expressed anger.

The Plaintiff was admitted to the Mater Private Hospital, Dublin between the 27th and the 28th days of April 2011 for sleep tests performed by Dr. Crowe. A Nocturnal Polysomnogram on the 27th day of April 2011 recorded short sleep latency and short REM latency. A Multiple Sleep Latency Test performed on the 28th day of April 2011 found severe daytime sleepiness with a mean sleep latency of 0.5 minutes and 4 sleep onset REM periods, findings which were highly abnormal and indicative of narcolepsy. The Plaintiff was consequently started on Provigil (at 100mg daily) (increasing to 200mg morning and 100mg at lunchtime) on or about the 18th day May 2011, which was increased to 200mg in the morning and 100mg at lunchtime on or about the 24th day May 2011. On or about the 20th day of August 2011, she was started on Ritalin (20mg in the morning and 20mg at lunchtime) to address the narcolepsy and on Venlafaxine (37.5mg, to be increased if necessary to twice daily) to address the cataplexy (which was changed subsequently to Efexor XL at 37.5mg twice daily).

The Plaintiff's quality of life has been seriously curtailed in consequence. She has also suffered significant mental distress, anxiety, and worry arising from the condition, its diagnosis, and the potential implications for her into the future, personally, socially, and occupationally.

The Plaintiff had always been a high achiever at school. After these injuries developed, however, she routinely suffered morning fatigue, significant drops in her concentration and energy levels, which hindered her abilities at college. Throughout 2010, she was observed by her teachers to 'zone out' in class, and she was required to miss 5 or 6 weeks of school in April-May 2010 as well as to shorten her class times. The medication she was prescribed contributed to her drowsiness. In September 2010, the Plaintiff commenced her leaving certificate year but due to her illness continued to miss significant amounts of school. Due to her absences from school and the stress caused to the Plaintiff during this period, it was decided that she should repeat fifth year in her secondary school, St Mary's College.

The Plaintiff had previously been a sporty girl and she represented her school in athletics, cross country running and volleyball. She also represented her county for the All Irelands in cross country running. Following her profound tiredness and regular cataplectic episodes, she was required to discontinue her former physical pursuits such as athletics and volleyball. By the time she was examined by Dr. Crowe in or about the 18th day of April 2011, she was observed to have discontinued sports and to have gained two stone over the year. Her weight was observed by Dr. Crowe to have reduced a little by the 7th day of November 2011, and she was noted to have recommenced playing volleyball, following her prescription of Ritalin and Venlafaxine.

These personal injuries continue to present difficult challenges to the Plaintiff in all aspects of her ordinary life. The Plaintiff expressly reserves the right to furnish the Defendants with further and/or updated particulars of her personal injuries, damage, and loss hereafter where to hand.

AND THE PLAINTIFF CLAIMS AGAINST THE DEFENDANTS, THEIR SERVANTS OR AGENTS:

1. Damages.
2. Such further or other Order and / or direction as this Honourable Court shall deem appropriate.
3. Interest pursuant to Statute.
4. The costs of these proceedings.

JOHN HEALY B.L.

SCHEDULE

PARTICULARS OF ITEMS OF SPECIAL DAMAGE

(a) Medical expenses	€ to be ascertained
(b)Travel expenses	€ to be ascertained
(c) Loss of earnings	€ to be ascertained
(d) Miscellaneous / Other Expenses	€ to be ascertained

The Plaintiff is currently seeking to obtain full details of the relevant amounts for the above categories of Special Damage, but said details are not yet available. The Plaintiff shall provide these details when to hand. The Plaintiff reserves the right to serve updated and/or further Particulars of Special Damage in due course.

SIGNED: Augustus Cullen Law
Augustus Cullen Law Solicitors,
Solicitors for the Plaintiff,
7 Wentworth Place,
Wicklow

INDORSEMENT PURSUANT TO ORDERS 4 AND 11A OF THE RULES OF THE SUPERIOR COURTS

The High Court has power to hear and determine the within proceedings pursuant to Council Regulation (E.C.) No.44/2001 of the 22nd day of December 2000 on Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters, as amended, and the High Court should assume jurisdiction to hear and determine the said claims (*inter alia*) under the provisions of Article 5(3), Article 6(1) and Article 16 of Council Regulation (E.C.) No.44/2001. The harmful event, negligence, breaches of duty and/or damage herein asserted against the Defendants occurred when the Plaintiff received the Pandremrix vaccine in County Kildare in this jurisdiction.

No proceedings between the Plaintiff and the Defendants concerning the same cause of action are pending in any other Member State of the European Union or in a Contracting State of the Lugano Convention.

This Summons was issued by Augustus Cullen Law Solicitors, Solicitors for the Plaintiff, whose registered place of business is 7 Wentworth Place, Wicklow.

The Plaintiff's personal details are as follows:

1. The address at which the Plaintiff ordinarily resides is: 165 Lakelands, Naas, Co. Kildare.
2. The Plaintiff's address for service is at the offices of: Augustus Cullen Law Solicitors, 7 Wentworth Place, Wicklow.
3. The Plaintiff's occupation is a student.

4. The Plaintiff's date of birth is: the 21st of December 1992.
5. The Plaintiff's Personal Public Service Number is: 8160934V.

This Summons was served by me at

in the County of

on the Defendant

on day, the day of 20

Indorsed the day of 20

SIGNED:-_____

Address:-_____

_____

_____

RECORD NO

THE HIGH COURT

BETWEEN:

AOIFE BENNETT

PLAINTIF

AND

THE MINISTER FOR HEALTH AND CHILDREN,

THE HEALTH SERVICE EXECUTIVE,
AND
GLAXOSMITHKLINE BIOLOGICALS S.A.

DEFENDANT

PERSONAL INJURIES SUMMONS

Augustus Cullen Law
Solicitors for the Plaintiff
7 Wentworth Place
Wicklow

RECORD NO: 2012/12009P

THE HIGH COURT

BETWEEN:

AOIFE BENNETT

PLAINTIFF

AND

THE MINISTER FOR HEALTH AND CHILDREN, THE HEALTH SERVICE EXECUTIVE, AND GLAXOSMITHKLINE BIOLOGICALS S.A.

DEFENDANTS

AFFIDAVIT OF AOIFE BENNETT

I, Aoife Bennett, of 165 Lakelands, Naas, in the County of Kildare, Student and Plaintiff in the above entitled proceedings aged 18 years and upwards MAKE OATH and say as follows:

1. I beg to refer to the contents of the Personal Injuries Summons and Concurrent Personal Injuries Summons delivered herein on behalf of the Plaintiff on the 15th day of November 2013 and upon a true copy of which marked "A" I have signed my name prior to the swearing hereof.

2. The assertions, allegations and information contained in the said Personal Injuries Summons and Concurrent Personal Injuries Summons, which are within my own knowledge are true. I honestly believe that the assertions, allegations and information contained therein which are not within my own knowledge are true.

3. I am aware that it is an offence to make a statement in this Affidavit that is false or misleading in any material respect and that I know it to be false and misleading.

Aoife Bennett

SWORN by Aoife Bennett this 25 day of [illegible] 2013 at Wicklow in the County of Wicklow before me a ~~Commissioner for Oaths/Practising Solicitor~~ and I know the Deponent.

~~COMMISSIONER FOR OATHS/PRACTISING SOLICITOR~~

This Affidavit is filed on behalf of the Plaintiff by Augustus Cullen Law, Solicitors, 7 Wentworth Place, Wicklow.

AMBER CRAUGHWELL
PRACTISING SOLICITOR
FREEHILL SOLICITORS
WICKLOW TOWN

RECORD NO: 2012/12009P

THE HIGH COURT

BETWEEN:

AOIFE BENNETT

PLAINTIFF

AND

THE MINISTER FOR HEALTH AND CHILDREN, THE HEALTH SERVICE EXECUTIVE, AND GLAXOSMITHKLINE BIOLOGICALS S.A.

DEFENDANTS

AFFIDAVIT OF AOIFE BENNETT

AUGUSTUS CULLEN LAW,
SOLICITORS,
7 WENTWORTH PLACE,
WICKLOW.
BEN017/0001

FAO: Miriam Glynn
Chief State Solicitors Office
3/10 The Chancery
Chancery Lane
Dublin 8
BY HAND DELIVERY

Our Ref: DMCK/VK/BEN017/0001
Your Ref: MG/2012/05461

15 November 2013

Re: Aoife Bennett–v- The Minister for Health and Children, The Health Service Executive and GlaxoSmithKline Biologicals S.A.
High Court Record No: 2012/12009P

Dear Sirs,

We refer to the above and to your letter dated the 6th December 2012 confirming that you are acting on behalf of the Minister for Health and Children and that you have authority to accept service of proceedings on his behalf. We would also refer to recent communication with the State Claims Agency and your goodselves in which it has been confirmed that you have authority to accept service of proceedings on behalf of the Health Service Executive.

In those circumstances, please find enclosed herewith Original and Copy Concurrent Personal Injuries Summons by way of service upon you and we would be extremely grateful if you could endorse the original and return same to us and enter an Appearance on behalf of the First and Second Named Defendants in this matter.

Yours faithfully,

Augustus Cullen Law
info@aclsolicitors.ie
encl..

Chief State Solicitors Office
3/10 The Chancery
Chancery Lane
Dublin 8
DX 186-001

By Post & Fax: 01 4176299

Our Ref: DMCK/CJ/BEN017/0001
Your Ref: MG/2012/05461

26 November 2013

Re: Aoife Bennett–v- The Minister for Health and Children, The Health Service Executive and GlaxoSmithKline Biologicals S.A.
High Court Record No: 2012/12009P

Dear Sirs,

We refer to the above and enclose herewith by way of delivery upon you copy Affidavit of Verification of our client, the original of which has been sent to the Central Office for filing.

We await hearing from you with your Appearance.

Yours faithfully,

Augustus Cullen Law
info@aclsolicitors.ie
encl..

FAO Niamh O'Brien
McCann FitzGerald
Riverside One
Sir John Rogerson's Quay
Dublin 2
DX 31 Dublin

By Post & Fax: 01 8290010

Our Ref: DMCK/CJ/BEN017/0001 26 November 2013

Re: Aoife Bennett –v- The Minister for Health & Children, The Health Service Executive and GlaxoSmithKline Biologicals S.A
High Court Record Number 2012/12009P

Dear Sirs,

We refer to the above and enclose herewith copy Affidavit of Verification of our client by way of delivery upon you. Please be advised that the original has been sent to the Central Office for filing.

We await hearing from you with your Appearance.

Yours faithfully,

Augustus Cullen Law
info@aclsolicitors.ie

Encl...

BY HAND
FAO Niamh O'Brien
McCann FitzGerald
Riverside One
Sir John Rogerson's Quay
Dublin 2

Our Ref: AL/LOB/BEN017/0001 15 November 2013

Re: Aoife Bennett –v- The Minister for Health & Children, The Health Service Executive and GlaxoSmithKline Biologicals S.A
High Court Record Number 2012/12009P

Dear Sirs,

We refer to written correspondence received from the Third Named Defendant and to the conversation between David McKechnie of this office and Niamh O'Brien of your office in which it was confirmed that you had authority to accept service of proceedings on behalf of GlaxoSmithKline Biologicals S.A.

In those circumstances, please find enclosed herewith Original and Copy Personal Injuries Summons by way of service upon you and we would be extremely grateful if you could endorse the original, return same to us, and enter an Appearance on behalf of the Third Named Defendant in this matter.

Yours faithfully,

Augustus Cullen Law
info@aclsolicitors.ie

Exhibit "**GOC 2**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 28th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

~~Commissioner for Oa~~ths/Practising Solicitor

Niamh McArdle

From:	Louise B Mannion [louise.b.mannion@gsk.com]
Sent:	30 October 2009 12:40
To:	Niamh M Mcardle; Clara C Rafferty
Subject:	FW: information PV Swedish MPA , for distribution
Attachments:	pic30649.gif; Summary of SE reported side effects of Pandemrix Oct 29, 2009.doc

Dear Niamh, Ciara
you may have received this from another source but thought might be of interest
Louise

Louise Mannion
Scientific Advisor
GlaxoSmithKline Ireland
Tel 00353 1 4955219

—— Forwarded by: Louise B Mannion/PharmEuro/GSK on 30/10/2009 12:39 ——

Dirk Zi
Campens/PharmBio

29-Oct-2009 16:25

To: Joy S Dasgupta/MIS/Pharma/SB_PLC@G
Seet/PharmRD/GSK@GSK, Marc M
Vandenhaute/PharmEuro/GSK@GSK, Ko
Georgieva/PharmEuro/GSK@GSK, Magd
Berberova/PharmEuro/GSK@GSK, Georg
Constantinides/PharmEuro/GSK@GSKEU
Bartova/PRA/Pharma/SB_PLC@GSK, Ev
Kaliskova/PharmEuro/GSK@GSKEX, Ta
Holubova/PharmEuro/GSK@GSKEX, Ka
Pospisilova/PharmEuro/GSK@GSK, Ebb
Hagley/PharmEuro/GSK@GSK, Malene I
Hersløv/PharmEuro/GSK@GSK, Toomas
Pruuksild/TAL/Pharma/SB_PLC@GSKEU
Punmalainen/PharmEuro/GSK@GSK, Pet
Kotyusev/PharmEuro/GSK@GSK, Sophia
Muller/PharmEuro/GSK@GSK, Rupprecht
Ott/PharmEuro/GSK@GSK, Jens J Volln
Ioannis G Kotakis/PharmEuro/GSK@GS
Daskos/PharmEuro/GSK@GSK, Sigridur
Jakobsdottir/PharmEuro/GSK@GSK, T
Cunningham/PharmEuro/GSK@GSK, Ma
Akveld/PharmEuro/GSK@GSK, Magda C
Berkejeva/PharmEuro/GSK@GSK, Louis
Mannion/PharmEuro/GSK@GSK, Anton
Tjando/TEL/Pharma/SB_PLC@GSK, Noa
Rosenlund/PharmEuro/GSK@GSK, Krista
Lie/OSL/Pharma/SB_PLC@GSK, Olav
Flatoe/OSL/Pharma/SB_PLC@GSK, Arn
Terczynski/WAR/Pharma/SB_PLC@GSK
Stryjewska/PharmEuro/GSK@GSK, Alek
Jastrzebska/WAR/Pharma/SB_PLC@GSK

Mariazka/WAR/Pharma/SB_PLC@GSK, Paixao/LIS/Pharma/SB_PLC@GSK, Rudc den-Boogaardt/PharmEuro/GSK@GSK, S Tofant/PharmEuro/GSK@GSKEX, Kafae Ré/MAD/Pharma/SB_PLC@GSK, Pilar G Corbella/MAD/Pharma/SB_PLC@GSK, F Engetvall/PharmEuro/GSK@GSK, Hilar Kangro/PharmEuro/GSK@GSK, Peter M Richard R Brud/PharmEuro/GSK@GSK, Olden/PharmEuro/GSK@GSK, Pia 7 Ro Karen 2 Mullen/PharmEuro/GSK@GSK, Formica/PharmEuro/GSK@GSK, Arne X Marcel A Out/PharmEuro/GSK@GSK, R Remorde/PharmEuro/GSK@GSK

cc Per E Engetvall/PharmEuro/GSK@GSK, Monteyne/RIX/Pharma/SB_PLC@GSK, I Breuer/RIX/Pharma/SB_PLC@GSK, Ema Hanon/RIX/Pharma/SB_PLC@GSK, Dirk Poelaert/PharmBio/GSK@GSK, Anar E A John A Dillon/PharmEuro/GSK@GSK, D Drolet/PharmFat/GSK@GSK, Guillermo J Taracena/PharmRD/GSK@GSK, Dora D Juan C Jaramillo/PharmBio/GSK@GSK, Hugo/PharmEuro/GSK@GSK, Bruce 2 Innis/DEV/PHRD/SB_PLC@GSK, Thom Verstraete/RIX/Pharma/SB_PLC@GSK, Kenney/Complementary/PharmBio/GSK@

Subject Information FV Swedish MPA, for distrib

To the medical representatives of the 25 European countries with purchased Pandemrix, Switzerland and Canada

Dear All ,

Below please find cumulative Adverse Event reporting from Sweden. It is available on the web page of the public health agency (MPA) and updated once a week.

It is highly informative since it gives a good overview on the (current) profile of Pandemrix. However, please keep in mind that countries report to GSK SERIOUS Adverse events (related and unrelated) whereas the Swedish data are much broader since they report Adverse Events (serious, non serious, related and unrelated) from Health Care Professionals as well as from Consumer reports.

This is an English version of the Swedish MPA web page on cumulative weekly reporting of AE in Sweden.
We expect the Swedish MPA to publish an English version on the web soon.
Hereby the link to the MPA website: http://www.lakemedelsverket.se/Alla-nyheter/NYHETER-2009/Sammanstallning-av-inrapporterade-biverkningar-av-Pandemrix---vaccinet-mot-influensa-AH1N1/

Please distribute this important overview to the groups in your country that you consider appropiate.

Kind regards

Summary of the information published on the MPA website (Oct 29, 2009) regarding adverse drug reaction reports in Sweden with Pandemrix – the influenza A (H1N1) vaccine

Published October 29, 2009

As of today, about 1.4 million doses of Pandemrix have been distributed in Sweden. In total, about two hundred adverse drug reaction (ADR) reports have been received by the MPA from Health Care Professionals and between 400–500 reports from consumers. The ADR reporting pattern does not deviate from what has been seen in the clinical trials. However, there is particular reason to follow reports of allergic reactions.

It should be remembered that all ADR reports should be considered as part of a larger pattern in which one single report rarely means that an adverse reaction was caused by the vaccine. It is important to stress the following:

- The reports describe reactions that have occurred in close connection to when the vaccine was given.
- The reaction can thus be caused by the vaccine, but can also be signs of illness the patient suffered from regardless of the vaccination.
- Causality assessment can only be made after the report has been carefully assessed.

Since the vaccination campaign began, the MPA has published summaries of adverse events reported with Pandemrix. MPA will continue to review and assess all reports, but the published compilations will mainly focus on reports relating to unknown and serious suspected adverse reactions, while the presentation of reports on the known side effects are reported only briefly.

Reports from Health Care Professionals

Almost 200 reports have been received from health care professionals.

The majority of the adverse events are expected and known reactions such as soreness, redness and pain at the injection site and in the arm, and flu-like symptoms such as fever, shivering, fatigue, moderate/severe headaches, body aches and malaise. Experiences from certain vaccination sites point to the fact that these expected reactions have been very common. In a fewer number of reports, symptoms of nausea, vomiting, stomach pain, diarrhoea, dizziness, rashes and insomnia are reported. All these reactions are known from the studies performed on Pandemrix. Also a number of allergic reactions have been reported (see below).

Comments on some case reports

About 20 reports of the suspected adverse reactions have been identified as serious and with a casual relationship to the vaccination. Allergic adverse reactions represent the majority of these reports, see table below. Besides these, facial palsy (one case), paresthesia (three cases), sensibility disorder (one case), hypertension (one case), and absence attacks (one case) were reported.

Allergic reactions/allergic symptoms reported in relation to administration of Pandemrix

Included in SWEDIS data base 12 Oct - 27 Oct, 2009

	Related	(of which were serious)	Not related
Allergic reaction	10	(3)	2
Anaphylactic reaction	5	(5)	1
Angioedema	5	(3)	0
Urticaria	8	(2)	0
Exanthema	2	(0)	1
Flush	3	(0)	0
Swollen tongue	2	(0)	1
Dyspnoea	7	(2)	1
Cough	1	(0)	0
TOTAL no of symptoms (patients)	41 (37)	(15)	6

In total, 41 reports of allergic reactions/symptoms in 37 patients were considered to be related to the vaccination. Allergic reactions considered not related, were reported in 6 patients.

Four of the five patients with anaphylactic reactions had a known allergy to certain foods or medicines. In all cases the reactions occurred within one hour after the vaccination. In two of the patients, hypotension was reported, and four patients reported dizziness, tingling, oedema of the lips and throat, and moderate difficulty breathing. None of the patients developed anaphylactic shock. All patients recovered after treatment with adrenaline, corticosteroids and antihistamines. Allergic reactions such as anaphylaxis, angioedema and urticaria are not specified in the product information for Pandemrix.

Two of the patients who were diagnosed with "allergic reaction" had previously known egg allergy. One of these patients had a strong reaction directly after the vaccination, but the symptoms were relieved quickly with adrenaline, cortisone and antihistamine treatment. The other patient had a transient urticarial reaction.

Deaths reported

Five reports of death have been received all of which have had a temporal association with vaccination. The time between the vaccination and the death has varied between 12 hours and 4 days. These five patients had previously known chronic diseases such as cardiovascular disease, diabetes, renal failure, dystrophic muscle disease and senile dementia. All patients were on chronic medical treatment. Three of the patients were >74 years, the two others between 54 and 63. Autopsy result is available for the first reported case. This showed that the patient suffered from generalized atherosclerosis and previous heart attacks. The other reports are still under investigation and autopsy results are awaited. From what has

emerged so far for these cases, there is nothing to support a causal association between the vaccination and the death.

In assessing the number of reported deaths, it is important to take into account that in Sweden on average 200-250 deaths occur per day and at present a large proportion of the population, particularly the elderly and other risk groups, are being vaccinated. The majority of deaths occurring daily in Sweden are older people with complications of chronic diseases.

Experience from consumer reporting

Since the vaccination campaign with Pandemrix began, the MPA has received more than 350 consumer reports. Still a large majority, about 90% of reports, describe non-severe, expected and known reactions. The potentially serious cases are similar to the ones previously reported (such as events of transient flu-like symptoms, severe pain at the injection site, pain in arm and adjacent muscles).). Despite the fact that an adverse reaction is known and judged as non-serious, symptoms may of course still be perceived as troublesome to the individual. Some patients have reported that the reactions to this Influenza vaccine differ from their experience with previous seasonal flu vaccinations, such as more pronounced pain in the injection area and stronger flu-like symptoms.

Exhibit "**GOC 3**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 26th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

~~Commissioner for Oaths~~/Practising Solicitor

Niamh McArdle

From:	Martijn L Akveld [martijn.l.akveld@gsk.com]
Sent:	29 October 2009 16:58
To:	brenda.corcoran1@hse.ie
Cc:	Maeveanne X McHugh
Subject:	English translation of the Swedish MPA web page on cumulative weekly reporting of AE in Sweden.
Attachments:	Summary of SE reported side effects of Pandemrix Oct 29, 2009.doc

Dear Brenda,
This is an English translation of the Swedish MPA web page on cumulative weekly reporting of AE in Sweden as promised. We expect the Swedish MPA to publish an English version on the web soon. This is the link to the MPA website: http://www.lakemedelsverket.se/Alla-nyheter/NYHETER-2009/Sammanstallning-av-inrapporterade-biverkningar-av-Pandemrix---vaccinet-mot-influensa-AH1N1/
Kind regards,
Martijn.
(See attached file: Summary of SE reported side effects of Pandemrix Oct 29, 2009.doc)
Martijn Akveld
Scientific Affairs Manager
GlaxoSmithKline (Ireland) Ltd.
1800 244 255

Summary of the information published on the MPA website (Oct 29, 2009) regarding adverse drug reaction reports in Sweden with Pandemrix – the influenza A (H1N1) vaccine

Published October 29, 2009

As of today, about 1.4 million doses of Pandemrix have been distributed in Sweden. In total, about two hundred adverse drug reaction (ADR) reports have been received by the MPA from Health Care Professionals and between 400-500 reports from consumers. The ADR reporting pattern does not deviate from what has been seen in the clinical trials. However, there is particular reason to follow reports of allergic reactions.

It should be remembered that all ADR reports should be considered as part of a larger pattern in which one single report rarely means that an adverse reaction was caused by the vaccine. It is important to stress the following:

- **The reports describe reactions that have occurred in close connection to when the vaccine was given.**
- **The reaction can thus be caused by the vaccine, but can also be signs of illness the patient suffered from regardless of the vaccination.**
- **Causality assessment can only be made after the report has been carefully assessed.**

Since the vaccination campaign began, the MPA has published summaries of adverse events reported with Pandemrix. MPA will continue to review and assess all reports, but the published compilations will mainly focus on reports relating to unknown and serious suspected adverse reactions, while the presentation of reports on the known side effects are reported only briefly.

Reports from Health Care Professionals

Almost 200 reports have been received from health care professionals.

The majority of the adverse events are expected and known reactions such as **soreness, redness and pain at the injection site** and in the arm, and **flu-like symptoms** such as fever, shivering, fatigue, moderate/severe headaches, body aches and malaise. Experiences from certain vaccination sites point to the fact that these expected reactions have been very common. In a fewer number of reports, symptoms of nausea, vomiting, stomach pain, diarrhoea, dizziness, rashes and insomnia are reported. All these reactions are known from the studies performed on Pandemrix. Also a number of allergic reactions have been reported (see below).

Comments on some case reports

About 20 reports of the suspected adverse reactions have been identified as serious and with a casual relationship to the vaccination. **Allergic adverse reactions** represent the majority of these reports, see table below. Besides these, facial palsy (one case), paresthesia (three cases), sensibility disorder (one case), hypertension (one case), and absence attacks (one case) were reported.

Allergic reactions/allergic symptoms reported in relation to administration of Pandemrix

Included in SWEDIS data base 12 Oct - 27 Oct, 2009

	Related	(of which were serious)	Not related
Allergic reaction	10	(3)	2
Anaphylactic reaction	5	(5)	1
Angiooedema	5	(3)	0
Urticaria	6	(2)	0
Exanthema	2	(0)	1
Flush	3	(0)	0
Swollen tongue	2	(0)	1
Dyspnoea	7	(2)	1
Cough	1	(0)	0
TOTAL no of symptoms (patients)	41 (37)	(15)	6

In total, 41 reports of allergic reactions/symptoms in **37** patients were considered to be **related** to the vaccination. Allergic reactions considered **not related** were reported in **6** patients.

Four of the five patients with anaphylactic reactions had a known allergy to certain foods or medicines. In all cases the reactions occurred within one hour after the vaccination. In two of the patients, hypotension was reported, and four patients reported dizziness, tingling, oedema of the lips and throat, and moderate difficulty breathing. None of the patients developed anaphylactic shock. All patients recovered after treatment with adrenaline, corticosteroids and antihistamines. Allergic reactions such as anaphylaxis, angioedema and urticaria are not specified in the product information for Pandemrix.

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Deaths reported

Five reports of death have been received all of which have had a temporal association with vaccination. The time between the vaccination and the death has varied between 12 hours and 4 days. These five patients had previously known chronic diseases such as cardiovascular disease, diabetes, renal failure, dystrophic muscle disease and senile dementia. All patients were on chronic medical treatment. Three of the patients were >74 years, the two others between 54 and 65. Autopsy result is available for the first reported case. This showed that the patient suffered from generalized atherosclerosis and previous heart attacks. The other reports are still under investigation and autopsy results are awaited. From what has

emerged so far for these cases, there is nothing to support a causal association between the vaccination and the death.

In assessing the number of reported deaths, it is important to take into account that in Sweden on average 200-250 deaths occur per day and at present a large proportion of the population, particularly the elderly and other risk groups, are being vaccinated. The majority of deaths occurring daily in Sweden are older people with complications of chronic diseases.

Experience from consumer reporting

Since the vaccination campaign with Pandemrix began, the MPA has received more than 450 consumer reports. Still a large majority, about 90% of reports, describe non-severe, expected and known reactions. The potentially serious cases are similar to the ones previously reported (such as events of transient flu-like symptoms, severe pain at the injection site, pain in arm and adjacent muscles).). Despite the fact that an adverse reaction is known and judged as non-serious, symptoms may of course still be perceived as troublesome to the individual. Some patients have reported that the reactions to this influenza vaccine differ from their experience with previous seasonal flu vaccinations, such as more pronounced pain in the injection arm and stronger flu-like symptoms.

Exhibit "**GOC 4**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 28th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

~~Commissioner for Oaths~~/Practising Solicitor

Maeveanne McHugh

From:	Richard T Kenney [richard.t.kenney@gskbio.com]
Sent:	12 November 2009 05:34
To:	Carlos A LEANDRO; David J Krakovsky; Eugene X Goh; Eva E Kalickova; George C Constantinides; Geraldine A Cruz-Crimen; Halweh H Tang; Helen N Papathanasiou; Jana J Fesenkova; Joven Q Tanchuco; Kremena V Georgieva; Lea L Sernit; Lea M Hyllested; Maeveanne X McHugh; Marthe A Bonnin; Nancy N Yao; Niamh M Mcardle; Olav Flaten; Oleg B Milenin; Per E Engervall; Petteri K Klaudsen; Pierre P Jamous; Pilar Diego-Saiz; Pim T Kon; Sadhna J Joglekar; Thomas R Pruunsild; Ulrich U Hoelscher; Won W Choi; Yasunori Z Terashima; Yee-Leong Y Teoh; Yolanda M Cervantes; Yongyuth X Wangroongsarb
Cc:	Alain H Breux; Andrew R Rut; Anil K Dutta; Aurelie A Delaigle; Bruce Z Innis; Camilo A Moreno; Christophe G Mullinger; Dirk Z Campens; Dorothy A Slevin; Eduardo Z Ortega; Emilio F Ledesma; Emmanuel J Hanon; Fernanda P Tavares; Gary D Dubin; Gary P Ong; Hany A Seifert; Jean L O-Connor; Juan C Jaramillo; Michael H Bauer; Richard T Kenney; Romulo E Colindres; Stephen X Gardner; Thomas B Breuer; Thomas M Verstraeten; Vincent G Bauchau
Subject:	H1N1 Enhanced Safety Review Team (Team I) Communication on Safety Review for 4-10 Nov 09

Dear All,

We have two specific requests/reminders for you all:

1. It is crucial for us to have valid exposure data. Please forward any actual data that you have available on number of doses used in your countries, including use in pregnancy and children, to Aurélie Delaigle (aurelie.a.delaigle@gskbio.com) – these are difficult numbers to account for each week and we appreciate your help with updates.

2. Multiple agencies are putting summaries of their experience in thier websites. We expect you to screen these for AESIs and ensure you have already reported these to us. If not, please do so ASAP.

Here is the summary of the H1N1 pandemic vaccines safety review for Week 45:

The current review covers data which has been reported to GSK in the period **from 4 to 10 Nov 09**, as well as the cumulative safety. This data also includes information from clinical trials, spontaneous reports, phase IV studies and any other source of potential safety signals. The total number of subjects that have been enrolled in clinical trials is **2772, including 582 in pediatric studies**, (D-Pan program) and **2187, including 115 in pediatric studies** (Q-Pan program), including subjects of all ages down to 6 months old. A total of 20 SAEs have been reported in these trials, of which 3 were considered related to the H1N1 vaccine by the investigator. A review of these events as well as the non-serious events has not raised any safety concerns. The reactogenicity profile of the H1N1 adjuvanted vaccine appears to be broadly in line with the reactogenicity of the H5N1 adjuvanted vaccine.

It is our understanding that GSK's H1N1 pandemic vaccines are now being administered in at least **19 countries (Belgium, Canada, Denmark, Egypt, Finland, France, Germany, Greece, Ireland, Israel, Japan, Jersey, Luxembourg, Norway, Oman, Portugal, Sweden, Turkey, United Kingdom)**. The total number of doses of Pandemrix distributed cumulatively **as of 9 Nov is 30.5 million doses to 34 countries**. For **Arepanrix**, the total number delivered **is 6.5 million doses to 1 country (Canada)**. Current estimates are that a total of **6.4 million** doses have been administered to date, including at least **37,300** doses to children and **15,000**

doses in pregnant women. Please inform Dirk Campens (Dirk.Campens@gskbio.com) if your country has started its vaccination campaign and we have not listed the country.

The total number of adverse events that have been reported spontaneously during this review period for is **469, mostly from Finland, Germany, Ireland, Norway, Sweden, UK, and Belgium**, reflecting the known usage patterns. The total number of adverse events that have been reported spontaneously during this review period for Arepanrix (antigen source Quebec) **is 21, and all are from Canada**, reflecting the known usage pattern.

The current cumulative number of safety events captured in our Oceans data base is **642**, which gives a rate of about **100 reports/million doses administered**, compared to **173** reports received by the week before. The majority of the adverse events that have been reported are in line with those expected and described in the core safety information (pain, induration, swelling, redness, headache, fever, and fatigue are the most common). For the other events, no causal relationship to the vaccine is established or expected.

A total of **11 fatal cases** have been reported to date. A cumulative review of fatal cases is performed on a weekly basis and the latest review did not suggest any realtionship between the fatalities and vaccination. A total of **46 AESIs** have been reported to date. For **Arepanrix**, there have been **14 reports of anaphylaxis**, of which 7 were reported to fulfill either level 1 or 3 of the Brighton Criteria. The Arepanrix anaphylaxis cases are being further investigated. For **Pandemrix**, there have been **18 reports of anaphylaxis**, of which 4 meet the Brighton criteria. Other reports include **6 reports of facial palsy** (of which one is from an unknown manufacturer in the US), **6 reports of convulsion** (5 in children with febrile convulsion following vaccination [2 with prior history] and 1 in a 40-year-old female with history of seizure disorder), **1 report of possible optic neuritis**, and **1 case of local neuritis**. A review of facial palsy cases is ongoing.

The Phase IV cohort safety study (PASS) in the UK has enrolled 320 subjects to date and a single unrelated SAE has been reported in this study so far.

In summary, the risk/benefit profile of GSK's H1N1 pandemic vaccines has not changed and remains favorable. The events of interest are under close monitoring and the list remains unchanged. Reviews of anaphylaxis after Arepanrix and facial palsy after Pandemrix are ongoing.

Note that the information I am providing you is for your information only, so you can be prepared to answer questions that require this level of detailed knowledge. Any further communication internally or externally should be based on information provided by Team II and following the rules established by that team. Your preferred communication tool with the regulators should be the sPSURs, which will be added to the PSUR website alongside the other PSURs as soon as we finalize them. The next sPSUR is scheduled for submission on **23Nov.**

Kind Regards

Tom

Thomas Verstraeten, MD, MSc

Vice President
Head Biologicals Clinical Safety and Pharmacovigilance
Deputy Qualified Person for PharmacoVigilance

GlaxoSmithKline Biologicals
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B-1330 Rixensart, Belgium
Tel. 32-(0)2-656-8828 (new extension!)
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Email thomas.verstraeten@gskbio.com
Secretary: Nancy Visser Tel 32-(0)2-656-8850 or
Valérie Popieu Tel 32-(0)-6563798

Exhibit "**GOC 5**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 28th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

~~Commissioner for Oaths~~/Practising Solicitor

H1N1 Enhanced Safety Review Team (Team I) Communication on Safety Review for 24-30 Nov 09

From:

Thomas M Verstraeten <"/o=mms/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=verstt00">

To:

Carlos A LEANDRO <carlos.a.leandro@gsk.com>, David J Krakovsky <david.j.krakovsky@gsk.com>, Eugene X Goh <eugene.x.goh@gsk.com>, Eva E Kaliskova <eva.e.kaliskova@gsk.com>, George C Constantinides <george.c.constantinides@gsk.com>, Geraldine A Cruz-Crimen <geraldine.a.cruz-crimen@gsk.com>, Haiwen H Tang <haiwen.h.tang@gsk.com>, Helen N Papathanasiou <helen.n.papathanasiou@gsk.com>, Jana J Fesenkova <jana.j.fesenkova@gsk.com>, Joven Q Tanchuco <joven.q.tanchuco@gsk.com>, Kremena V Georgieva <kremena.v.georgieva@gsk.com>, Lea L Semri <lea.l.semri@gsk.com>, Lea M Hyllested <lea.m.hyllested@gsk.com>, Maeveanne X McHugh <maeveanne.x.mchugh@gsk.com>, Marthe A Bonnin <marthe.a.bonnin@gsk.com>, Nancy N Yao <nancy.n.yao@gsk.com>, Niamh M Mcardle <niamh.m.mcardle@gsk.com>, Olav Flaten <olav.flaten@gsk.com>, Oleg B Milenin <oleg.b.milenin@gsk.com>, Per E Engervall <per.e.engervall@gsk.com>, Petteri K Knudsen <petteri.k.knudsen@gsk.com>, Pierre P Jamous <pierre.p.jamous@gsk.com>, Pilar Diego-Salz <pilar.diego-salz@gsk.com>, Pim 7 Kon <pim.7.kon@gsk.com>, Sadhna J Joglekar <sadhna.j.joglekar@gsk.com>, Toomas R Pruunsild <toomas.r.pruunsild@gsk.com>, Ulrich U Hoelscher <ulrich.u.hoelscher@gsk.com>, Won W Choi <won.w.choi@gsk.com>, Yasunori 2 Terashima <yasunori.2.terashima@gsk.com>, Yee-Leong Y Teoh <yee-leong.y.teoh@gsk.com>, Yolanda M Cervantes <yolanda.m.cervantes@gsk.com>, Yongyuth X Wangroongsarb <yongyuth.x.wangroongsarb@gsk.com>

Cc:

Alain H Brecx <alain.brecx@gskbio.com>, Andrew R Rut <andrew.r.rut@gsk.com>, Anil K Dutta <anil.k.dutta@gskbio.com>, Antonio M Olivieri <antonio.m.olivieri@gskbio.com>, Aurelie A Delaigle <aurelie.a.delaigle@gskbio.com>, Barbara J Howe <barbara.j.howe@gsk.com>, Bruce 2 Innis <bruce.2.innis@gsk.com>, Camilo A Moreno <camilo.a.moreno@gsk.com>, Christophe C Mulfinger <christophe.mulfinger@gskbio.com>, Dirk Z Campens <dirk.z.campens@gskbio.com>, Dorothy A Slavin <dorothy.a.slavin@gsk.com>, Eduardo Z Ortega <eduardo.z.ortega@gsk.com>, Emilio F Ledesma <emilio.f.ledesma@gskbio.com>, Emmanuel J Hanon <emmanuel.hanon@gskbio.com>, Fernanda F Tavares <fernanda.tavares@gskbio.com>, Gary O Dubin <gary.o.dubin@gsk.com>, Gary P Ong <gary.p.ong@gsk.com>, Harry A Seifert <harry.a.seifert@gsk.com>, Jean L O-Connor <jean.l.o-connor@gskbio.com>, Juan C Jaramillo <juan.c.jaramillo@gskbio.com>, Michael H Bauer <michael.h.bauer@gskbio.com>, Richard T Kenney <richard.t.kenney@gskbio.com>, Romulo E Colindres <romulo.e.colindres@gsk.com>, Stephen X Gardner <stephen.x.gardner@gskbio.com>, Thomas B Breuer <thomas.breuer@gskbio.com>, Thomas M Verstraeten <thomas.verstraeten@gskbio.com>, Vincent G Bauchau <vincent.g.bauchau@gskbio.com>, Jean L O-Connor <jean.l.o-connor@gskbio.com>

Bcc:

Romulo E Colindres <romulo.e.colindres@gsk.com>

Date:

Wed, 02 Dec 2009 15:03:00 +0000

Dear All,

As always, we would like to remind you of the **importance of valid exposure data** and your role in updating our records with this information. Please forward any actual data that you have available on number of doses used in your countries each week, including use in

pregnancy and children, to Aurélie Delaigle (aurelie.a.delaigle@gskbio.com) - these are difficult numbers to account for each week and we appreciate your help with updates.

Here is the summary of the H1N1 pandemic vaccines safety review for Week 49:

The current review covers data which has been reported to GSK in the period from 24 to 30 Nov 09, as well as the cumulative safety. This data also includes information from clinical trials, spontaneous reports, phase IV studies and any other source of potential safety signals.
The total number of subjects that have been enrolled in clinical trials is 2778, including 582
in pediatric studies (D-Pan program) and 5998, including 256 in pediatric studies (Q-Pan program), including subjects of all ages down to 6 months old. A total of 27 SAE reports in D-PAN H1N1 and 8 reports in Q-PAN H1N1 studies, of which 4 were considered related to the H1N1 vaccine by the investigator have been received. A review of these events as well as the non-serious events has not raised any safety concerns, except for a relatively high rate of fever following the second dose in children. This observation has been communicated to authorities and a labelling variation has been submitted. Besides this, the reactogenicity profile of the H1N1 adjuvanted vaccine appears to be broadly in line with the reactogenicity of the H5N1 adjuvanted vaccine.

It is our understanding that GSK's H1N1 pandemic vaccines are now being administered in at least 34 countries (Bahrain, Brunei, Belgium, Canada, Cyprus, Czech Republic, Denmark, Egypt, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Jersey, Kuwait, Luxembourg, Libya, Malaysia, Morocco, Netherlands, Norway, Philippines, Portugal, Qatar, Saudi Arabi, Slovenia, Spain, Sweden, Switzerland, Turkey, UAE, UK). The total number of doses of Pandemrix distributed cumulatively as of 30 Nov is 54.5 million doses to 34 countries. For Arepanrix, the total number delivered is 15.5 million doses to 1 country (Canada). A total of 3.4 million doses of non-adjuvanted H1N1 vaccine have been delivered to Canada and US. This gives a grand total of 73.4 million doses delivered worldwide. GSK has been made aware of a total of 27 million doses administered to date (15 million doses of Pandemrix and 12 million doses of Arepanrix plus unadjuvanted H1N1 vaccine), including at least 840,000 doses to children and 110,000 doses to pregnant women. Please inform Dirk Campens (Dirk.Campens@gskbio.com) if your country has started its vaccination campaign and we have not listed the country.

The total number of AE reports that have been reported spontaneously during this review period for Pandemrix is 1276, mostly from UK, Germany, France, Denmark, Switzerland and Sweden. The total number of AE reports that have been reported spontaneously during this review period for Arepanrix (antigen source Quebec) is 84, and all are from Canada. Two reports have been received for the unadjuvanted vaccine.

As of data lock point 30 Nov 2009, a search of the OCEANS safety database identified a total of **4319 AE reports** (3807 Pandemrix, 510 Arepanrix and 2 for the unadjuvanted vaccine), compared to 2957 reports received by the week before. This gives a rate of about **160 reports/million doses administered.** The majority of the adverse events that have been reported are in line with those expected and described in the core safety information (pyrexia, headache, pain, fatigue, nausea, malaise, chills and myalgia are the most common). For the other events, no causal relationship to the vaccine is established or expected. In total, there have been **1233 SAE reports** (1138 Pandemrix and 95 Arepanrix) and **53 reported fatalities** (47 Pandemrix and 6 Arepanrix). For reports of fatalities, based on available data, there is no evidence for a causal association between vaccination and fatal outcome.

Event	Pandemrix	Arepanrix	Swine flu split Quebec without AS03	Total
All adverse events	3807	510	2	4319
Serious adverse events	1138	95	0	1233
Fatal outcomes	47	6	0	53
AESIs				
Anaphylaxis	141	43	0	184
Facial palsy	12	2	0	14
Guillain-Barré syndrome	3	1	0	4
Encephalitis	2	0	0	2
Demyelinating disorders	3	0	0	3
Convulsions	51	6	0	57
Neuritis	6	0	0	0
Vasculitis	10	0	0	10

For AESIs, there have been **184 reports of anaphylaxis** (141 Pandemrix and 43 Arepanrix, 7 of the cases reported were from the same Arepanrix lot; a manufacturing investigation is in progress to further evaluate this lot), **14 reports of facial palsy** (12 Pandemrix and 2 Arepanrix; causes other than influenza vaccine were present in 5 of the reports), **4 reports of GBS** (3 Pandemrix and 1 Arepanrix; one was diagnosed 4 months prior to Pandemrix vaccination, one provided no detail and the remaining 2 cases reported symptoms of ascending paresthesias diagnosed clinically as GBS with no testing [lumbar puncture, EMG, MRI] provided or negative results), and **2 report of encephalitis** (Pandemrix; symptoms one day after vaccination in a 51yo that resolved after 48 hrs for 1 case and no details provided yet for the other case). There have been **3 reports of multiple sclerosis** (Pandemrix); 2 were exacerbations of MS and in the third one, the subject had a history of intermittent neurological symptoms since 1997. There have been **57 reports of convulsions** (51 Pandemrix and 6 Arepanrix), 15 cases were reported in subjects with a history of epilepsy/convulsions and 14 cases were reported in association with a vasovagal response to the vaccine; an evaluation is ongoing. There have been **6 reports of neuritis** (unspecified or localized neuritis and

1 diagnosis of plexus femoralis) and **10 reports of vasculitis** following Pandemrix.

The Phase IV cohort safety study (PASS) in the UK has enrolled **about 6000** subjects to date, including 408 children and 162 pregnant women. A total of 8 SAEs have been reported in this study so far, with 2 considered related by the investigator (cough and atrial fibrillation). The first cumulative reports will be available in late December.

In summary, the risk/benefit profile of GSK's H1N1 pandemic vaccines has not changed and remains favourable. The events of interest are under close monitoring and the list remains unchanged. A review of dysgeusia, anaphylaxis, transplant rejections and convulsions is ongoing.

Note that the information I am providing you is for your information only, so you can be prepared to answer questions that require this level of detailed knowledge. Any further communication internally or externally should be based on information provided by Team II and following the rules established by that team. Your preferred communication tool with the regulators should be the sPSURs, which will be added to the PSUR website alongside the other PSURs as soon as we finalize them. The next **Pandemrix** sPSUR is scheduled for submission on **21Dec** and the next **Arepanrix** sPSUR is scheduled for submission on **2Dec.**

Tom

Thomas Verstraeten, MD, MSc

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Head Biologicals Clinical Safety and Pharmacovigilance
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Secretary: Nancy Visser Tel 32-(0)10-85-4843 or
Valérie Popieu Tel 32-(0)10-85-4823

Exhibit "**GOC 6**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 28th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

~~**Commissioner for Oaths**~~**/Practising Solicitor**

Niamh McArdle

From: Jean O'Connor (Biologicals, BE) on behalf of GCRD-Internal-Communications, Bio
Sent: 18 December 2009 16:21
To: WAV_GLOBAL SAFETY COMMS NETWORK List 1 of 2; WAV_GLOBAL SAFETY COMMS NETWORK List 2 of 2
Subject: H1N1 VACCINES NEWSFLASH
Attachments: H1N1 Communications Availability.pdf

Sent to LOCs (NSCs, PRPs, Medical Directors, Regulatory Contacts, Communicators, GMs) Bio Clinical, Commercial & Medical Affairs colleagues and the Pandemic Centre of Excellence

The total number of doses of Pandemrix distributed cumulatively as of 14 December was 73 million doses to 34 countries - for Arepanrix, the total number delivered was 24.8 million doses to Canada. A total of 10.2 million doses of non-adjuvanted H1N1 has been delivered to Canada and the US. That gives a grand total of 108 million doses delivered worldwide.

It is currently estimated that a minimum of 44.8 million doses have been administered to date - 31.3 million doses of Pandemrix and 13.5 million doses of Arepanrix and non-adjuvanted H1N1 vaccine, including at least 1.2 million doses to children and 132,000 doses to pregnant women. More detailed break-down per county can be viewed in the vaccines delivery and administration table housed in the pink tab below - the benefit/risk profile of GSKs H1N1 pandemic vaccines has not changed and remains favourable.

H1N1 News

- With the end of the year coming, the H1N1 pandemic is being listed as the most high profile crisis of 2009, with the pandemic vaccine the biggest health breakthrough of the year (CNN and other media outlets)
- The UK HPA revealed that only 1 in 5 people who were diagnosed with H1N1 actually had the disease and 800,000 prescriptions of Tamiflu were unnecessary (Natural News)
- US experts who study emergency preparedness have said that the trickle of vaccine and the failure to get it to those who need it most, show that we remain unprepared for widespread health emergencies and slow to address the problem. The H1N1 pandemic should have come with an announcement: this is a test of the public health emergency system (Daily Herald)
- Economists have said that H1N1 may decrease Australia's GDP by 0.5 percent this year but would not have an effect on the economy in 2010 (Bloomberg)
- Lack of surveillance has led to the perception that Africa has a low prevalence of influenza, but sporadic reports show that flu is circulating there undetected (CIDRAP)
- The NIAID is recruiting HIV-positive volunteers to test whether they need a larger-than-standard dose of H1N1 vaccine (CIDRAP)
- The CDC has said that about 15 percent of the entire USA has been infected with H1N1, about one in every six people (LA Times)

- A UK study has found that the H1N1 death rate in the country is 0.026 percent - far less than all three other 20th century pandemics (Reuters)
- According to reporters in the US and Europe, 99 percent of influenza cases tested last week were H1N1, which means the seasonal flu virus may not appear this winter season (Bloomberg)

H1N1 Vaccination Programme News

- Germany and Spain want to reduce deliveries of H1N1 vaccine and potentially return excess supplies to manufacturers due to low uptake of shots, in a move that could hit drug-makers' profits (Reuters)
- The UK Government has recommended 1x 0.25ml dose of GSK's H1N1 vaccine for children under the age of 10 after reports that two doses may induce fever (Daily Mail)
- Demonstrators have marched through Edinburgh to protest against H1N1 vaccination, highlighting that H1N1 is not as serious as it is claimed and concerns about the safety and usefulness of the vaccine (Press Association)
- China's H1N1 vaccination campaign is not proceeding as fast as it should because people are worried about the safety of the vaccine (Xinhua)

If you are not receiving a full summary of all media reports on a regular basis and would like to, please ask Michael Bauer (Senior Manager Product Communications Flu) michael.b.bauer@gskbio.com to add you to his media report mailing list.

H1N1 Vaccines Delivery & Administration Update

Country	Start Date	Vaccine
Croatia	27 November	Novartis
Romania	26 November	Domestic
Mexico	w/c 23 November (Arepanrix vaccination not yet started)	Sanofi/GSK
Czech Republic	23 November	GSK
Cyprus	23 November	GSK
Spain	16 November	GSK/Novartis (~300,000 doses Pandemrix adm.)
Syria	16 November	GSK
Greece	16 November	GSK/Sanofi/ Novartis (~220,000 doses Pandemrix adm.)
Saudi Arabia	w/c 9 November	GSK
Singapore	w/c 9 November (Pandemrix vaccination not yet started)	GSK/CSL

Austria	9 November	Baxter
Russia	9 November	Domestic
UAE	9 November	GSK
The Netherlands	9 November	Novartis/GSK (~1.4 million doses Pandemrix adm.)
Croatia	5 November	Novartis
Denmark	3 November	GSK (~300,000 doses adm.)
Slovenia	2 November	GSK
Ireland	2 November	GSK
Israel	2 November	GSK/Sanofi/ Novartis (~5,000 doses Pandemrix adm.)
Turkey	2 November	Novartis/GSK
Various Chinese Provinces	28 October	Sinovac Biotech
Luxembourg	27 October	GSK (~25,000 doses adm.)
Oman	27 October	GSK/Novartis
Iceland	27 October	GSK
Jersey	26 October	GSK
Canada	26 October	GSK/CSL (~9 million Arepanrix doses adm.)
Germany	26 October	GSK/Baxter (~5.8 million doses Pandemrix adm.)
Portugal	26 October	GSK (~70,000 doses adm.)
Finland	22 October	GSK (~1.7 million doses adm.)
UK	21 October	GSK/Baxter (~2.8 million doses Pandemrix adm.)
Norway	21 October	GSK (~1.2 million doses adm.)
Belgium	20 October	GSK (~1.7 million doses adm.)
France	20 October	Sanofi/GSK/Novartis (~2.4 million doses Pandemrix adm.)
Japan	19 October	Domestic/GSK/Novartis (will start in mid-Jan with

		GSK vaccine)
Tibet	14 October	Supplier(s) unknown
Italy	14 October	Novartis
Sweden	12 October	GSK (~3.9 million doses adm.)
USA	5 October	MedImmune/ CSL/Sanofi/ Novartis, (GSK) / ID Biomedical vaccine
Australia	30 September	CSL
Hungary	29 September	Omnivest
Beijing (China)	21 September	Sinovac Biotech (~5.3 million doses adm.)

H1N1 Global Epidemiology Overview

ILI = Influenza-Like Illness
ARI = Acute Respiratory Illness

Influenza activity has continued to decrease across Canada this week, ILI consultation rate is within the expected range for this time of the year and there has been an overall decrease in antiviral prescriptions in all provinces and territories. In the US 14 States have reported geographically widespread influenza activity compared to 25 last week. There has been a decrease in influenza associated hospitalisations and deaths, however pneumonia and influenza mortality remains above threshold for the 10th consecutive week.

The pandemic is affecting most countries across Europe with some indication that Central and Eastern countries are currently experiencing the greatest intensity of influenza activity. The intensity of clinical activity has been described as very high in Lithuania and 14 countries have reported high intensity. Clinical respiratory disease activity has declined over the past three weeks in 10 countries (Belgium, Bulgaria, Iceland, Ireland, Israel, the Netherlands, Norway, Portugal, Sweden and the Ukraine.

In Western and Central Asia ILI or ARI disease activity continues to increase in Kazakhstan and Kyrgyzstan, while activity may have peaked in Israel, Oman and Afghanistan. Pandemic H1N1 continues to circulate in Iran, Iraq, Jordan and in much of the surrounding region. Influenza transmission remains variable in East Asia - there has been a decline in activity in Northern China and Mongolia, elevated but stable ILI activity in Southern China and increased activity in Japan and Hong Kong. For South Asia activity continues to increase in Northwestern parts of India and Sri Lanka.

If you are not receiving a full H1N1 epidemiology update on a regular basis and would like to, please ask Natasha Nanwa natasha.nanwa@gsk.com to add you to her epidemiology update mailing list. You can also access detailed Northern Hemisphere Epi Updates on the European Centre for Disease Control website.

H1N1 Vaccines Safety Update

AEs = Adverse Events

sPSUR = Supplementary Periodic Safety Update Report

The current review covers data reported to GSK to date and includes information from spontaneous reports, Phase IV studies, clinical trials and any other source of potential safety signals. The total number of subjects that have been enrolled in clinical trials is 2,805, including 602 in paediatric studies for the D-Pan programme and 6,386, including 316 in paediatric studies for the Q-Pan programme.

The total number of AEs that have been reported to GSK spontaneously during this review period for Pandemrix (antigen source Dresden) is 1,880, mostly from Germany, the UK, Greece and France reflecting the known usage patterns. The total number for Arepanrix (antigen source Quebec) is 22 from Canada. No reports have been received for unadjuvanted vaccine.

The review of the available safety data to date does not show any unexpected safety findings. The majority of adverse events that have been reported are in line with those expected and described in the core safety information (pain, induration, swelling, redness, headache, fever, and fatigue are the most common). A cumulative review of fatal cases is also performed on a weekly basis and the latest review has not suggested any relationship between fatalities and vaccination.

The preferred communication tool to be used for regulators remains sPSURs. The next Pandemrix sPSUR is scheduled for submission on 21 December and an Arepanrix sPSUR was submitted on 2 December.

Please note that all information contained in this communication is confidential and intended for internal use only. For those of you communicating with external stakeholders please ensure you only use data approved for external use such as exposure slidesets issued by Dirk Campens, VP Global Vaccine Development Elderly Vaccines. You may notice slight discrepancies between data contained in this H1N1 NewsFlash and in materials approved for external use - this is due to the time lag incurred during the approval process needed for external communication purposes.

In the event that you are directly involved in safety-related aspects of H1N1 and need more detailed information to help you in your work, please contact Aurelie Delaigle (BCSP Safety Scientist) aurelie.delaigle@gsk.com.

Over the end of year break, your main points of contact in the event of an urgent safety query are noted below - please be aware that both are located on the East Coast of the US and are therefore operating at GMT-5):

- Harry Seifert +1 610 716 3077
- Dorothy Slavin +1 610 973 4715 (not available 24-25 Dec)

H1N1 Medical Information (unsolicited requests from HCPs)

Master Global Responses (MGR) for GSK H1N1 Vaccines are placed into the new GSK Global Medical Information tool: WISDOM. For countries who do not yet have access to WISDOM, MGRs are also placed on the MoVe website. To ensure consistency in global responses, we ask that LOCs identify highly repetitive queries where a Master Global Response (standard letter) would ensure greater consistency – please send queries to the Global Designate Team (Timothy A Schnaare, Kevin M Curtin, Sami H Litram). Requests will be prioritised and you will be informed of timelines for response preparation.

H1N1 Medical Support Materials

New medical backgrounders are now available on Guillain-Barre syndrome and on current exposure to GSK AS03-containing influenza vaccine. CTRS on H1N1 and CTRS on H5N1 are also accessible, while FAQs can be answered by accessing the MoVe Information Resource on H1N1 Vaccines.

Below are some supplementary links which could also be of use to you:

WHO H1N1 PORTAL
WHO Briefing Note 16 (Safety of Pandemic Vaccines)
WHO Briefing Note 14 (Experts advise WHO on pandemic vaccine policies and strategies)
Uppsala Monitoring Centre

European Centre for Disease Prevention and Control (ECDC)

MoVe H1N1 Section
MoVe H1N1 Links

GSK Pandemic Website
GSK Pandemic Side Effect Reporting Website

If you are in need of more detailed Medical Affairs information in order for you to conduct your work with relevant stakeholders more effectively, please contact Dirk Campens (VP Global Medical Affairs Elderly Vaccines) dirk.campens@gskbio.com. Statements for use in external scientific communication are discussed during a weekly technical TC.

In the event of an urgent H1N1 communications issue over the end of year break, your main points of contact are noted in the document attached:
(See attached file: H1N1 Communications Availability.pdf)

Jean d'Oultre
Internal Communications Business Partner
Global Clinical R&D
D1-810PWP
GSK Biologicals
Wavre Nord

Avenue Fleming 20
1300 Wavre
Belgium

Tel: 00 32 (0)10 85 47 01
GSM: 00 32 (0)478 927 054

Exhibit "**GOC 7**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 28th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

~~Commissioner for Oaths~~/Practising Solicitor

Niamh McArdle

From: Maeveanne McHugh
Sent: 30 December 2009 11:02
To: kevin.odonnell@imb.ie; aoife.farrell@imb.ie; Joan.Gilvarry@imb.ie; Aidath.Spooner; Niamh Arthur; nigel.fox@imb.ie
Cc: Jenny Hughes; Martijn Akveld; Derek Moriarty; Niamh McArdle
Subject: H1N1 Enhanced Safety Review Team (Team I) Communication on Safety Review for 22-28 Dec 09

Dear all

Please find below GSK's Enhanced Safety Review Team Report for Week 53 (22-28 Dec 09). Please note the below report is partially based on unreviewed/unconfirmed reports, as it is primarily generated to update internally.

I hope you will find this information useful.

Kind regards
Maeveanne

Pharmacovigilance, Quality and Compliance Manager
GlaxoSmithKline Ireland

Tel: +353 1 4955212
email: maeveanne.x.mchugh@gsk.com

Here is the summary of the H1N1 pandemic vaccines safety review for Week 53:

The current review covers data which has been reported to GSK in the period **from 22 to 28 Dec 09**, as well as the cumulative safety. This data also includes information from clinical trials, spontaneous reports, phase IV studies and any other source of potential safety signals.

The clinical trial information is unchanged from last week as no new subjects have been enrolled and no new SAEs have been reported.

The total number of doses of **Pandemrix** distributed cumulatively **as of 28 Dec is 86 million doses.** For **Arepanrix**, the total number delivered is **35 million doses.** No update for the doses of unadjuvanted vaccines was received, it is assumed that the total of **14.5 million doses of non-adjuvanted H1N1 vaccine** delivered to Canada and US remains unchanged. This gives an estimated grand total of **135.5 million doses** delivered worldwide.

GSK estimates that a minimum of 61.5 million doses have been administered to date (48 million doses of Pandemrix and 13.5 million doses of Arepanrix plus unadjuvanted H1N1 vaccine), including at least 2.9 million doses to children and 285,000 doses to pregnant women.

The total number of AE reports that have been reported spontaneously during this review period for Pandemrix is 1500. The total number of AE reports that have been reported spontaneously during this review period for Arepanrix is 4. No reports have been received for the unadjuvanted vaccine.

As of data lock point 14 Dec 2009, a search of the OCEANS safety database identified a total of 12768 AE reports (12180 Pandemrix, 584 Arepanrix and 2 for the unadjuvanted vaccine), compared to 11262 reports received by the week before. This gives a rate of about 208 reports/million doses administered. The majority of the adverse events that have been reported are in line with those expected and described in the core safety information (pyrexia, headache, pain, fatigue, nausea, myalgia, malaise and chills are the most common). For the other events, no causal relationship to the vaccine is established or expected. In total, there have been 3388 SAE reports and 118 reported fatalities. For reports of fatalities, based on available data, there is no evidence for a causal association between vaccination and fatal outcome.

Summary of Spontaneous Adverse Event Reports: Data Lock Point 28 December 2009

Event	Pandemrix	Arepanrix	Swine flu split Quebec without AS03	Total
All adverse events	12180	584	2	12768
Serious adverse events	3280	108	0	3388
Fatal outcomes	107	6	0	113
Drug exposure during pregnancy	214	27	0	241
Stillbirth	8 (+1)	0	0	8
Abortion spontaneous	30 (+2)	0	0	30
AESIs				
Anaphylaxis	264 (+26)	47	0	311
Facial palsy	35 (+6)	2	0	37
Guillain-Barré syndrome	28 (+7)	4	0	32
Encephalitis	7 (+2)	0	0	7
Demyelination	18 (+2)	0	0	18
Convulsions	214 (+48)	7	0	221
Neuritis	11 (+1)	0	0	11
Vasculitis	21 (+2)	0	0	
Vaccination failure	18 (+5)	0	0	18

The increased number of pregnancy outcomes and AESIs cases is noted between brackets for those counts that have increased. Given an estimated increased exposure of approximately 15%, a slightly higher than expected increase has occurred for Guillain Barré Syndrome, encephalitis, convulsions and vaccination failure.
None of the newly reported GBS cases have sufficient details to confirm the diagnosis.
The two new cases of encephalitis relate to a report of varicella zoster meningoencephalitis in an HIV-positive subject and a report of a 48-year-old male wit unspecified neurological symptoms; MRI consistent with brain stem encephalitis.
The increased rate in convulsions reports may be related to various communications on seizures following Pandemrix. An update of the global assessment will be performed regularly.
Of the 5 new reports of vaccination failure, 2 had laboratory confirmation (of which one was only Influenza A pos on rapid test following exposure to a H1N1 case). This brings the total number of laboratory confirmed cases to 8.
In summary, the newly reported AESIs do not suggest a new safety signal.

The Phase IV cohort safety study (PASS) in the UK has enrolled all 8000 subjects to date. An updated review of the events reported to date has not raised any safety concerns.

In summary, the risk/benefit profile of GSK's H1N1 pandemic vaccines has not changed and remains favourable. The events of interest are under close monitoring and the list remains unchanged. An updated review of convulsions is ongoing.

The second Pandemrix sPSUR has been made available on 21Dec and the second Arepanrix sPSUR has been made available on 24 Dec.

Thomas Verstraeten, MD, MSc

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Secretary: Nancy Visser Tel 32-(0)10-85-4843 or
Valérie Popleu Tel 32-(0)10-85-4823

Exhibit "**GOC 8**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 28th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

~~Commissioner for Oaths~~/Practising Solicitor

Niamh McArdle

From:	Niamh McArdle
Sent:	27 January 2010 16:18
To:	'kevin.odonnell@lmb.ie'; 'aoife.farrell@lmb.ie'; 'Joan.Gilvarry@lmb.ie'; 'Almath Spooner'; 'Niamh Arthur'; 'nigel.fox@lmb.ie'
Cc:	Martijn Alvelt; Derek Moriarty; Jenny Hughes; Maeveanne McHugh
Subject:	FW: H1N1 Enhanced Safety Review Team (Team I) Communication on Safety Review for 19 Jan 10 - 25 Jan 10

Dear all

Please find below GSK's Enhanced Safety Review Team Report for 19 Jan 2010 – 25 Jan 2010. Please note the below report is partially based on unreviewed/unconfirmed reports, as it is primarily generated to update internally.

I hope you will find this information useful.

Kind regards
Niamh McArdle
Pharmacovigilance Executive

Here is the summary of the H1N1 pandemic vaccines safety review for Week 4 2010:
The current review covers data which has been reported to GSK in the period from 19 Jan to 25 Jan 10, as well as the cumulative safety. This data also includes information from clinical trials, spontaneous reports, phase IV studies and any other source of potential safety signals.
The total number of subjects that have been enrolled in clinical trials is 2917, including 666 in pediatric studies (Q-Pan program) and 6397, including 259 in pediatric studies (Q-Pan program), including subjects of all ages down to 6 months old. A total of 46 SAE reports in Q-PAN H1N1 and 52 SAE reports in Q-PAN H1N1 studies, of which 5 were considered possibly related to the H1N1 vaccine by the investigator, have been received. A review of these events as well as the non-serious events has not raised new safety concerns. The reactogenicity profile of the H1N1 adjuvanted vaccine appears to be broadly in line with the reactogenicity of the H5N1 adjuvanted vaccine.

It is our understanding that GSK's H1N1 pandemic vaccines are now being administered in at least 38 countries (Bahrein, Brunei, Belgium, Canada, Cyprus, Czech Republic, Denmark, Egypt, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Jersey, Kuwait, Libya, Luxembourg, Malaysia, Malta, Mexico, Morocco, Netherlands, Norway, Philippines, Portugal, Qatar, Saudi Arabi, Singapore, Slovenia, Spain, Sweden, Switzerland, Syria, Turkey, UAE, UK). The total number of doses of Pandemrix distributed cumulatively as of 25 Jan is 108.5 million doses to 35 countries. For Arepanrix, the total number of doses distributed is 62.2 million doses to 16 countries. A total of 4.8 million doses of unadjuvanted H1N1 vaccine have been delivered to 4 countries. This gives a grand total of 175.3 million doses delivered worldwide. GSK estimates that a minimum of 75 million doses have been administered to date (61 million doses of Pandemrix, 14 million doses of Arepanrix plus unadjuvanted H1N1 vaccine), including at least

3.6 million doses to children and 360,000 doses to pregnant women. Please inform Dirk Campens (Dirk.Campens@gskbio.com) if your country has started its vaccination campaign and we have not listed the country.

The total number of AE reports that have been reported spontaneously during this review period for Pandemrix is 652, mostly from UK, Ireland and the Netherlands. The total number of AE reports that have been reported spontaneously during this review period for Arepanrix is 4. No report has been received for the unadjuvanted vaccine.

As of data lock point 25 Jan 10, a search of the OCEANS safety database identified a total of 16170 AE reports (15552 Pandemrix, 615 Arepanrix and 3 for the unadjuvanted vaccine), compared to 15514 reports received by the week before. This gives a rate of about 215 reports/million doses administered. The majority of the adverse events that have been reported are in line with those expected and described in the core safety information (pyrexia, headache, pain, fatigue, nausea, myalgia, vomiting, malaise and chills are the most common). For the other events, no causal relationship to the vaccine is established or expected. In total, there have been 4210 SAE reports and 139 reported fatalities. For reports of fatalities, based on available data, there is no evidence for a causal association between vaccination and fatal outcome.

Event	Pandemrix	Arepanrix	Swine flu split Quebec without AS03	Total
All adverse events	15552 (652)	615 (4)	3(0)	16170
Serious adverse events	4094 (203)	116 (3)	0	4210
Fatal outcomes	132 (7)	7 (0)	0	139
Drug exposure during pregnancy	262 (6)	28 (1)	0	290
Stillbirth	18 (-1)	21	0	19
Abortion spontaneous	43 (2)	0	0	43
AESIs				
Anaphylaxis	287 (8)	48 (1)	0	335
Facial palsy	43 (3)(-1)	2 (0)	0	45
Guillain-Barré syndrome	62 (5)	4 (0)	0	66
Encephalitis	9 (0)	0	0	9
Demyelination	31 (7)	0	0	31
Convulsions	256 (15)	7 (0)	0	263
Neuritis	12 (0)	0	0	12
Vasculitis	28 (1)	1 (0)	0	29
Vaccination failure	27 (2)	0	0	27

( ) : Number of new cases since last week.

Regarding AESIs,

- Anaphylaxis: A safety review has been performed with DLP 05 Jan 10 and showed that the global reporting rate for anaphylaxis following vaccination with Arepanrix and Pandemrix is consistent with the background rates for anaphylaxis following vaccination. The benefit/risk balance remains favourable and GSK will continue to closely monitor reports of anaphylaxis. The newly reported cases after DLP do not suggest a safety signal.

- Facial palsy: 25 confirmed reports (1 new during the review period). A safety review has been performed with DLP 03 Jan 10. The benefit/risk balance of the vaccines remains favourable and GSK will continue to closely monitor reports of facial palsy. The newly reported cases after DLP do not suggest a safety signal.
- GBS: 7 confirmed reports (no new during the reporting period). The newly reported cases do not suggest a safety signal.
- Encephalitis: No new case reported.
- Demyelination: The newly reported cases do not suggest a safety signal.
- Convulsions: A safety review has been performed with DLP 21 Dec 2009 and showed that the global reporting rate for convulsions following vaccination with Arepanrix and Pandemrix is consistent with the background rates for convulsions following vaccination. The benefit/risk balance remains favourable and GSK will continue to closely monitor reports of convulsions. The newly reported cases do not suggest a safety signal.
- Neuritis: No new case reported.
- Vasculitis: The newly reported cases do not suggest a safety signal.
- Vaccination failure: 14 confirmed reports (1 new reported during this review period). 13 reports did not meet criteria for vaccination failure.

RMP-related AESIs:
- Maladministration: No new signal this week.
- Contamination: No new signal this week.
- Autoimmune hepatitis: No new signal this week.

In summary, the newly reported AESIs or pregnancy outcomes do not suggest a new safety signal.

The Phase IV cohort safety study (PASS) in the UK has enrolled all 9000 subjects to date. A total of 78 SAE reports (3 fatal cases reported before last week) have been reported in this study so far, with 16 considered related by the investigator. A review of these events has not raised any safety concerns.

In summary, the risk/benefit profile of GSK's H1N1 pandemic vaccines has not changed and remains favourable. The events of interest are under close monitoring and the list remains unchanged.

Exhibit "**GOC 9**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 28th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

~~Commissioner for Oaths~~/Practising Solicitor

[redacted]

Niamh McArdle

From:	Aurélie Delaigle (Biologicals, BE)
Sent:	03 February 2010 10:33
To:	Carlos Arturo Leandro-Calderon; David Krakovsky; Eugene Goh; Eva Kalliskova; George Constantinides; Geraldine Cruz-Criniere; Haiwen Tang; Eleni Papathanasiou; Jana Fesenkova; Joven Jeremius Tanchuco; Kremena Georgieva; Lea Senni; Lea Hyllested; Maeveanne McHugh; Martha Bonoin; Nancy Yao; Niamh McArdle; Olav Flaten; Oleg Milenin; Per Engervall; Petteri Knudsen; Pierre Jamous; Maria Pilar Diego-Saiz; Pimprapa Kon; Sachna Jogtekar; Tomas Pruunsild; Ulrich Hoelscher; Won Choi; Yasunori Terashima; Yee Leong Teoh; Maria Yolanda Cervantes-Apolinar; Yongyuth Wangroongsarb
Cc:	Alain Brecx (Biologicals, BE); Andrew Rut; Anil Dutta (Biologicals, BE); Antonio Olivieri (Biologicals, BE); Aurélie Delaigle (Biologicals, BE); Barbara Howe; Bruce Innis; Camilo Moreno; Christophe Mullinger (Biologicals, BE); Dirk Campens (Biologicals, BE); Dorrie Slayin; Eduardo Ortega; Emilio Ledesma; Emmanuel Hanon (Biologicals, BE); Fernanda Tavares Da Silva (Biologicals, BE); Gary Dubin; Pang Yeow Gary Ong; Hany Seifert; Jean O'Connor (Biologicals, BE); Juan Jaramillo (Biologicals, BE); Michael Bauer (Biologicals, BE); Romula Collndres; stephen.x.gardner@gskbio.com; Thomas Breuer (Biologicals, BE); Thomas Verstraeten (Biologicals, BE); Vincent Gpy Bauchiar (Biologicals, BE); Jean O'Connor (Biologicals, BE); Aurélie Delaigle (Biologicals, BE)
Subject:	H1N1 Enhanced Safety Review Team (Team I) Communication on Safety Review for Week 5 2010

Sent on behalf of Thomas Verstraeten

Dear All,

As always, we would like to remind you of the importance of valid exposure data and your role in updating our records with this information. Please forward any actual data that you have available on number of doses used in your countries each week, including use in pregnancy and children, to Christophe Dessart (christophe.d.dessart@gskbio.com)- these are difficult numbers to account for each week and we appreciate your help with updates.

Here is the summary of the H1N1 pandemic vaccines safety review for Week 5 2010:

The current review covers cumulative safety data which have been reported to GSK up to 27 Jan 10*. This data also includes information from clinical trials, spontaneous reports, phase IV studies and any other source of potential safety signals.

The total number of subjects that have been enrolled in D-PAN and Q-PAN H1N1 clinical trials has remained unchanged since last data lock point. A total of 48 SAE reports in D-PAN H1N1 and 52 SAE reports in Q-PAN H1N1 studies, of which 5 were considered possibly related to the H1N1 vaccine by the investigator, have been received. A review of these events as well as the non-serious events has not raised new safety concerns. The reactogenicity profile of the H1N1 adjuvanted vaccine appears to be broadly in line with the reactogenicity of the H5N1 adjuvanted vaccine.

It is our understanding that GSK's H1N1 pandemic vaccines are now being administered in at least 39 countries (Bahrein, Brunei, Belgium, Canada, Cyprus, Czech Republic, Denmark, Egypt, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Jersey, Kuwait, Libya, Luxembourg, Malaysia, Malta, Mexico, Morocco, Netherlands, Norway, Oman, Philippines, Portugal, Qatar, Saudi Arabi, Singapore, Slovenia, Spain, Sweden, Switzerland, Syria, Turkey, UAE, UK). The total number of doses of Pandemrix distributed cumulatively as of 01 Feb 10 is 112.4 million doses to 35 countries. For Arepanrix, the total number of doses distributed is 72.2 million doses to 17 countries. A total of 4.6 million doses of

unadjuvanted H1N1 vaccine have been delivered to 4 countries. This gives a grand total of 189.2 million doses delivered worldwide. GSK estimates that about 76 million doses have been administered to date (62 million doses of Pandemrix, 14 million doses of Arepanrix plus unadjuvanted H1N1 vaccine), including at least 3.9 million doses to children and 870,000 doses to pregnant women. Please inform Dirk Campens (Dirk.Campens@gskbio.com) if your country has started its vaccination campaign and we have not listed the country.

As of data lock point 27 Jan 10*, a search of the OCEANS safety database identified a total of 16280 AE reports (15662 Pandemrix, 615 Arepanrix and 3 for the unadjuvanted vaccine). This gives a rate of about 215 reports/million doses administered. The majority of the adverse events that have been reported are in line with those expected and described in the core safety information (pyrexia, headache, pain, fatigue, nausea, myalgia, vomiting, malaise and chills are the most common). For the other events, no causal relationship to the vaccine is established or expected. In total, there have been 4272 SAE reports and 143 reported fatalities. For reports of fatalities, based on available data, there is no evidence for a causal association between vaccination and fatal outcome.

Event	Pandemrix	Arepanrix	Swine flu split Quebec without AS03	Total
All adverse events	15662 (110)	615 (0)	3(0)	16280
Serious adverse events	4156 (62)	116 (0)	0	4272
Fatal outcomes	136 (4)	7 (0)	0	143
AESIs				
Anaphylaxis	210 (1)	48 (0)	0	258
Facial palsy	50 (2)	2 (0)	0	52
Guillain-Barré syndrome	55 (1)	4 (0)	0	59
Encephalitis	11 (0)	0	0	11
Demyelination	40 (0)	0	0	40
Convulsions	299 (2)	7 (0)	0	306
Neuritis	12 (0)	0	0	12
Vasculitis	30 (0)	1 (0)	0	31
Vaccination failure	27 (0)	0	0	27

( ) : Number of new cases since last update.

Regarding AESIs,

- Anaphylaxis: The newly reported case do not suggest a safety signal.
- Facial palsy: 31 confirmed reports. A safety review has been performed with DLP 03 Jan 10. The benefit/risk balance of the vaccines remains favourable and GSK will continue to closely monitor reports of facial palsy. The newly reported cases after DLP do not suggest a safety signal.
- GBS: 7 confirmed reports (no new during the reporting period). A safety review has been performed with DLP 18 Jan 10. The benefit/risk balance of the vaccines remains favourable and GSK will continue to closely monitor reports of GBS.
- Encephalitis: No new case reported.
- Demyelination: No new case reported.
- Convulsions: The newly reported cases do not suggest a safety signal.
- Neuritis: No new case reported.

- Vasculitis: No new case reported.
- Vaccination failure: No new case reported.

RMP-related AESIs:

- Maladministration: No new signal this week.
- Contamination: No new signal this week.
- Autoimmune hepatitis: No new signal this week.

A safety review of pregnancy outcomes has been performed with DLP 17 Jan 10 and concluded that the benefit/risk balance of the vaccines remains favourable. GSK will continue to closely monitor reports of pregnancy.

In summary, the newly reported AESIs or pregnancy outcomes do not suggest a new safety signal.

The Phase IV cohort safety study (PASS) in the UK has enrolled all 8000 subjects to date. A total of 90 SAE reports (4 fatal cases) have been reported in this study so far, with 17 considered related by the investigator. A review of these events has not raised any safety concerns.

In summary, the risk/benefit profile of GSK's H1N1 pandemic vaccines has not changed and remains favourable. The events of interest are under close monitoring and the list remains unchanged.

Note that the information I am providing you is for your information only, so you can be prepared to answer questions that require this level of detailed knowledge. Any further communication internally or externally should be based on information provided by Team II and following the rules established by that team. Your preferred communication tool with the regulators should be the sPSURs, which will be added to the PSUR website alongside the other PSURs as soon as we finalize them. A Pandemrix sPSUR has been submitted on 18 Jan 10 and an Arepanrix sPSUR has been submitted on 27 Jan 10.

* Due to alignment of data lock points, the reporting period for spontaneous cases from last update contains only 2 days. The next updates will cover again a reporting period of one week.

Aurélie Delaigle, Ir., PhD
Biologicals Clinical Safety and Pharmacovigilance
GlaxoSmithKline Biologicals
Avenue Fleming, 20
1300 Wavre, Belgium
Tel. +32-(0)10-85-4806

Exhibit "**GOC 10**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 28th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

Commissioner for Oaths/Practising Solicitor

[redacted]

Niamh McArdle

From: Niamh McArdle
Sent: 10 February 2010 15:51
To: 'kevin.odonnell@imb.ie'; 'aoife.farrell@imb.ie'; 'Joan.Gilvarry@imb.ie'; 'Almath Spooner'; 'Niamh Arthur'; 'nigel.fox@imb.ie'
Cc: Martijn Akveld; Derek Moriarty; Jenny Hughes; Maeveanne McHugh
Subject: FW: H1N1 Enhanced Safety Review Team (Team I) Communication on Safety Review for Week 6 2010

Dear all

Please find below GSK's Enhanced Safety Review Team Report for week 6 2010. Please note the below report is partially based on unreviewed/unconfirmed reports, as it is primarily generated to update internally.

I hope you will find this information useful.

Kind regards.
Niamh McArdle
Pharmacovigilance Executive

Here is the summary of the H1N1 pandemic vaccines safety review for Week 6 2010:
The current review covers cumulative safety data which have been reported to GSK up to **03 Feb 10.** This data also includes information from clinical trials, spontaneous reports, phase IV studies and any other source of potential safety signals.
The total number of subjects that have been enrolled in D-PAN and Q-PAN H1N1 clinical trials has remained unchanged since last data lock point. A total of **48** SAE reports in D-PAN H1N1 and **60** SAE reports in Q-PAN H1N1 studies, of which 5 were considered possibly related to the H1N1 vaccine by the investigator, have been received. A review of these events as well as the non-serious events has not raised new safety concerns. The reactogenicity profile of the H1N1 adjuvanted vaccine appears to be broadly in line with the reactogenicity of the H5N1 adjuvanted vaccine.

It is our understanding that GSK's H1N1 pandemic vaccines are now being administered in at least **41** countries (Bahrein, Brunei, Belgium, Canada, Cyprus, Czech Republic, Denmark, Estonia, Egypt, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Japan, Jersey, Kuwait, Libya, Luxembourg, Malaysia, Malta, Mexico, Morocco, Netherlands, Norway, Oman, Philippines, Portugal, Qatar, Saudi Arabia, Singapore, Slovenia, Spain, Sweden, Switzerland, Syria, Turkey, UAE, UK). The total number of doses of Pandemrix distributed cumulatively as of **08 Feb 10** is **115** million doses to 35 countries. For Arepanrix, the total number of doses distributed is **73** million doses to 17 countries. A total of about **5** million doses of unadjuvanted **H1N1** vaccine have been delivered to 4 countries. This gives a grand total of **194** million doses delivered worldwide. GSK estimates that about **79** million doses have been administered to date (**64** million doses of Pandemrix, **15** million doses of Arepanrix plus unadjuvanted **H1N1** vaccine), including at least **4.2** million doses to children and **380,000**

doses to pregnant women. Please inform Dirk Campens (Dirk.Campens@gskbio.com) if your country has started its vaccination campaign and we have not listed the country.

The total number of AE reports that have been reported spontaneously during this review period for Pandemrix is 271, mostly from UK, Norway and Ireland. The total number of AE reports that have been reported spontaneously during this review period for Arepanrix is 27, all from Canada. No report has been received for the unadjuvanted vaccine.

As of data lock point 03 Feb 10, a search of the OCEANS safety database identified a total of 16578 AE reports (15933 Pandemrix, 642 Arepanrix and 3 for the unadjuvanted vaccine), compared to 16280 reports received by the week before. This gives a rate of about 215 reports/million doses administered. The majority of the adverse events that have been reported are in line with those expected and described in the core safety information (pyrexia, headache, pain, fatigue, nausea, myalgia, vomiting, malaise and chills are the most common). For the other events, no causal relationship to the vaccine is established or expected. In total, there have been 4431 SAE reports and 149 reported fatalities. For reports of fatalities, based on available data, there is no evidence for a causal association between vaccination and fatal outcome.

Event	Pandemrix	Arepanrix	Swine flu split Quebec without AS03	Total
All adverse events	15933	642	3 (0)	16578
Serious adverse events	4291	140	0	4431
Fatal outcomes	142	7	0	149
AESIs				
Anaphylaxis	300	61	0	361
Facial palsy	46	3	0	49
Guillain-Barré syndrome	67	26	0	93
Encephalitis	10	0	0	10
Demyelination	32	0	0	32
Convulsions	277	7	0	284
Neuritis	12	1	0	13
Vasculitis	30	1	0	31
Vaccination failure	28	0	0	28

Regarding AESIs,

- Anaphylaxis: 70 confirmed reports. The newly reported cases do not suggest a safety signal.
- Facial palsy: No new confirmed reports. A safety review has been performed with DLP 03 Jan 10. The benefit/risk balance of the vaccines remains favourable and GSK will continue to closely monitor reports of facial palsy. The newly reported cases after DLP do not suggest a safety signal.
- GBS: 10 confirmed reports. There were 22 new unassessable reports of GBS for Arepanrix this week; these were identified in a newspaper article. The article described 2 of the cases (minimal detail provided) and quoted PHAC as stating that there have been a total of 22 reports of GBS following H1N1 pandemic vaccines received by PHAC. A safety review has been performed with DLP 18 Jan 10. The benefit/risk balance of the vaccines remains favourable and GSK will continue to closely monitor

reports of GBS.
- Encephalitis: No new case reported.
- Demyelination: 1 new confirmed report of optic neuritis. The newly reported cases do not suggest a safety signal.
- Convulsions: 111 confirmed cases. The newly reported cases do not suggest a new safety concern.
- Neuritis: 1 new case of neuritis involving the vaccinated arm.
- Vasculitis: No new case reported.
- Vaccination failure: No new confirmed case reported.

RMP-related AESIs:
- Maladministration: No new signal this week.
- Contamination: No new signal this week.
- Autoimmune hepatitis: No new signal this week.

A safety review of pregnancy outcomes has been performed with DLP 17 Jan 10 and concluded that the benefit/risk balance of the vaccines remains favourable. GSK will continue to closely monitor reports of pregnancy.

In summary, the newly reported AESIs or pregnancy outcomes do not suggest a new safety signal.

The Phase IV cohort safety study (PASS) in the UK has enrolled all 9000 subjects to date. A total of 94 SAE reports (5 fatal cases) have been reported in this study so far, with 18 considered related by the investigator. A review of these events has not raised any safety concerns.

In summary, the risk/benefit profile of GSK's H1N1 pandemic vaccines has not changed and remains favourable. The events of interest are under close monitoring and the list remains unchanged.

Exhibit "**GOC 11**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 28th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

~~Commissioner for Oaths~~/Practising Solicitor

Maeveanne McHugh

From: Clara Rafferty
Sent: 24 February 2010 15:55
To: kevin.odonnell@imb.ie; aoife.farrell@imb.ie; Joan.Glivarry@imb.ie; Almath Spooner; Niamh Arthur; nigel.fox@imb.ie
Cc: Martijn Akveld; Derek Moriarty; Jenny Hughes; Maeveanne McHugh; Colin Hester
Subject: FW: H1N1 Enhanced Safety Review Team (Team I) Communication on Safety Review for Week 8 2010

Dear all

Please find below GSK's Enhanced Safety Review Team Report for Week 8 2010. Please note the below report is partially based on unreviewed/ unconfirmed reports, as it is primarily generated to update internally.

I hope you will find this information useful.

Clara Rafferty |
Quality & Pharmacovigilance Officer |
GlaxoSmithKline Ireland | Stonemasons Way | Rathfarnham, Dublin 16
t 353 1 4955553. e ciara.c.rafferty@gsk.com

From: Aurélie Delaigle (Biologicals, BE)
Sent: 24 February 2010 15:25
To: Carlos Arturo Leandro-Calderon; David Krakovsky; Eugene Goh; Eva Kaliskova; George Constantinides; Geraldine Cruz-Crimen; Haiwen Tang; Eleni Papathanasiou; Jana Fesenkova; Joven Jeremius Tanchuco; Kremena Georgieva; Lea Semri; Lea Hyllested; Maeveanne McHugh; Marthe Bonnin; Nancy Yao; Olav Flaten; Oleg Milenin; Per Engervall; Petteri Knudsen; Pierre Jamous; Maria Pilar Diego-Saiz; Pimprapa Kon; Sadhna Joglekar; Toomas Pruunsild; Ulrich Hoelscher; Won Choi; Yasunori Terashima; Yee Leong Teoh; Maria Yolanda Cervantes-Apolinar; Yongyuth Wangroongsarb; Clara Rafferty
Cc: Alain Brecx (Biologicals, BE); Andrew Rut; Anil Dutta (Biologicals, BE); Antonio Olivieri (Biologicals, BE); Aurélie Delaigle (Biologicals, BE); Barbara Howe; Bruce Innis; Camilo Moreno; Christophe Mulfinger (Biologicals, BE); Dirk Campens (Biologicals, BE); Dorrie Slavin; Eduardo Ortega; Emilio Ledesma; Emmanuel Hanon (Biologicals, BE); Fernanda Tavares Da Silva (Biologicals, BE); Gary Dubin; Pang Yeow Gary Ong; Harry Seifert; Jean O'Connor (Biologicals, BE); Juan Jaramillo (Biologicals, BE); Michael Bauer (Biologicals, BE); Romulo Colindres; stephen.x.gardner@gskbio.com; Thomas Breuer (Biologicals, BE); Thomas Verstraeten (Biologicals, BE); Vincent Guy Bauchau (Biologicals, BE); Jean O'Connor (Biologicals, BE); Aurélie Delaigle (Biologicals, BE)
Subject: H1N1 Enhanced Safety Review Team (Team I) Communication on Safety Review for Week 8 2010

Sent on behalf of Thomas Verstraeten

Dear All,

As always, we would like to remind you of the **importance of valid exposure data** and your role in updating our records with this information. Please forward any actual data that you have available on

number of doses used in your countries each week, including use in pregnancy and children, to Christophe Dessart (christophe.d.dessart@gskbio.com)- these are difficult numbers to account for each week and we appreciate your help with updates.

Here is the summary of the H1N1 pandemic vaccines safety review for Week 8 2010:

The current review covers cumulative safety data which have been reported to GSK up to **17 Feb 10.** This data also includes information from clinical trials, spontaneous reports, phase IV studies and any other source of potential safety signals.

The total number of subjects that have been enrolled in clinical trials is **2864, including 666 in pediatric studies** (D-Pan program) and **6833, including 259 in pediatric studies** (Q-Pan program), including subjects of all ages down to 6 months old. A total of **52** SAE reports in D-PAN H1N1 and **70** SAE reports in Q-PAN H1N1 studies, of which 5 were considered possibly related to the H1N1 vaccine by the investigator, have been received. A review of these events as well as the non-serious events has not raised new safety concerns. The reactogenicity profile of the H1N1 adjuvanted vaccine appears to be broadly in line with the reactogenicity of the H5N1 adjuvanted vaccine.

It is our understanding that GSK's H1N1 pandemic vaccines have been administered in at least **41 countries** (Bahrein, Brunei, Belgium, Canada, Cyprus, Czech Republic, Denmark, Estonia, Egypt, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Japan, Jersey, Kuwait, Libya, Luxembourg, Malaysia, Malta, Mexico, Morocco, Netherlands, Norway, Oman, Philippines, Portugal, Qatar, Saudi Arabi, Singapore, Slovenia, Spain, Sweden, Switzerland, Syria, Turkey, UAE, UK). The total number of doses of **Pandemrix** distributed cumulatively **as of 17 Feb 10** is **124 million doses** to 36 countries. For **Arepanrix**, the total number of doses distributed is **75.5 million doses** to 17 countries. A total of about **5 million doses of unadjuvanted H1N1 vaccine** have been delivered to 4 countries. This gives a grand total of **204.5 million doses** delivered worldwide. GSK estimates that about **81 million doses** have been administered to date **(66 million doses of Pandemrix, 15 million doses of Arepanrix plus unadjuvanted H1N1 vaccine)**, including at least **4.2 million doses** to children and **390,000 doses** to pregnant women. Please inform Dirk Campens (Dirk.Campens@gskbio.com) if your country has started its vaccination campaign and we have not listed the country.

The total number of AE reports that have been reported spontaneously during this review period for Pandemrix is **839, mostly from UK, Ireland and Norway.** The total number of AE reports that have been reported spontaneously during this review period for Arepanrix is **29, all from Canada.** No report has been received for the unadjuvanted vaccine.

As of data lock point 17 Feb 10, a search of the OCEANS safety database identified a total of **17446 AE reports** (16772 Pandemrix, 671 Arepanrix and 3 for the unadjuvanted vaccine), compared to 16578 reports received by the 2 weeks before. This gives a rate of about **215 reports/million doses administered.** The majority of the adverse events that have been reported are in line with those expected and described in the core safety information (pyrexia, headache, pain, fatigue, nausea, myalgia, vomiting, malaise and chills are the most common). For the other events, no causal relationship to the vaccine is established or expected. In total, there have been **4778 SAE reports** and **166 reported fatalities.** For reports of fatalities, based on available data, there is no evidence for a causal association between vaccination and fatal outcome.

Event	Pandemrix	Arepanrix	Swine flu split Quebec without AS03	Total
All adverse events	16772 (839)	671 (29)	3 (0)	17446
Serious adverse events	4619 (328)	159 (19)	0	4778
Fatal outcomes	156 (14)	10 (3)	0	166
AESIs				
Anaphylaxis	308 (8)	61 (0)	0	369
Facial palsy	52 (6)	3 (0)	0	55
Guillain-Barré syndrome	68 (11)	28 (2)	0	96
Encephalitis	11 (1)	0	0	11
Demyelination	40 (8)	0	0	40
Convulsions	287 (10)	7 (0)	0	294
Neuritis	13 (1)	1 (1)	0	13
Vasculitis	32 (2)	1 (0)	0	33
Vaccination failure	29 (1)	0	0	29

() Number of new reports in the last 2 weeks

Regarding AESIs,

- **Anaphylaxis:** 73 confirmed reports. The newly reported cases do not suggest a safety signal.
- **Facial palsy:** 36 confirmed reports. The newly reported cases do not suggest a safety signal.
- **GBS:** 22 confirmed reports out of which possible duplicates (cases identified in a newspaper article quoting PHAC stating that there have been a total of 22 reports of GBS following H1N1 pandemic vaccines received by PHAC). A safety review has been performed with DLP 18 Jan 10 and concluded that the benefit/risk balance of the vaccines remains favourable. GSK will continue to closely monitor reports of GBS.
- **Encephalitis:** No new confirmed report.
- **Demyelination:** 1 new confirmed report of optic neuritis. The newly reported cases do not suggest a safety signal.
- **Convulsions:** 122 confirmed cases. The newly reported cases do not suggest a new safety concern.
- **Neuritis:** 1 new case of neuritis involving the vaccinated arm.
- **Vaccination failure:** No new confirmed case reported.

RMP-related AESIs:

- Maladministration: No new signal this week.
- Contamination: No new signal this week.
- Autoimmune hepatitis: No new signal this week.

A safety review of pregnancy outcomes has been performed with DLP 17 Jan 10 and concluded that the benefit/risk balance of the vaccines remains favourable. GSK will continue to closely monitor reports of pregnancy.

In summary, the newly reported AESIs or pregnancy outcomes do not suggest a new safety signal.

The Phase IV cohort safety study (PASS) in the UK has enrolled all 9000 subjects to date. A total of 108 SAE reports (10 fatal cases) have been reported in this study so far, with 19 considered

related by the investigator. A review of these events has not raised any safety concerns.

In summary, the risk/benefit profile of GSK's H1N1 pandemic vaccines has not changed and remains favourable. The events of interest are under close monitoring and the list remains unchanged.

Aurélie Delaigle, Ir., PhD
Expert Scientist
Biologicals Clinical Safety and Pharmacovigilance
GlaxoSmithKline Biologicals
Avenue Fleming, 20
1300 Wavre, Belgium
New Tel. +32-(0)10-85-4806

Exhibit "**GOC 12**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 28th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

~~Commissioner for Oaths~~/Practising Solicitor

Maeveanne McHugh

From: Clara Rafferty
Sent: 03 March 2010 15:04
To: kevin.odonnell@imb.ie; aoife.farrell@imb.ie; Joan.Gilvarry@imb.ie; Almath Spooner; Niamh Arthur; nigel.fox@imb.ie
Cc: Martijn Akveld; Derek Moriarty; Jenny Hughes; Maeveanne McHugh; Colin Hester
Subject: H1N1 Enhanced Safety Review Team (Team I) Communication on Safety Review for Week 9 2010

Dear all

Please find below GSK's Enhanced Safety Review Team Report for week 8 2010. Please note the below report is partially based on unreviewed/ unconfirmed reports, as it is primarily generated to update internally.

I hope you will find this information useful.

Clara Rafferty |
Quality & Pharmacovigilance Officer |
GlaxoSmithKline Ireland | Stonemasons Way | Rathfarnham, Dublin 16
t 353 1 4955553 e clara.c.rafferty@gsk.com

From: Aurélie Delaigle (Biologicals, BE)
Sent: 03 March 2010 11:08
To: Carlos Arturo Leandro-Calderon; David Krakovsky; Eugene Goh; Eva Kaliskova; George Constantinides; Geraldine Cruz-Crimen; Haiwen Tang; Eleni Papathanasiou; Jana Fesenkova; Joven Jeremius Tanchuco; Kremena Georgieva; Lea Semri; Lea Hyllested; Maeveanne McHugh; Marthe Bonnin; Nancy Yao; Olav Flaten; Oleg Milenin; Per Engervall; Petteri Knudsen; Pierre Jamous; Maria Pilar Diego-Saiz; Pimprapa Kon; Sadhna Joglekar; Toomas Pruunsild; Ulrich Hoelscher; Won Choi; Yasunori Terashima; Yee Leong Teoh; Maria Yolanda Cervantes-Apolinar; Yongyuth Wangroongsarb; Clara Rafferty
Cc: Alain Brecx (Biologicals, BE); Andrew Rut; Anil Dutta (Biologicals, BE); Antonio Olivieri (Biologicals, BE); Aurélie Delaigle (Biologicals, BE); Barbara Howe; Bruce Innis; Camilo Moreno; Christophe Mulfinger (Biologicals, BE); Dirk Campens (Biologicals, BE); Dorrie Slavin; Eduardo Ortega; Emilio Ledesma; Emmanuel Hanon (Biologicals, BE); Fernanda Tavares Da Silva (Biologicals, BE); Gary Dubin; Pang Yeow Gary Ong; Harry Seifert; Jean O'Connor (Biologicals, BE); Juan Jaramillo (Biologicals, BE); Michael Bauer (Biologicals, BE); Romulo Colindres; stephen.x.gardner@gskbio.com; Thomas Breuer (Biologicals, BE); Thomas Verstraeten (Biologicals, BE); Vincent Guy Bauchau (Biologicals, BE); Jean O'Connor (Biologicals, BE); Aurélie Delaigle (Biologicals, BE)
Subject: H1N1 Enhanced Safety Review Team (Team I) Communication on Safety Review for Week 9 2010

Sent on behalf of Thomas Verstraeten

Dear All,

As always, we would like to remind you of the importance of valid exposure data and your role in

updating our records with this information. Please forward any actual data that you have available on number of doses used in your countries each week, including use in pregnancy and children, to Christophe Dessart (christophe.d.dessart@gskbio.com)- these are difficult numbers to account for each week and we appreciate your help with updates.

Here is the summary of the H1N1 pandemic vaccines safety review for Week 9 2010:

The current review covers cumulative safety data which have been reported to GSK up to **24 Feb 10**. This data also includes information from clinical trials, spontaneous reports, phase IV studies and any other source of potential safety signals.
The total number of subjects that have been enrolled in clinical trials is **2864, including 666 in pediatric studies (D-Pan program)** and **7112, including 259 in pediatric studies (Q-Pan program)**, including subjects of all ages down to 6 months old. A total of **56** SAE reports in D-PAN H1N1 and **79** SAE reports in Q-PAN H1N1 studies, of which 5 were considered possibly related to the H1N1 vaccine by the investigator, have been received. A review of these events as well as the non-serious events has not raised new safety concerns. The reactogenicity profile of the H1N1 adjuvanted vaccine appears to be broadly in line with the reactogenicity of the H5N1 adjuvanted vaccine.

It is our understanding that GSK's H1N1 pandemic vaccines have been administered in at lea **41 countries** (Bahrein, Brunei, Belgium, Canada, Cyprus, Czech Republic, Denmark, Estonia, Egypt, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Japan, Jersey, Kuwait, Libya, Luxembourg, Malaysia, Malta, Mexico, Morocco, Netherlands, Norway, Oman, Philippines, Portugal, Qatar, Saudi Arabi, Singapore, Slovenia, Spain, Sweden, Switzerland, Syria, Turkey, UAE, UK). The total number of doses of **Pandemrix** distributed cumulatively **as of 24 Feb 10 is 125 million doses** to 36 countries. For **Arepanrix**, the total number of doses distributed is **78 million doses** to 17 countries. A total of about **2.5 million doses of unadjuvanted H1N1 vaccine** have been delivered to 4 countries (data corrected). This gives a grand total of **205.5 million doses** delivered worldwide. GSK estimates that about **82 million doses** have been administered to date (**67 million doses of Pandemrix, 15 million doses of Arepanrix plus unadjuvanted H1N1 vaccine**), including at least **4.2 million doses** to children and **400,000 doses** to pregnant women. Please inform Dirk Campens (Dirk.Campens@gskbio.com) if your country has started its vaccination campaign and we have not listed the country.

The total number of AE reports that have been reported spontaneously during this review period for Pandemrix is **311, mostly from Ireland, UK and Sweden.** The total number of AE reports that have been reported spontaneously during this review period for Arepanrix is **31, mostly from Brunei.** No report has been received for the unadjuvanted vaccine.

As of data lock point 24 Feb 10, a search of the OCEANS safety database identified a total of **17788 AE reports** (17083 Pandemrix, 702 Arepanrix and 3 for the unadjuvanted vaccine), compared to 17446 reports received by the week before. This gives a rate of about **215 reports/million doses administered.** The majority of the adverse events that have been reported are in line with those expected and described in the core safety information (pyrexia, headache, pain, fatigue, nausea, myalgia, vomiting, malaise and chills are the most common). For the other events, no causal relationship to the vaccine is established or expected. In total, there have been **4910 SAE reports** and **168 reported fatalities.** For reports of fatalities, based on available data, there is no evidence for a causal association between vaccination and fatal outcome.

Event	Pandemrix	Arepanrix	Swine flu split Quebec without AS03	Total
All adverse events	17083 (311)	702 (31)	3 (0)	17788
Serious adverse events	4748 (129)	162 (3)	0	4910
Fatal outcomes	158 (2)	10 (0)	0	168
AESIs				
Anaphylaxis	312 (4)	62 (1)	0	374
Facial palsy	54 (2)	3 (0)	0	57
Guillain-Barré syndrome	70 (3) (-1)	28 (0)	0	98
Encephalitis	11 (0)	0	0	11
Demyelination	42 (2)	0	0	42
Convulsions	288 (1)	7 (0)	0	295
Neuritis	13 (0)	1 (0)	0	14
Vasculitis	34 (2)	1 (0)	0	35
Vaccination failure	29 (0)	0	0	29

() Number of new reports in the last week

Regarding AESIs,

- **Anaphylaxis:** 1 new confirmed report (total of 74 confirmed reports). The newly reported cases do not suggest a safety signal.
- **Facial palsy:** 2 new confirmed reports (total of 38 confirmed reports). The newly reported cases do not suggest a safety signal.
- **GBS:** No new confirmed report (total of 22 confirmed reports out of which possible duplicates - cases identified in a newspaper article quoting PHAC stating that there have been a total of 22 reports of GBS following H1N1 pandemic vaccines received by PHAC). A safety review has been performed with DLP 18 Jan 10 and concluded that the benefit/risk balance of the vaccines remains favourable. An update of this review is ongoing.
- **Encephalitis:** No new report.
- **Demyelination:** No new confirmed report. The newly reported cases do not suggest a safety signal.
- **Convulsions:** 1 new confirmed report (total of 123 confirmed cases). The newly reported cases do not suggest a new safety concern.
- **Neuritis:** No new report.
- **Vaccination failure:** No new report.

RMP-related AESIs:

- Maladministration: No new signal this week.
- Contamination: No new signal this week.
- Autoimmune hepatitis: No new signal this week.

A safety review of pregnancy outcomes has been performed with DLP 17 Jan 10 and concluded that the benefit/risk balance of the vaccines remains favourable. GSK will continue to closely monitor reports of pregnancy.

In summary, the newly reported AESIs or pregnancy outcomes do not suggest a new safety signal.

The Phase IV cohort safety study (PASS) in the UK has enrolled all 9000 subjects to date. A total of 122 SAE reports (10 fatal cases) have been reported in this study so far, with 19 considered related by the investigator. A review of these events has not raised any safety concerns.

In summary, the risk/benefit profile of GSK's H1N1 pandemic vaccines has not changed and remains favourable. The events of interest are under close monitoring and the list remains unchanged.

Aurélie Delaigle, Ir., PhD
Expert Scientist
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Exhibit "**GOC 13**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 28th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

~~Commissioner for Oaths~~/Practising Solicitor

Maeveanne McHugh

From: Maeveanne McHugh
Sent: 17 March 2010 16:12
To: kevin.odonnell@imb.ie; aoife.farrell@imb.ie; Joan.Gilvarry@imb.ie; Almath Spooner; Niamh Arthur; nigel.fox@imb.ie
Cc: Martijn Akveld; Derek Moriarty; Jenny Hughes; Colin Hester; Clara Rafferty
Subject: FW: H1N1 Enhanced Safety Review Team (Team I) Communication on Safety Review for Week 11 2010

Dear all

Please find below GSK's Enhanced Safety Review Team Report for week 11 2010. Please note the below report is partially based on unreviewed/ unconfirmed reports, as it is primarily generated to update internally.

I hope you will find this information useful.

Kind regards
Maeveanne

Pharmacovigilance, Quality and Compliance Manager
GlaxoSmithKline Ireland

Tel:+353 1 4955212
email: maeveanne.x.mchugh@gsk.com

From: Aurélie Delaigle (Biologicals, BE)
Sent: 17 March 2010 12:40

Sent on behalf of Thomas Verstraeten

Here is the summary of the H1N1 pandemic vaccines safety review for Week 11 2010:

The current review covers cumulative safety data which have been reported to GSK up to **10 March 10.** This data also includes information from clinical trials, spontaneous reports, phase IV studies and any other source of potential safety signals.

The total number of subjects that have been enrolled in clinical trials is **2864, including 666 in pediatric studies (D-Pan program) and 7538, including 259 in pediatric studies (Q-Pan program),** including subjects of all ages down to 6 months old. A total of **57** SAE reports in D-/ PAN H1N1 and **91** SAE reports in Q-PAN H1N1 studies, of which 5 were considered possibly related to the H1N1 vaccine by the investigator, have been received. A review of these events

as well as the non-serious events has not raised new safety concerns. The reactogenicity profile of the H1N1 adjuvanted vaccine appears to be broadly in line with the reactogenicity of the H5N1 adjuvanted vaccine.

It is our understanding that GSK's H1N1 pandemic vaccines have been administered in at least **41 countries** (Bahrein, Brunei, Belgium, Canada, Cyprus, Czech Republic, Denmark, Estonia, Egypt, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Japan, Jersey, Kuwait, Libya, Luxembourg, Malaysia, Malta, Mexico, Morocco, Netherlands, Norway, Oman, Philippines, Portugal, Qatar, Saudi Arabi, Singapore, Slovenia, Spain, Sweden, Switzerland, Syria, Turkey, UAE, UK). The total number of doses of **Pandemrix** distributed cumulatively **as of 10 March 10 is 126 million doses** to 36 countries. For **Arepanrix**, the total number of doses distributed is **102.5 million doses** to 17 countries. A total of about **1.5 million doses of unadjuvanted H1N1 vaccine** have been delivered to 2 countries (data corrected). This gives a grand total of **230 million doses** delivered worldwide. GSK estimates that about **85 million doses** have been administered to date **(69 million doses of Pandemrix, 16 million doses of Arepanrix plus unadjuvanted H1N1 vaccine)**, including at least **4.2 million doses** to children and **410,000 doses** to pregnant women. Please inform Dirk Campens (Dirk.Campens@gskbio.com) if your country has started its vaccination campaign and we have not listed the country.

The total number of AE reports that have been reported spontaneously since last review for Pandemrix is **348, mostly from Ireland, UK and Germany.** The total number of AE reports that have been reported spontaneously since last review for Arepanrix is **23, mostly from Canada.** No report has been received for the unadjuvanted vaccine.

As of data lock point 10 March 10, a search of the OCEANS safety database identified a total of **18156 AE reports** (17431 Pandemrix, 725 Arepanrix and 3 for the unadjuvanted vaccine), compared to 17788 reports received by 2 weeks before. This gives a rate of about **215 reports/million doses administered.** The majority of the adverse events that have been reported are in line with those expected and described in the core safety information (pyrexia, headache, pain, fatigue, nausea, myalgia, vomiting, malaise and chills are the most common). For the other events, no causal relationship to the vaccine is established or expected. In total, there have been **5069 SAE reports** and **174 reported fatalities.** For reports of fatalities, based on available data, there is no evidence for a causal association between vaccination and fatal outcome.

Event	Pandemrix	Arepanrix	Swine flu split Quebec without AS03	Total
All adverse events	17431 (348)	725 (23)	3 (0)	18156
Serious adverse events	4903 (155)	166 (4)	0	5069
Fatal outcomes	164 (6)	10 (0)	0	174
AESIs				
Anaphylaxis	316 (4)	62 (0)	0	378
Facial palsy	55 (1)	3 (0)	0	58
Guillain-Barré syndrome	74 (4)	29 (1)	0	103
Encephalitis	13 (2)	0	0	13
Demyelination	39 (-3)	0	0	39

Convulsions	301 (13)	7 (0)	0	308
Neuritis	16 (3)	2 (1)	0	18
Vasculitis	37 (3)	1 (0)	0	36
Vaccination failure	29 (0)	0	0	29

() Number of new reports in the last 2 weeks

Regarding AESIs,

- **Anaphylaxis:** No new confirmed report (total of 74 confirmed reports).
- **Facial palsy:** No new confirmed report (total of 38 confirmed reports).
- **GBS:** 3 new confirmed reports (total of 25 confirmed reports out of which possible duplicates - cases identified in a newspaper article quoting PHAC stating that there have been a total of 22 reports of GBS following H1N1 pandemic vaccines received by PHAC). A safety review has been performed with DLP 28 Feb 10 and concluded that the benefit/risk balance of the vaccines remains favourable.
- **Encephalitis:** No new confirmed report.
- **Demyelination:** No new confirmed report.
- **Convulsions:** 10 new confirmed reports (total of 133 confirmed reports). The newly reported cases do not suggest a new safety concern.
- **Neuritis:** 4 new reports. The newly reported cases do not suggest a safety signal.
- **Vasculitis:** No new confirmed report (total of 5 confirmed reports).
- **Vaccination failure:** No new report.

RMP-related AESIs:

- Maladministration: No new signal this week.
- Contamination: No new signal this week.
- Autoimmune hepatitis: No new signal this week.

In summary, the newly reported AESIs or pregnancy outcomes do not suggest a new safety signal.

The Phase IV cohort safety study (PASS) in the UK has enrolled all 9000 subjects to date. A total of 146 SAE reports (13 fatal cases) have been reported in this study so far, with 22 considered related by the investigator. A review of these events has not raised any safety concerns.

Potency testing has revealed that Arepanrix antigen lot AFLPA340C is out of specification; in addition several other lots have hemagglutinin concentrations <15 ug HA/ml. On 15 March 2010, BGTD notified GSK that it will no longer issue new lot release letters until the shelf life of Arepanrix H1N1 has been revised to ensure that all lots released meet the Health Canada approved specification of 15 ug HA/ml to the end of their shelf life. A meeting between Health Canada and GSK is scheduled for 18 March 2010; GSK will present immunogenicity and safety data following administration of adjuvanted or unadjuvanted vaccine with HA levels well below 15 ug/ml.

In summary, the risk/benefit profile of GSK's H1N1 pandemic vaccines has not changed and remains favourable. The events of interest are under close monitoring and the list remains unchanged.

Review of autoimmune haemolytic anemia, cough/bronchospasm/obstruction and maladministrations, and updated review of pregnancy outcomes and fatal outcomes are ongoing.

A Pandemrix sPSUR has been submitted on 12 March 10 and an Arepanrix sPSUR will be submitted on 24 March 10.

Aurélie Delaigle, Ir., PhD
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1300 Wavre, Belgium
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Exhibit "**GOC 14**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 28th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

~~Commissioner for Oaths~~/Practising Solicitor

Maeveanne McHugh

From: Ciara Rafferty
Sent: 31 March 2010 11:32
To: kevin.odonnell@imb.ie; aoife.farrell@imb.ie; Joan.Gilvarry@imb.ie; Almath Spooner; Niamh Arthur; nigel.fox@imb.ie
Cc: Martijn Akveld; Maeveanne McHugh; Derek Moriarty; Jenny Hughes; Colin Hester
Subject: H1N1 Enhanced Safety Review Team (Team I) Communication on Safety Review for Week 13 2010

Dear all

Please find below GSK's Enhanced Safety Review Team Report for week 13 in 2010. Please note the below report is partially based on unreviewed/ unconfirmed reports, as it is primarily generated to update internally.

I hope you will find this information useful.

Kind regards

Ciara

Ciara Rafferty |
Quality & Pharmacovigilance Advisor|
GlaxoSmithKline Ireland | Stonemasons Way | Rathfarnham, Dublin 16
t 353 1 4955553 e ciara.c.rafferty@gsk.com

Here is the summary of the H1N1 pandemic vaccines safety review for Week 13 2010:

The current review covers cumulative safety data which have been reported to GSK up to **24 March 10.** This data also includes information from clinical trials, spontaneous reports, phase IV studies and any other source of potential safety signals.
The total number of subjects that have been enrolled in clinical trials is **2864, including 666 in pediatric studies (D-Pan program)** and **7920, including 259 in pediatric studies (Q-Pan program)**, including subjects of all ages down to 6 months old. A total of **75** SAE reports in D-PAN H1N1 and **110** SAE reports in Q-PAN H1N1 studies, of which 5 were considered possibly related to the H1N1 vaccine by the investigator, have been received. A review of these events as well as the non-serious events has not raised new safety concerns. The reactogenicity profile of the H1N1 adjuvanted vaccine appears to be broadly in line with the reactogenicity of the H5N1 adjuvanted vaccine.

It is our understanding that GSK's H1N1 pandemic vaccines have been administered in at least **42 countries** (Bahrein, Brunei, Belgium, Brazil, Canada, Cyprus, Czech Republic, Denmark,

Estonia, Egypt, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Japan, Jersey, Kuwait, Libya, Luxembourg, Malaysia, Malta, Mexico, Morocco, Netherlands, Norway, Oman, Philippines, Portugal, Qatar, Saudi Arabi, Singapore, Slovenia, Spain, Sweden, Switzerland, Syria, Turkey, UAE, UK). The total number of doses of Pandemrix distributed cumulatively as of 24 March 10 is 138 million doses to 36 countries. For Arepanrix, the total number of doses distributed is 123.5 million doses to 18 countries. A total of about 1.5 million doses of unadjuvanted H1N1 vaccine have been delivered to 2 countries. This gives a grand total of 263 million doses delivered worldwide. GSK estimates that about 87 million doses have been administered to date (70 million doses of Pandemrix, 17 million doses of Arepanrix plus unadjuvanted H1N1 vaccine), including at least 4.4 million doses to children and 420,000 doses to pregnant women. Please inform Dirk Campens (Dirk.Campens@gskbio.com) if your country has started its vaccination campaign and we have not listed the country.

The total number of AE reports that have been reported spontaneously since last review for Pandemrix is 409, mostly from Netherlands, Germany and UK. The total number of AE reports that have been reported spontaneously since last review for Arepanrix is 83, mostly from Canada. No report has been received for the unadjuvanted vaccine.

As of data lock point 24 March 10, a search of the OCEANS safety database identified a total 18651 AE reports (17840 Pandemrix, 808 Arepanrix and 3 for the unadjuvanted vaccine), compared to 18159 reports received by 2 weeks before. This gives a rate of about 215 reports/million doses administered. The majority of the adverse events that have been reported are in line with those expected and described in the core safety information (pyrexia, headache, pain, fatigue, nausea, myalgia, vomiting, malaise and chills are the most common). For the other events, no causal relationship to the vaccine is established or expected. In total, there have been 5239 SAE reports and 180 reported fatalities. For reports of fatalities, based on available data, there is no evidence for a causal association between vaccination and fatal outcome.

Event	Pandemrix	Arepanrix	Swine flu split Quebec without AS03	Total
All adverse events	17840 (409)	808 (83)	3 (0)	18651
Serious adverse events	5069 (166)	170 (4)	0	5239
Fatal outcomes	169 (5)	11 (0)	0	180
AESIs				
Anaphylaxis	318 (2)	62 (0)	0	380
Facial palsy	56 (1)	3 (0)	0	59
Guillain-Barré syndrome	80 (5)	29 (0)	0	109
Encephalitis	13 (0)	0	0	13
Demyelination	49 (10)	0	0	49
Convulsions	310 (9)	8 (1)	0	318
Neuritis	19 (3)	2 (0)	0	21
Vasculitis	41 (4)	1 (0)	0	42
Vaccination failure	31 (2)	0	0	29

() Number of new reports in the last 2 weeks

Regarding AESIs,

- **Anaphylaxis:** The newly reported cases do not suggest a safety signal.
- **Facial palsy:** No new confirmed report.
- **GBS:** 1 new confirmed report. The newly reported cases do not suggest a safety signal.
- **Encephalitis:** No new report.
- **Demyelination:** 1 new confirmed report of optic neuritis. The newly reported cases do not suggest a safety signal.
- **Convulsions:** The newly reported cases do not suggest a new safety concern.
- **Neuritis:** 3 new reports. The newly reported cases do not suggest a safety signal.
- **Vasculitis:** The newly reported cases do not suggest a safety signal.
- **Vaccination failure:** 2 new confirmed reports. The newly reported cases do not suggest a safety signal.

RMP-related AESIs:

- Maladministration: No new signal this week.
- Contamination: No new signal this week.
- Autoimmune hepatitis: No new signal this week.

In summary, the newly reported AESIs or pregnancy outcomes do not suggest a new safety signal.

The Phase IV cohort safety study (PASS) in the UK has enrolled all 9000 subjects to date. A total of 165 SAE reports (17 fatal cases) have been reported in this study so far, with 23 considered related by the investigator. A review of these events has not raised any safety concerns.

In summary, the risk/benefit profile of GSK's H1N1 pandemic vaccines has not changed and remains favourable. The events of interest are under close monitoring and the list remains unchanged.

Review of autoimmune haemolytic anaemia and maladministrations, and updated review of pregnancy outcomes and fatal outcomes are ongoing.

Note that the information I am providing you is for your information only, so you can be prepared to answer questions that require this level of detailed knowledge. Any further communication internally or externally should be based on information provided by Team II and following the rules established by that team. Your preferred communication tool with the regulators should be the sPSURs, which will be added to the PSUR website alongside the other PSURs as soon as we finalize them. A Pandemrix sPSUR has been submitted on 12 March 10 and an Arepanrix sPSUR has been submitted on 24 March 10.

Exhibit "**GOC 15**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 28th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

~~**Commissioner for Oaths**~~**/Practising Solicitor**

53

National Public Health Emergency Team
Minutes 7th January 2010

Attendance
Department of Health and Children:
Mr Michael Scanlan, (Chair), Dr Tony Holohan, Dr John Devlin,
Ms Sheila O'Malley, Mr Robbie Breen, Mr Martin Woods, Mr Peter Hanrahan.

Health Service Executive
Dr Pat Doorley, Dr Kevin Kelleher, Mr Gavin Maguire, Mr Kilian McGrane,
Ms Louise McMahon, Ms Fidelma Browne (by teleconference).

HPSC
Dr Derval Igoe (by teleconference).

IMB
Dr Joan Gilvarry.

1. The minutes of previous meeting were agreed.

2. Situation Update
HPSC circulated and commented on the usual reports. No additional deaths in confirmed cases of pandemic (H1N1) 2009 have been reported since the last meeting. Influenza activity in Ireland continued to decrease during weeks 52 and 53. The sentinel GP influenza-like illness (ILI) consultation rate was 16.6 and 16.5 per 100,000 population during weeks 52 and 53 respectively, a decrease compared to the updated rate of 40.4 per 100,000 reported during week 51. These rates are now below the Irish baseline threshold. The highest sentinel GP age specific ILI consultation rates occurred in the 0-4 year age group (53.1 per 100,000 population) during week 52 and the 5-14 year age group (26.4 per 100,000 population) during week 53. As of 2nd January 2010 a total of 4,521 laboratory confirmed cases of pandemic (H1N1) 2009 have been reported in Ireland. Children and young adults remain the most affected groups with 80.2% of cases being less than 35 years of age.

3. Report from the Irish Medicines Board (IMB)
The IMB circulated and commented on a report on pandemic vaccines. On the basis of the most recently available data the IMB and EMEA continues to recommend two doses of Celvapan to all adults and children at an interval of at least three weeks apart. Further data will be available for consideration in mid-January.

No further data is available in the last few weeks in relation to Pandemrix which has implications for the licence.

Up to Tuesday 5th January 2010, 944 reports of suspected adverse reactions to the Pandemic H1N1 vaccines (Pandemrix and Celvapan) have been received by the Irish Medicines Board (IMB). A single report may include more than one suspected reaction.

The reports received to date remain consistent with the expected pattern of adverse effects for the pandemic vaccines. The balance of risks and benefits for Celvapan and Pandemrix remains positive.

European Experience Risk-Benefit Surveillance

Data available on 4 January 2010 from Member States and from the companies indicate that at least 95.8 million doses have been distributed and at least 29 million patients have been vaccinated in the EEA with one of the three centrally-authorised vaccines. From limited information available, at least 218,000 pregnant women have been vaccinated.

The most frequent adverse reactions that have been reported are non serious and as expected. These included symptoms such as fever, chills, nausea, vomiting, headache, allergic reactions, injection site reactions, myalgia and arthralgia and confirm the expected safety profile of the three vaccines in use.

A review of cases of Guillain-Barré syndrome reported up to 27 December has shown that a total of 19 cases have been reported so far in patients vaccinated with Celvapan (1), Focetria (4) and Pandemrix (14). Taking into account the number of patients vaccinated with one of the three vaccines and the background incidence rate of Guillain-Barré syndrome, the number of reported cases is lower than the number of cases that is expected to occur naturally in the vaccinated population. These cases and every new case will be closely followed.

The benefit-risk balance of the pandemic vaccines used for the current H1N1 influenza pandemic continues to be positive.

4. Report from HSE

The HSE circulated a document – Update on Swine Flu dated 6th January 2010 and there was a discussion on the document. The HSE said that it had lost a significant number of school vaccination days. It estimates that it has offered vaccine to approximately 1.3m people and about 700,000 doses have been administered giving an uptake rate of approximately 50%. 1.6m doses have been distributed with 550,000 gone to GPs. The DoHC noted that the MVCs are still running well below notional capacity and the HSE said that they are running at approximately 2/3 capacity and that for any future event we would probably not use the exact same plan.

There was a discussion on when and how we should finish vaccinations in schools and vaccination of the other target groups (under 5s; over 65s and "at risk" groups). It was agreed that the efficiency issue needs to be monitored. The HSE pointed out that a big consideration is the resources being diverted and that there is a document with the HSE Management Team on the effect of the diversion of resources. It was agreed that the HSE would come back with an outline plan on this taking account of the various caveats/scenarios etc.

There was a discussion on an "end date" for the under 5s, over 65s, "at risk" groups and HCWs. It was agreed that we should stop vaccination of these groups by the end of January and that we should send this message out as soon as possible.

There was a discussion on "if and how" we vaccinate the general population. The DoHC pointed out that based on our best estimate we have approximately 40%

population immunity and that this is the figure we had targeted at the last meeting. It was agreed that we should offer vaccine to the general population. We have not changed our policy in this regard but did agree to keep it under review. Vaccination of the general population should not have an impact on existing services. We have to consider how we can justify diverting HSE resources to vaccinate people who are not at high risk. What are the options? One clinic once a week in each LHO area – distribute vaccine to private industry/large employers – use pharmacists. We will also need to get the Expert Group view on the need to offer vaccine to the general population. The HSE said that we should put extra efforts into getting the uptake rate in schools as high as possible because if we can get the rate of vaccination in the under 20s as high as possible it will benefit us. After that we should offer the vaccine in a passive way and the HSE should not be involved in it at that stage. We wouldn't refuse to make it available to the public but the question is how best to do so. We have only two alternatives – HSE contractors (dentists/pharmacists/GPs) or the HSE itself. It was suggested that the GPs would be the best option. The DoHC suggested that we think about how we are going to finish the vaccination campaign and said that maybe we should put a "line in the sand" at the end of June. It should be offered to the general population with minimum impact on services and cost. It was agreed to ask the Expert Group for its view on the relevant issues.

The DoHC said that we have received 2.3 million doses of vaccine out of approximately 4 million doses and the question is do we need any or all of the undelivered quantity. HSE said that a lot will depend on whether or not H1N1 is included in the seasonal flu vaccine and that at best we could only stop delivery of about 1.7 million doses. It was agreed that the HSE could ask GSK if they will hold some stock outside the country – we may have to pay for this but it would make it a lot easier to divert it if that is what is decided.

The HSE asked if non vaccination issues could be included in any discussions on planning for the second wave.

The DoHC said it wants to go to Government in week beginning 18th January and we need to agree on 3 issues:- (i) completion of current vaccination campaign, (ii) plan for the general population and (iii) what to do with the 1.7 million doses of surplus vaccine. It was agreed that the DoHC and the HSE would meet next Thursday to finalise these issues and that the HSE would submit an outline in advance of this meeting.

6. AOB

It was agreed that finance would be discussed offline.

The HSE is following up on the issue of GPs charging for H1N1 vaccination and has received a reply in relation to one complaint. It was agreed that the HSE will send a report to the Secretary General when finalised.

7. Next Meeting

The next meeting will take place on Thursday 21st January 2010.

(54)

National Public Health Emergency Team
Minutes 21st January 2010

Attendance
Department of Health and Children:
Dr Tony Holohan (Chair), Mr Luke Mulligan, Ms Sheila O'Malley, Mr Martin Woods, Ms Marita Kinsella, Ms Roisin Heuston, Mr Peter Hanrahan.

Health Service Executive
Dr Pat Doorley, Dr Kevin Kelleher, Mr Kilian McGrane, Ms Fidelma Browne.

HPSC
Dr Darina O'Flanagan.

IMB
Dr Joan Gilvarry.

1. The minutes of previous meeting were agreed as amended.

2. Situation Update
HPSC circulated and commented on the usual reports. No additional deaths in confirmed cases of pandemic (H1N1) 2009 have been reported since the last meeting. The sentinel GP influenza-like illness (ILI) consultation rates of 15.9 per 100,000 population in the week 2 (11th to 17th January) were lower than the rates of 21.1 per 100,000 in the previous week. These rates are now below the Irish baseline threshold. The highest sentinel GP age specific ILI consultation rates occurred in the 0-4 year age group (18.5 per 100,000 population) during week 2. As of 20th January 2010 a total of 4,568 laboratory confirmed cases of pandemic (H1N1) 2009 have been reported in Ireland. Children and young adults remain the most affected groups with 80.1% of cases being less than 35 years of age. ECDC is setting up a group to look at a proposal to undertake a sero epidemiology study and the HPSC will be represented on this group.

3. Report from the Expert Group
A report from the Expert Group was circulated and commented on. The Expert Group advises that it is reasonable to offer vaccine to the whole population, as it may increase herd immunity but it is important to focus most efforts on completing the schools programme and vaccination of those in "at risk" groups. On the question of use of residual vaccine the Expert Group advises that decisions on this issue should be made following the European meeting due on 26th January that will discuss the constituents of the seasonal flu vaccine for 2010/2011. We may need to review our seasonal flu target group at that stage. The Expert Group advises that given that the ILI rates are now below the baseline, and that ILI symptoms are less predictive of pandemic (H1N1) 2009, it is no longer appropriate to treat all those with ILI in "risk" groups with oseltamivir.

4. Report from the Irish Medicines Board (IMB)
The IMB circulated and commented on a report on pandemic vaccines. Immunogenicity results following vaccination with Celvapan, in particular data from trials involving the H1N1 strain from studies in both children and adults were

reviewed this week by the Scientific Committee (Committee for Human Medicinal Products (CHMP)) of the European Medicines Agency (EMA). The Committee was of the opinion that these results were not sufficient to support a change from the current two-dose recommendation to a single-dose vaccination schedule. IMB advice is in line with the CHMP opinion is that all patients who have received one dose of Celvapan should receive the second dose. For those subjects who have not yet been vaccinated Pandemrix should be used unless there is a true contraindication preventing its use.

The product information of Pandemrix is to be updated to include additional data on the immunogenicity and safety in 3-to-9 year old children after the first half dose of Pandemrix that confirm the expected reactogenicity and immunogenicity profile. There are no changes in the dosing recommendations for Pandemrix accordingly.

Up to Tuesday 19th January 2010, 1080 reports of suspected adverse reactions to the Pandemic H1N1 vaccines (Pandemrix and Celvapan) have been received by the IMB. A single report may include more than one suspected reaction.

The reports received to date remain consistent with the expected pattern of adverse effects for the pandemic vaccines. The balance of risks and benefits for Celvapan and Pandemrix remains positive.

European Experience Risk-Benefit Surveillance
Data available on 18 January 2010 from Member States and from the vaccine's marketing-authorisation holders indicate that at least 112.1 million doses had been distributed and 33.9 million patients including at least 258,000 pregnant women have been vaccinated with one of the three centrally-authorised vaccines in the EEA. Some of these have received two doses of a vaccine, but the percentage varies across countries.

The most frequent adverse reactions that have been reported are considered to be non serious and as expected. These included symptoms such as fever, chills, nausea, vomiting, headache, allergic reactions, injection site reactions, myalgia and arthralgia and confirm the expected safety profile of the three vaccines in use.

The benefit-risk balance of the pandemic vaccines used for the current H1N1 influenza pandemic continues to be positive.

5. Report from HSE
Vaccine delivery
We have received 1,976,000 dose of GSK vaccine into the country and the HSE will meet GSK on Tuesday next, 26th January to discuss the options for future deliveries.

Vaccination Campaign
It is estimated that we have offered vaccine to approximately 1.4 million people and approximately 750,000 people had been vaccinated giving an uptake rate of about 50%. The GPs have done at least 275,000 vaccinations; the clinics 405,000 vaccinations; 64,000 vaccinations have been done in schools and 48,500 Health Care Workers have been vaccinated. We have vaccinated at least 45% of under 5s; at least 15% of 5-19s; at least 25% of over 64s and at least 18% of the whole population. It is now planned to finish the vaccination programme for under 5s and the "at risk"

groups by 1st February and finish the over 65s by 15th February. This message will be conveyed to the public. The schools vaccination programme will finish by the end of March

It was agreed that the vaccine should now be offered to the general public from the beginning of February on the understanding that it does not have an impact on the delivery of services. This will be done in the first instance via the Mass Vaccination Clinics already in place which will remain open on one to two days a week and through any GPs who still have a supply of vaccine. We will need to ensure that the system will be able to cope with any initial surge that might occur when we invite the general public to get vaccinated. This will continue until the end of March with regular reviews. A meeting of the Inter-Departmental Committee has now been called for 26th January to consider whether over the same period it would be feasible to arrange supply of vaccine to major private sector employers, local government and other public bodies, third level and other educational establishments etc in order to allow them to vaccinate their own staff/students, using their own occupational health professionals.

The question of making the vaccine available for pregnant women on an ongoing basis was raised – should it be available for say 6 months until the new seasonal flu vaccine is available? It was agreed that the Expert Group would be asked for advice on the continuing risks and ongoing requirements for pregnant women between now and the next seasonal flu vaccine campaign.

There was a discussion on possible surplus vaccine and what options we have in relation to it. The HSE said that we will have to make a decision on a possible stockpile as part of our preparedness for a second or third wave. It becomes technically more difficult to offload it once it is in the country because of the logistics etc. We probably have enough vaccine out in the system to cope with the demand between now and September and this makes the 1 million or so doses in store in United Drug more available for distribution elsewhere. The DoHC said that once we have decided what if any surplus vaccine we have we will make contact with the Health Security Committee with a view to offering it to any country that is looking for vaccine. The HSE said that it will forward a memo on numbers of doses received etc to the Expert Group to assist in the deliberations on the need for a stockpile.

The HSE raised the issue of H5N1 vaccine – we have 400,000 dose of pre-pandemic vaccine that was to be offered to essential workers. This has now lost its potency and we need to decide whether or not we should go back into the market to buy new stock. It was agreed that the Expert Group should be asked to examine this issue.

6. Future Arrangements

The Chair said that NPHET should now revert to meeting 3 or 4 times a year and that we should once again continue in planning mode. This can be changed if circumstances change. We have made all the necessary decisions and we can deal with issues bilaterally as required. There will be certain pieces of information on numbers vaccinated etc that will be required on a regular basis. We will need to continue with Press Briefings until the vaccination campaign is finished and then have a final Press Briefing by way of a Press Release on what happened, what we did, what we learned etc. We should have an evaluation of the whole experience maybe in the

second half of the year and we need to look again at the Pandemic Plan. The HSE said that it will also review Pandemic Planning internally.

The Chair once again thanked everyone for all the work that has gone into dealing with the Pandemic.

7. Next Meeting .
The next meeting will take place sometime mid/end March 2010.

Exhibit "**GOC 16**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 28th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

~~**Commissioner for Oaths**~~**/Practising Solicitor**

2.1 Influenza

Summary

The 2009 influenza A (H1N1) pandemic summary:

Peak influenza-like illness rate: 201.3 /100,000 population (week 43 2009)

Total confirmed pandemic cases hospitalised: 1059

Total confirmed pandemic cases admitted to ICU: 100

Total deaths associated with pandemic: 27

European data available at:
http://ecdc.europa.eu/en/Activities/Surveillance/EISN/

On 25th April 2009, a public health emergency of international concern was declared by the World Health Organization (WHO) due to an outbreak of 2009 pandemic influenza A (H1N1) infection in Mexico and the USA. On 11th June 2009, WHO raised the pandemic alert level to phase six, announcing the first influenza pandemic of the 21st century. WHO classified the severity of the disease as "moderate" based on scientific evidence available to them as well as the impact of the pandemic on member states' health systems and social and economic functioning. On July 16th 2009, the Department of Health and Children announced that Ireland would change the national approach to managing the pandemic from one of containment (or limiting the entrance and initial spread of the pandemic virus into the country) to one of mitigation (or minimising the impact of the pandemic virus as its circulation increased).

The vaccination campaign against 2009 pandemic influenza A (H1N1) started on 2nd November 2009. Individuals at highest risk of influenza disease and its complications were provided with the vaccine in the early stages, with those at less risk of severe disease vaccinated later on. The mass vaccine programme concluded on 31st March 2010 as the numbers contracting pandemic influenza declined significantly. However, pandemic vaccine continued to be provided over the summer to those individuals at highest risk of influenza complications.

On 10th August 2010, the WHO declared the end of the 2009 influenza A (H1N1) pandemic.

Since 2000, HPSC has worked in collaboration with the National Virus Reference Laboratory (NVRL), the Irish College of General Practitioners (ICGP) and the Departments of Public Health on the influenza sentinel surveillance project. During the pandemic period, 60 practices (located in all HSE-Areas) were recruited to report electronically, on a weekly basis, the number of patients who consulted with influenza-like illness (ILI). Sentinel GPs were requested to send a combined nasal and throat swab to the NVRL on at least five ILI patients per week. Other indicators of influenza activity included a network of sentinel hospitals reporting admission levels and sentinel schools reporting absenteeism.

Once the public health emergency was declared, routine seasonal influenza surveillance was augmented as follows:

- Two additional regional laboratories, Cork University Hospital (CUH) and Galway University Hospitals (GUH), started testing for 2009 pandemic influenza A (H1N1), in addition to the NVRL.
- Enhanced surveillance of the first 200 laboratory confirmed 2009 pandemic influenza A (H1N1) cases was implemented, thereafter enhanced surveillance data were collated on hospitalised cases only.
- Critical care/ICU surveillance of probable and confirmed adult and paediatric pandemic influenza A (H1N1) cases commenced in October 2009.
- Data on all calls to GP out-of-hours centres were monitored for self reported influenza by HSE-NE.
- Additional surveillance projects included monitoring mortality data from the General Register Office and an influenza vaccine effectiveness study (IMOVE project).

Data in this report covers the entire pandemic period from April 2009 (week 17 2009) to August 2010 (week 32 2010). During the 2009 pandemic, ILI activity peaked during week 43 2009, at 201.3 per 100,000 population (figure 1). This is the highest rate recorded since sentinel influenza surveillance commenced in 2000. The previous highest peaks occurred in week 2 2009 (120.6 per 100,000 population) and week 8 2001 (122.9 per 100,000 population). In mid-July 2009 (week 30), the ILI rate was above the baseline threshold of 17.8 per 100,000. This level of influenza activity during the inter-seasonal period had never been experienced

in Ireland. The peak age specific ILI rates during the pandemic were in 5-14 year olds, followed by 0-4 year olds. ILI rates in the 0-4, 5-14 and 15-64 year olds were the highest age specific rates recorded since sentinel influenza surveillance began. ILI rates in those aged 65 years or older were lower than the 2008/2009 season and were comparable to other seasons.

The percentage of influenza-related calls to GP out-of-hours services in Ireland, peaked during week 45 2009 at 10.6%. During the peak of the pandemic, the highest number of calls relating to influenza received by each service was on average three per hour.

The NVRL, CUH and GUH tested a total of 23,142 specimens for influenza virus during the pandemic period. Twenty one percent (n=4797; 20.7%) were positive for influenza virus. Over 99% (n=4759; 99.2%) of positive influenza specimens were confirmed (n=4464) or probable (n=295) 2009 pandemic influenza A (H1N1). Thirty-eight (0.8%) specimens were positive for seasonal influenza: 1 influenza A (unsubtyped), 5 A (H1), 27 A (H3) and 5 B. The NVRL performed neuraminidase sequencing on 36 non-sentinel 2009 pandemic influenza A (H1N1) isolates, all of which were susceptible to oseltamivir and zanamivir. The NVRL also sequenced and phylogenetically characterised the haemagglutinin gene from 18 2009 pandemic influenza A (H1N1) isolates, all of which form a monophyletic group with A/California/07/2009, demonstrating a very good match between the circulating and vaccine strains.

A total of 1,059 confirmed cases of 2009 pandemic influenza A (H1N1) were admitted to hospital. Of these, 100 (9.4%) were admitted to ICU (76 adults and 24 paediatric cases). For hospitalised and ICU patients, the highest age-specific rates were in the 0-4 year age group. Of the 1,059 confirmed cases hospitalised, 507 (47.9%) had pre-existing clinical conditions.[1] The most frequently reported underlying medical conditions included: asthma (n=127, 12.0%), chronic respiratory disease[2] (n=114, 10.8%), immunosuppression (n=79, 7.5%) and chronic heart disease (n=62, 5.9%). Seventy-three (6.9%) of all hospitalised confirmed cases were in pregnant women, eight of whom were admitted to ICU.

Twenty-seven patients with confirmed 2009 pandemic influenza A (H1N1) died (pandemic (H1N1) 2009 was a contributing cause on the death certificate); 12 males and 15 females. Twenty (74.1%) deaths occurred in adults 35 years of age and older. The age range was 8-83 years, with a median age of 52 years. Underlying medical conditions[1] (including pregnancy) were reported for 25 of the 27 deaths (92.6%), with two deaths having no reported underlying medical conditions. Underlying conditions included chronic respiratory disease [2] (n=11), chronic neurological disease (n=9), immunosuppression (n=7), chronic heart disease (n=3), chronic liver disease (n=2), asthma (n=2), chronic renal disease (n=1) and severe obesity i.e. BMI ≥40 (n=1). One death (3.7%) occurred in a pregnant woman. Twenty five of the deaths (92.6%) occurred in hospitalised cases and 15 (55.6%) deaths were in cases admitted to ICU. A summary of pandemic severity indicators is shown in table 1.

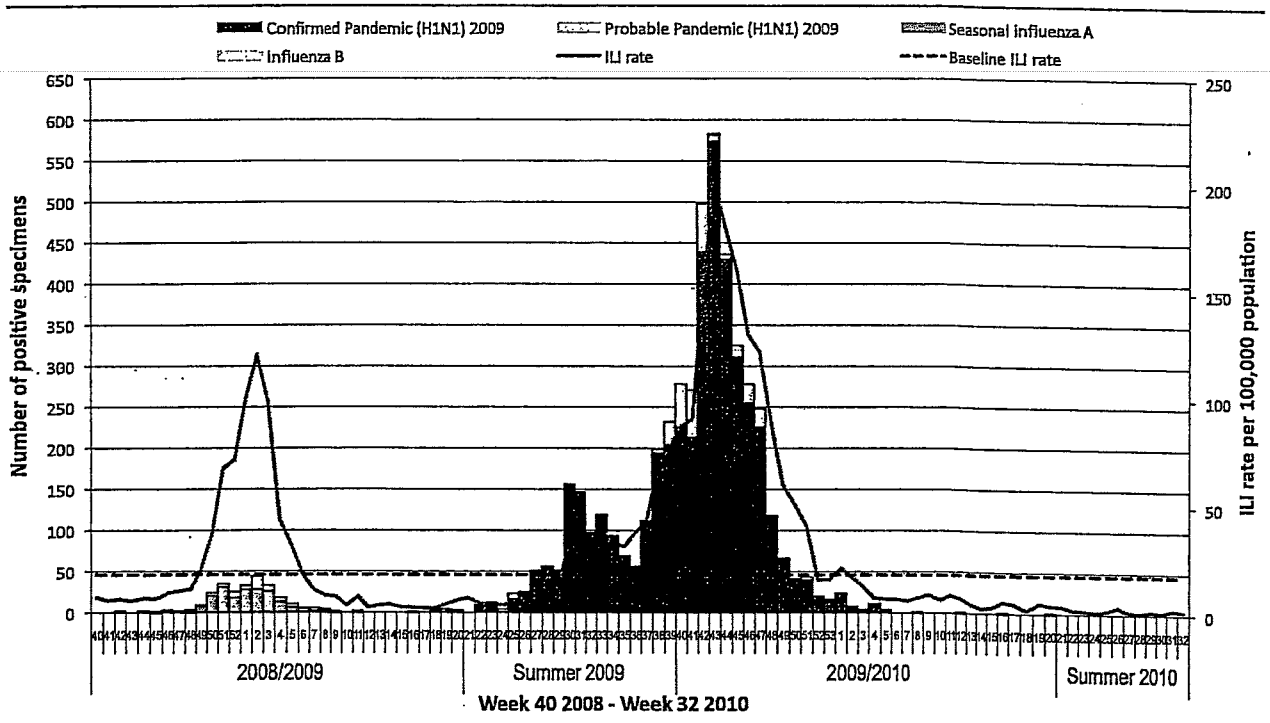

Figure 1: GP ILI consultation rate per 100,000 population, baseline ILI threshold rate, and number of positive influenza specimens, by influenza week and season, week 40 2008-week 32 2010. Source: ICGP clinical ILI data and NVRL, CUH and GUH laboratory data. Virological data for the NVRL includes sentinel and non-sentinel data for all weeks. Virological data from GUH and CUH includes non-sentinel data from weeks 29 and 31 2009, respectively.

1. Some cases had more than one underlying medical condition.
2. It cannot be established if chronic respiratory disease was in addition to, or included asthma.

One hundred and nine general outbreaks of ILI and 2009 pandemic influenza were reported in Ireland during the pandemic period. These outbreaks involved 2,578 people in total, of which 204 (7.9%) were reported as laboratory confirmed cases of 2009 pandemic influenza. Regional variation in ILI/pandemic activity was observed during the pandemic period. The majority of outbreaks were reported from HSE-E (n=29; 26.6%) and HSE-S (n=27; 24.8%). With the exception of HSE-M, all HSE-Areas reported general outbreaks of 2009 pandemic influenza and ILI during the pandemic period.

A total of 955,118 individuals were recorded as vaccinated with the pandemic vaccine, representing 23% of the population of Ireland eligible for vaccination. It should be noted that pandemic vaccination data are provisional.

In the post-pandemic period, based on knowledge about past pandemics the 2009 pandemic influenza virus is expected to continue to circulate as seasonal virus for some years to come. Therefore, cases and local outbreaks due to 2009 pandemic influenza will continue to occur and such outbreaks could have a substantial impact on communities. WHO advises that national health authorities remain vigilant in the immediate post-pandemic period as the behaviour of the virus as a seasonal virus cannot be reliably predicted.

In addition, it is most likely that, compared with seasonal influenza, younger age groups will continue to be affected disproportionately by the virus. Groups identified during the pandemic as being at higher risk of severe or fatal disease will remain at increased risk though the number of such cases should diminish.

In August 2010, WHO issued guidance on recommended activities during the post-pandemic period including advice on epidemiological and virological surveillance, vaccination and the clinical management of cases. WHO recommends: (1) the monitoring of clusters of severe respiratory illness or death; (2) investigation of severe or unusual cases clusters or outbreaks to facilitate rapid identification of important changes in the epidemiology and severity of influenza; and (3) maintaining routine ILI surveillance and surveillance of severe cases of influenza and respiratory illness.

For the 2010/2011 influenza season, existing surveillance systems have been strengthened and maintained. Data from these surveillance systems will assist in guiding the prevention, control and management of ILI/influenza.

Further information on influenza is available on the HPSC website www.hpsc.ie

Table 1: Summary table of severity indicators for laboratory confirmed 2009 pandemic influenza A (H1N1) cases - hospitalised cases, ICU cases and deaths.

	Hospitalised confirmed 2009 pandemic influenza A (H1N1) cases	ICU confirmed 2009 pandemic influenza A (H1N1) cases	Deaths in confirmed 2009 pandemic influenza A (H1N1) cases
Total cases	1059	100	27
Crude rate per 100,000 population	25.0	2.4	0.6
Age range (years)	0-84	0-79	8-83
Median age (years)	17	34	52
Females	533	50	15
	50.3%	50.0%	55.6%
Cases with risk factor[1]	507	81	25
	47.9%	81.0%	92.6%

1. Some cases had more than one underlying medical condition.

Exhibit "**GOC 17**" referred to in the Affidavit of Gillian O'Connor

Sworn on the 28th day of June 2017

Signed: .....

Gillian O'Connor

Signed: .....

~~**Commissioner for Oaths**~~**/Practising Solicitor**

PREGNANT? ASTHMA? HEART DISEASE?
CANCER? OBESITY? DIABETES?
LONG-TERM ILLNESS?

SWINE FLU

IT STOPS FOR YOU

Getting the Swine Flu vaccine will protect you from Swine Flu and will also stop it spreading to people around you.

HSE
Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Department of Health & Children

Getting the Swine Flu vaccine will protect you from Swine Flu and will also stop it spreading to people around you.

Swine Flu is a new flu virus that, for most people, has caused mild to moderate illness. However, some children, pregnant women and people with long-term illnesses have been hit harder by this flu, and some have died. Most people have no immunity to Swine Flu so, over the coming months, the HSE intends to offer a Swine Flu vaccine to everyone living in Ireland.

Who will get the vaccine first?

Everyone will be offered the Swine Flu vaccine, but we are giving the first supplies to those who are more at risk from Swine Flu. Healthcare workers will also be vaccinated to protect themselves and their patients.

Who is most at risk from Swine Flu?

- Pregnant women – from 14 weeks pregnant to 6 weeks after giving birth and
- Anyone aged over 6 months and under 65 years who has:
  - Long-term Lung Disease (like Asthma and Cystic Fibrosis)
  - Long-term Heart Disease
  - Long-term Kidney Disease
  - Long-term Liver Disease
  - Long-term Neurological Disease (like MS, Cerebral Palsy)
  - Immunosuppression e.g. cancer treatment (and their household contacts)
  - Haemoglobinopathies
  - Diabetes
  - Morbid Obesity (check with your GP)

People aged 65 and over seem to have some immunity to Swine Flu, so are not in the most At-Risk Group.

IT STOPS FOR YOU

How does the Swine Flu vaccine work?

The vaccine helps your immune system to produce antibodies to the Swine Flu virus. When a person who has been vaccinated comes into contact with Swine Flu these antibodies attack the virus and prevent you getting the flu.

How safe is the Swine Flu vaccine?

We expect the Swine Flu vaccine to be as safe as the usual seasonal flu vaccine, which has been used for more than 60 years. Serious side effects are expected to be very rare and the Swine Flu vaccine cannot give you Swine Flu. The vaccines are fully licensed and clinically tested. You can read more about vaccine safety on swineflu.ie.

Is it safe for pregnant women to be vaccinated?

Yes. The vaccine is safe to use in pregnancy and is recommended for all women from 14 weeks pregnant to 6 weeks after giving birth. Pregnant women under 14 weeks pregnant who have an existing at-risk medical condition are also advised to get the vaccine.

Is there anyone who cannot get Swine Flu vaccine?

The vaccine should not be given to children under 6 months of age, and should be postponed if you have a temperature over 38°C. Everyone in the at-risk groups aged over 6 months and under 65 years should get the vaccine – unless they have a severe allergy to eggs or other substances in the vaccine or have previously had Guillain Barré Syndrome. If you have any concerns you can discuss these with your GP.

How long does it take the vaccine to work?

The vaccine starts to work within two weeks – our current advice is that for you to be fully protected from Swine Flu, you need a second dose of vaccine three weeks after the first dose. It is hoped that more information will emerge confirming that one dose of vaccine will be enough to protect people aged 13 years and over.

Freephone **1800 94 11 00** **www.swineflu.ie**

IT STOPS FOR YOU

What can I expect after vaccination?

The most common side effects will be mild and may include soreness, redness or swelling where the injection was given. Headache, fever, aches and tiredness may occur. Some people may have mild sweating and shivering as their immune system responds to the vaccine, but this is not Swine Flu and will pass after a day or so.

What if I don't feel well after vaccination?

Take paracetamol or ibuprofen if you have a fever or any pain where the injection was given. If you are pregnant, take paracetamol for fever, not ibuprofen or aspirin. Avoid clothes rubbing against the injection area and drink plenty of fluids. Remember if you or a child is unwell after getting a vaccine, they could be sick for some other reason – don't assume it's the flu vaccine and take medical advice if needed.

Do I have to pay for the vaccine?

The vaccine and its administration are free of charge for everyone. You may be asked for your PPSN (Personal Public Service Number) when you go to have your vaccine.

Talk to your GP and make an appointment for a Swine Flu Vaccine now.

Where can I get more information?

Visit **www.swineflu.ie** or call **1800 94 11 00**

Produced by the HSE National Communications Unit,
Dr. Steeven's Hospital, Dublin 8.
October 2009.

Department of Health & Children

SWINE FLU

IT STOPS WITH YOU

Getting the Swine Flu vaccine will protect you from Swine Flu and will also stop it spreading to people around you.

HSE
Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Department of Health & Children
AN ROINN SLÁINTE AGUS LEANAÍ

The HSE is working to offer a Swine Flu Vaccine to everyone in Ireland over the coming months. This leaflet answers common questions about this vaccine and tells you who is being vaccinated, when and where.

Swine Flu is a new flu virus that has been spreading around the world since April this year. For most of us, it causes mild to moderate flu illness, and most people are able to get better at home after about a week. However, some children, pregnant women, people with long-term illnesses and previously healthy adults have been hit harder by this flu. During October and November the rate of flu illness has been at a record high for Ireland, and many more people are likely to catch this flu over the coming months.

Getting the Swine Flu vaccine is by far the best way to protect against Swine Flu. Also, if you don't get the flu, you can't pass it on to your family, friends, relatives, or someone close to you who is not in full health. So, the more people who get the vaccine, the less flu gets passed around.

The HSE is working to offer a Swine Flu vaccine to everyone in Ireland. This is being done in phases as we receive the limited supplies of this new vaccine, starting with people most at risk from this flu. This programme started in late October and will continue over a period of six to eight months. We have already vaccinated hundreds of thousands of people, and are working to ensure many more get protection from Swine Flu as we go forward through the winter.

What groups were offered the vaccine first?

Ireland has a National Immunisation Advisory Committee and Pandemic Influenza Expert Group, who recommended that the vaccine should be given first to those most at risk of Swine Flu complications.

The first group of people to get Swine Flu vaccine included pregnant women and people aged over 6 months and under 65 with certain long term illnesses. These were vaccinated primarily by their GPs, and also at HSE Clinics nationwide. While we continue to vaccinate this group, we have already moved on to the next priority groups for Swine Flu vaccination. These are children over 6 months up to 18 years, people aged 65 and over and and healthcare workers. Since babies under 6 months cannot get the vaccine, we are also giving the vaccine to parents and families of babies under 6 months, to protect the infants from the flu.

Once these priority groups are vaccinated the vaccine will be offered to the rest of the population, during early 2010.

The table below describes the different groups, and tells you when and where they are being vaccinated.

Priority Groups	Where?	When?
Pregnant women – from 14 weeks pregnant to 6 weeks after giving birth and People aged over 6 months and under 65 years who have long-term conditions (see below)	Vaccination by GP or by HSE Vaccination Clinic	Started at the end of October and continues in November and December
Children from 6 months to Under 5 years of age and parents and household contacts of children under 6 months	Vaccination primarily by HSE Clinic – parents will be given a personal invitation by letter	Started in November and continues in December
65 years of age and older	Vaccination primarily by HSE Clinic – people will be sent a personal invitation by letter	Starting in November and continues in December
Healthcare Workers	Vaccination at work in occupational health clinics	Started in November and continues in December
Children 5-18 years of age	Vaccination by HSE School vaccinations teams. Information and consent forms for parents will be sent to schools in advance	Starting 1st week in December and continues in January
General Population	Vaccination by HSE Clinic	Commencing in early 2010 when the groups above are completed

Risk conditions: Lung Disease (like Asthma and Cystic Fibrosis), Heart Disease, Kidney Disease, Liver Disease, Neurological Disease (like MS, Cerebral Palsy), Immunosuppression e.g. Cancer treatment (and their household contacts), Haemoglobinopathies (Sickle Cell Disease, Thalassemia Major), Diabetes and Morbid Obesity.

Where are the HSE Vaccination Clinics?

Clinics have been set up all over the country, usually in existing HSE health facilities. The HSE also rotates the clinics to different locations to give easier access for people from particular localities. When it is your turn to get your vaccine, you will find details of the clinic locations on www.swineflu.ie, in local and national newspapers, and on Freephone 1800 94 11 00. Giving this important vaccine to the whole population is a massive logistical exercise, which has never been done before in Ireland. As we move through the next few months, vaccinating the various groups, some health services may have to be disrupted to allow for the vaccination programme. We will work to keep this to a minimum.

How will the next priority groups get their vaccine?

During November and December, the main groups being vaccinated are children and older people. The HSE is writing to parents of children aged 6 months to under 5 years and people aged 65 and over with personal invitations to make appointments at HSE vaccination clinics. The letters will explain that it is now time to make your appointment on www.swineflu.ie or by phone. People in these groups are asked to please wait for their letter, and not to attend a clinic for a vaccine in the meantime. This is because we do not want people to be inconvenienced by queues at our clinics.

If you book a visit to a HSE clinic online or on the phone, please be aware that even though you book for a specific time slot, there will be up to 30 people in your time slot. Please be patient and take some time to read the information available at the clinic. When they get their letter and make an appointment, they should bring the invitation letter to the clinic with them.

IT STOPS WITH YOU

What about school age children?

School age children will be invited to attend for vaccination via their schools. Vaccinations for these children will be carried out using one of three methods – in their school premises, in a school premises near their own school or by arranging an appointment at a HSE Mass Vaccination Clinic when requested to do so. Parents will be notified in advance and will be sent a consent form and information sheet.

What can I expect when I attend a clinic?

The HSE Swine Flu Vaccine clinics are staffed with healthcare professionals and administration staff. On entering the clinic you will be offered a consent form and information sheet. You should fill in the form and ensure that you read the information provided. You will then be met by an administration assistant who will enter your details on to a computerised record system. Once this is done you will be asked to take a seat in the vaccine administration area while your chart is checked.

The vaccine will be administered by a healthcare professional who will check some clinical details with you – how you are feeling; if you have any known reactions or allergies etc. You will then be vaccinated and you will have to wait for a minimum of 15 minutes in the recovery area being observed to ensure that you have no adverse reaction. The whole process takes around 45-60 minutes. Before you leave the clinic you will receive a vaccine card – this card gives details of which vaccine you have received; the batch number; the date and your client number. You should ensure that you keep this card in a safe place.

Does everyone need to get the vaccine?

We intend to offer the vaccine to everyone in Ireland. If you have had flu since April, you should still get the vaccine, as it may not have been the Pandemic H1N1 2009 or Swine Flu virus. If you have had a confirmed positive lab test for Swine Flu or Pandemic H1N1 2009, you do not need the vaccine.

How long does it take the vaccine to work?

The vaccine starts to work within two weeks, so please ensure that you continue to follow good infection control after being vaccinated. If you cough or sneeze – **Catch It** in a tissue, **Bin It** and **Kill It** by washing your hands with soap and water.

Do I need one or two doses of vaccine?

There are two different makes of vaccine being used in Ireland; Pandemrix (manufactured by GSK) and Celvapan (manufactured by Baxter). The National Immunisation Advisory Committee has confirmed that for the Pandemrix vaccine, one dose of the vaccine will be enough to protect most people from Swine Flu. The only exception to this is children aged under 13 years and people with immunosuppression who will require two doses of this vaccine. People who are immunosuppressed would include people with cancer or on cancer treatment – check with your doctor if you are unsure.

For the Celvapan vaccine, 2 doses of vaccine are required to give full protection from Swine Flu. Both vaccines are considered to be equally effective and have the same safety profile.

Where a second dose of vaccine is needed, it should be given after a gap of at least three weeks or longer. If you need a second dose of vaccine, the HSE will let you know when it is available and invite you to attend to get it.

How do the pandemic vaccines work?

Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Both vaccines contain a virus called Pandemic (H1N1) 2009 that is causing the current Swine Flu pandemic. The virus has been inactivated (killed) so that it does not cause any disease.

When a person is given the vaccine, the immune system recognises the inactivated virus as 'foreign' and makes antibodies against it. The immune system will then be able to produce antibodies more quickly when it comes across the live virus. The antibodies will then destroy the flu virus and stop you getting the flu.

Are the Swine Flu vaccines safe?

Yes, the two Swine Flu vaccines being used in Ireland, Pandemrix and Celvapan, are both licensed by the Irish Medicines Board and have been given to millions of people across Europe already this year.

Reactions have been as expected and similar to seasonal flu vaccines, which have been used for more than 60 years. Serious side effects or allergic reactions are very rare and the Swine Flu vaccine cannot give you Swine Flu.

Is there anyone who can't get the vaccine?

The vaccine should not be given to children under 6 months of age, and should not be given to anyone who has a temperature over 38°C or 100.4°F. If you have a severe allergy to eggs, you can have the Celvapan vaccine, as the Pandemrix vaccine is made using eggs. If you or your child have any other severe allergies or previously had Guillain Barré Syndrome, you should discuss this with the clinic staff before being vaccinated.

Is it safe to get the vaccine if you are pregnant?

Yes. Women have a reduced immune system during pregnancy and so pregnant women are more at risk from complications or hospitalisation from Swine Fu. The risk of these complications is also higher after 14 weeks of pregnancy. The Institute of Obstetricians and Gynaecologists in Ireland, the National Immunisation Advisory Committee, the World Health Organisation, the European Centre for Disease Prevention and Control, the Irish College of General Practitioners and the Irish Medical Organisation all recommend that pregnant women from 14 weeks pregnant to 6 weeks after giving birth get the vaccine. If you are less than 14 weeks pregnant and have an at-risk medical condition or are a healthcare worker, you should also get the vaccine. Having the vaccine while pregnant will protect the mother, and will protect their baby for up to 6 months after birth. The vaccine is safe for breastfeeding mothers and their babies.

IT STOPS WITH YOU

What can I expect after vaccination?

The most common side effects being seen are mild and may include soreness, redness or swelling where the injection was given. Headache, fever, aches, a mild rash and tiredness may occur. Some people may have mild sweating and shivering as their immune system responds to the vaccine, but this is not Swine Flu and will pass after a day or so. Severe or life threatening allergic reactions to vaccines are very rare.

What if I don't feel well after vaccination?

Take paracetamol if you or your child has a fever or any pain where the injection was given. Avoid clothes rubbing against the injection area and drink plenty of fluids. Remember, if you or your child is unwell after getting a vaccine, don't assume the vaccine is the cause – it could be for some other reason, and take medical advice if needed.

Do I have to pay for the vaccine?

The vaccine and its administration are free of charge for everyone.

Where can I get more information?

Visit www.swineflu.ie or Freephone 1800 94 11 00, listen to the HSE radio advertisements and HSE information in national and local newspapers.

STOP THE FLU FROM SPREADING!

Remember, it's very important that everyone continues to avoid spreading flu around – catching coughs and sneezes in a paper tissue, binning it straightaway and killing it by washing hands well and often. If you or a loved one has flu-like illness, you will find simple guidance on how to recognise the symptoms and how to care for flu at home at **www.hse.ie** or on the 24 Hour HSE Flu Information Line Freephone **1800 94 11 00.**

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