

Report of the Risk Review Group

Established to examine and report on
the causes of the underdosing of some
patients with seasonal influenza vaccine
by some pharmacists

June 2012

Ms Ciara McGoldrick,
Acting Registrar,
The Pharmaceutical Society of Ireland,
PSI House,
Fenian St.,
Dublin 2.

14th June 2012

Re: Report of the Risk Review Group

Dear Ms McGoldrick,

I enclose the report of the risk review group which was established as an independent review group to examine and report on the causes of the underdosing of some patients with seasonal influenza vaccine by certain pharmacists during the 2011/2012 influenza season.

The review was carried out in compliance with the assigned terms of reference and in an open and 'blame free' manner. While the group identified a number of factors that caused and contributed to the event, the focus of the report is on the learning and changes that are required as a result of this incident. In addition the group has advised on some associated issues that were identified during the review. In compiling the report, the group has attempted to be fair and equitable.

I would like on behalf of the review group, to extend its gratitude to those bodies and individuals who made submissions to it and who assisted and co-operated in various ways and for the open manner in which all of the parties approached the review.

I would also thank the individual members of the review group who gave their time generously in attending meetings, reviewing submissions and other documents made available to the group.

I would also like on behalf of the review group to thank Dr Cora Nestor for acting as secretary to the review group.

Yours sincerely,



Prof. Peter Weedle, Chairman of Risk Review Group

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Executive summary

1 Introduction and background to the review:

For the 2011/2012 seasonal influenza season, pharmacists in Ireland were enabled to participate in the annual vaccination campaign for the first time. In November 2011, a superintendent pharmacist noticed a difference between the instructions on measuring the dose of vaccine outlined in an online training video made available by the training company, and the instructions set out in the summary of product characteristics (SmPC) for the Inactivated Influenza Vaccine (Split virion) BP. It was confirmed that this inconsistency in the information provided led to some patients receiving an underdose of the vaccine from their pharmacist which resulted in those patients requiring revaccination with the full dose of the vaccine.

The Pharmaceutical Society of Ireland (PSI) established a Risk Review Group to review and report on the underdosing of patients with the seasonal influenza vaccine, in some pharmacies. It was intended that the output of this review would focus on the learning and changes that may be required and to advise on any contributory factors and associated issues identified during the course of the review. The review was to be independent, fair and equitable.

Methodology:

In order to ensure compliance with its terms of reference in undertaking the review, the group used the evidence based review model of 'The London Protocol - Systems Analysis of Clinical Incidents'¹. This protocol is an internationally recognised method for reviewing adverse events in healthcare. The method outlines a systematic and structured study of a system with a view to establishing the root causes of and the contributory factors to adverse events. The method also aims to identify actions necessary to prevent or mitigate further adverse events and to allow reflection and learning from clinical incidents.

The review group identified and invited submissions from 19 stakeholders. In response to their invitations the group received and reviewed 16 submissions. The group also reviewed a number of relevant background documents and literature available to them as outlined in appendix 1. The group held a total of 7 meetings and met with 4 stakeholders. In addition, a sample of patients who received the incorrect dose of the vaccine were contacted and interviewed by telephone by a member of the Review Group, who was not a pharmacist and who has considerable experience in carrying out such telephone interviews. The aim of this process was to gain insight into patients'

¹Systems analysis of clinical incidents -The London Protocol. Sally Taylor-Adams and Charles Vincent 2006

experience and to gain learning in relation to the occurrence and response to the error from the point of view of the patient.

Key findings of the review:

Overall conclusion of the review group:

The review group supports initiatives to maximise seasonal influenza vaccination uptake and concludes that measures to increase uptake should be strongly encouraged and facilitated, including the increased accessibility provided through pharmacist participation in vaccination campaigns. However, the review group advises that any such expansion in the scope of practice of a healthcare professional must be accompanied by robust and appropriate training to appropriately upskill the healthcare professional in the professional activity they are about to undertake. This training must be appropriately approved and accredited, and must involve trainers with up-to-date knowledge and experience. Robust governance and coordinated management of the overall project must be in place to ensure smooth implementation of such services and to ensure that the continued care and safety of patients is assured.

Following review of the submissions, it was clear to the review group that the primary cause of some patients receiving an underdose of the vaccine was that, during training, incorrect instruction on measuring the dose of the vaccine for administration was given to some pharmacists.

The review group focussed on discovering the factors that contributed to the error occurring within the training course and also not being detected through the regulatory and governance systems prior to administration of the vaccine to patients.

Identification of causes of the error:

Review of the training course provided to pharmacists: In order to participate in the vaccination programme, it was a requirement that pharmacists undergo certified training in seasonal influenza vaccination. This training was provided by Hibernian Healthcare Ltd., a private company experienced in the provision of vaccination services. The training provided was based on a series of lectures, a video and a demonstration of injection technique using an anatomical model arm followed by a practice session with tutors.

Following review of the submissions and meetings with stakeholders, it was clear to the review group that the prime cause of patients receiving an underdose of the vaccine was that incorrect instructions in measuring the dose of the vaccine were given to some pharmacists during the training. The review group noted that the source of this incorrect instruction was the misinterpretation of a black line marking on the vaccine syringe and the incorporation of this incorrect information into the training materials used to train some trainers and which was then conveyed to some pharmacists.

It was reported to the review group that of the 1462 pharmacists trained, only 203 pharmacists were vaccinating using the wrong dosing instructions, therefore there was great variability in whether the incorrect or correct instruction was given to a pharmacist during the training course. The review group considers that a number of factors contributed to the error occurring within the training course including: within the training body there was inadequate version control on documents within the training body, leading to inadequate quality control and quality assurance of changes to training materials. The training body also had insufficient input of appropriate clinical expertise. Therefore the clinical and non-clinical governance within the training body required improvement both during the development of the training course content and in the training of trainers. The training body also undertook its own internal review following the discovery of the error which had resulted in their own learning and introduction of a number of improvements within their own internal processes. The review group makes a number of recommendations to ensure that the deficiencies identified during the review on the cause of the error and the subsequent learnings are addressed and incorporated in the future education and training of healthcare professionals, including pharmacists.

Contributory factors:

In addition to the primary cause of the error, the review group considers that there were a number of factors that contributed to the error occurring and not being detected prior to patients being vaccinated incorrectly. These factors were each identified as contributory factors and the review group makes a number of recommendations to implement these learnings for future developments.

Review of the vaccine products and product information: Three influenza vaccines were available on the Irish market for the 2011/2012 influenza season: Inactivated Influenza Vaccine (split virion) BP suspension for injection from Sanofi Pasteur (MSD), Influvac sub-unit 2011/2012 suspension for injection from Abbott Healthcare Products Ltd. and Fluarix Suspension for injection from

GlaxoSmithKline (Ireland) Ltd. As part of the national influenza vaccination campaign the HSE supplied Inactivated Influenza Vaccine (split virion) BP for eligible public patients and expired samples of this vaccine were used during training. The two remaining products were used for vaccination of private patients and were therefore in lower use in Ireland in the 2011/2012 influenza season.

As part of their review the group examined these three vaccine products and associated product information as set out in the SmPC, package leaflet and labelling. In addition the group received submissions from each of the vaccine manufacturers and from the IMB, the licensing authority for these products. The review group made a number of findings in relation to the vaccine products. Two of the vaccines were presented as a pre-filled syringe of 0.5ml with a black line marking (but no numbers) on the syringe to indicate a 0.25ml dose of vaccine. The review group concludes that the purpose of the black line markings included on the vaccine syringe was unclear and the group identified these markings as a contributory factor to the error occurring. In addition, during the review it was noted that a recent recommendation from the National Immunisation Advisory Committee (NIAC) was that the paediatric dose for the seasonal influenza vaccine is 0.5ml (the same as the adult dose) in Ireland. Therefore the group concludes that the black line markings on the syringe should be removed or its purpose clearly identified. The review group also concludes that the location of instructions within the SmPC on measuring the dose should be moved and should be included in section 4.2 titled 'Posology and method of administration' and not in the current location in section 6.6 titled 'Special precautions for disposal and other handling'. The review group also considered that the new NIAC recommendation on the dose for children should be incorporated into the SmPCs for the vaccine products in Ireland.

Review of the professional and clinical judgement of pharmacists: The review group notes from the submissions, and discussions with stakeholders, that the error that occurred was wholly unexpected. There was a confident expectation expressed by many stakeholders that pharmacists, because of their training and experience, would be particularly alert to the importance of giving the correct dose of a medicine and on the need to comply with the requirements of the relevant SmPCs. Because of this confidence, the major focus of the training was on acquiring the new skills required namely the IM injection technique and the steps to be taken in the event that an anaphylactic reaction resulted from vaccination. For some pharmacists, since this was the first time they were required to administer a medicinal product by injection in the course of their professional practice their concentration also appeared to be on that part of the procedure, and the usual critical

examination by the pharmacist of the medicinal product, including the dosage of the product, did not occur in some cases.

The review group considers that it is extremely important that pharmacists apply their core knowledge and skills to ensure that they are thoroughly familiar with any product they are about to administer, and that the pharmacist perform an independent double check of a product against its SmPC and other relevant product literature. The group considers that this independent professional role of the pharmacists should be highlighted and supported during the delivery of training and be part of the requirements for implementation of a new service.

Review of the training accreditation: Following the publication of the regulations on the 14th October 2011, the PSI became responsible for the recognition of a training body and approval of a training course to train pharmacists in the administration of the seasonal influenza vaccine. In anticipation of pharmacists' participation in the seasonal influenza vaccination programme and the PSI's role in the regulation of this service, the PSI accepted in August 2011 a proposal by Hibernian Healthcare and the IPU that the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin (TCD) would accredit the pharmacist vaccination training course. The PSI developed and published the 'PSI Interim Accreditation Standards for Seasonal Influenza Vaccination Training Programmes for Pharmacists'. The School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin (TCD), formed an accreditation group for the purpose of accrediting the vaccination training course for pharmacists. The TCD accreditation group undertook a four week accreditation process using the PSI Draft accreditation standards. Following this process the School of Pharmacy and Pharmaceutical Sciences accredited the Hibernian Healthcare training course and on that basis, the PSI formally recognised Hibernian Healthcare as the training body and approved the course of training provided by Hibernian Healthcare Ltd.

The review group notes that the delivery of the training course to pharmacists had started before the accreditation process was completed and accreditation granted. Therefore these two processes were in parallel which in the opinion of the group compromised the process and the purpose of the accreditation. The review group also notes that due to these parallel timelines, changes made to training materials were not seen during the accreditation process e.g. the training video was not viewed in its final format by the accreditation group. In addition the group notes that while the accreditation group had the academic expertise and rigour required to carry out the accreditation, the accreditation group had insufficient input from experienced vaccinating practitioners which

would have been necessary if they were to identify the incorrect instruction provided during training. The review group concludes that the accreditation process undertaken to accredit the training course ought to have been sufficient to detect any error in the training material within the training course and that this did not occur. It is therefore identified as a contributory factor to the error that occurred remaining undetected. The review group makes a number of recommendations to ensure that this process is improved.

Project Management and timeframe of the service development and implementation: From all the submissions received and review of the material, the review group appreciates that the development and implementation of the major policy development of including pharmacists, for the first time, in the vaccination service in time for the commencement of the national seasonal flu vaccination campaign in Oct 2011, was a complex and time-consuming process. This process involved many agencies and stakeholders responsible for different aspects of development and implementation. The timing of the development and introduction of this new service coincided with the start of the influenza season and the national vaccination campaign. This involved a significant complex workload to be completed within a short period of time. The review group notes that all stakeholders were committed to timely implementation of the service being achieved and each agency and body worked to ensure implementation of their respective roles within these timelines. However the group concludes that no one person or agency had overall control or a coordinating function for development and implementation; no person or agency was appointed to be responsible for the management of all aspects of the project. Many stakeholders referred in their submissions to the added pressures that timelines caused, especially in the availability of appropriate expertise for the training and accreditation process. The review group considers that the lack of overall project management and governance and the time pressure experienced by those implementing the service was a contributory factor to the error occurring and to the delayed detection of the error. The review group considers that for future national development projects, the Department of Health should appoint one lead agency with responsibility for project management including risk assessment and that implementation of an overall project management would also assess and mitigate any risk in timeframe for implementation.

Associated issues identified:

The review group noticed a number of associated matters which were not directly related to the error that occurred but were nonetheless issues that the review group considers ought to be addressed or warrant further investigation. These should be considered as incidental findings.

Response to the error: The group examined the process around the response to the error. The steps taken by individuals and organisations are described in the report. From the patient contact, most patients reported that the source of their initial knowledge of the issue was contact from their pharmacist, and that this contact happened within a very short time of the error being discovered. All patients contacted were satisfied with how the error was dealt with and the group believed that the direct pharmacist contact with the patients following the error was a very positive aspect of the process. The review group considers the response to the error once identified was very open by all the stakeholders involved and the actions taken by agencies in responding to the error was rapid and the relevant agencies worked together to ensure that the correct advice on rectifying the error was ascertained and given. The group considers the response to this error was in line with the principles outlined in the Report of the Commission for Patient Safety and Quality Assurance² which recommends open communication of errors with patients following the event and a speedy and effective style of communication of errors.

However, the review group notes that the vaccination service was underway for six weeks before the error was detected, and this is of concern. In addition this error was not reported and recorded in any national system. The manufacturers of the vaccine products indicated in their submissions that they had reports on their vigilance systems of previous underdosing with the seasonal influenza vaccine albeit in low numbers compared to overall use of the products. The review group considers that it is important that a 'no blame' reporting system is in place at a national level to ensure that a system is available to detect and report errors and ensure early detection and learning is in place. The group recommends implementation of such a system within the primary care service. This is supported by the recommendations of the Commission for Patient Safety and Quality Assurance that the dissemination of learning throughout the system is crucial to minimise error and protect future patients.

Reporting and notification of vaccinations: Under the regulations, a number of requirements on record keeping for vaccinations were introduced for pharmacists. Under these, pharmacists were obliged to keep individual records for each patient vaccinated in the pharmacy and also to notify the HSE of all patients, public and private, within 7 days of the vaccination. For this purpose the PCRS set up an electronic notification system to facilitate these notifications and to pay pharmacists for their

² Building a Culture of Patient Safety - Report of the Commission on Patient Safety and Quality Assurance. 2008 http://www.dohc.ie/publications/pdf/en_patientsafety.pdf May 2012.

services to eligible patients. Those patients who had received an underdose of vaccine required a second vaccination with the full 0.5ml dose of the vaccine and pharmacists were required to notify these revaccinations to PCRS. Initially the PCRS had incorporated a validation check on their IT notification system to allow only one record/claim to be made for one patient. This caused an initial lag time until November 29th before a revaccination record could be accepted by the PCRS.

The data provided by Hibernian Healthcare indicated that 203 pharmacists had incorrectly vaccinated 1231 patients. As of the 6th December 2011, Hibernian Healthcare indicated that pharmacists reported that 80% of these patients had been revaccinated or had scheduled an appointment for revaccination. The PCRS reported in February 2012, that a total of 9904 vaccination records had been received from 484 pharmacies and that they had received notifications that 454 patients had been revaccinated. This number of revaccinations was significantly lower than the figures suggested by the training body. The review group is concerned with the discrepancy in figures between the two reporting systems. A number of submissions received by the review group described difficulties encountered with the IT notification system made available by the PCRS. Some pharmacists reported they were unable to submit notifications of revaccinations to PCRS electronically and had therefore sent these to PCRS by fax. The PCRS indicated that they had received some faxed notifications but that they were not recognised for the purpose of notification. The PCRS did not provide the number of revaccination notifications received by fax. In April 2012, PCRS undertook some further validation work with the IT notification system and issued a further communication to pharmacists to request notification of revaccination following updating of the notification system.

The PCRS reported that as of 25th April 2012, 583 records of revaccinations notifications had been electronically received giving a revaccination rate of 47% (583/1231). This is significantly less than the 80% as self-reported by pharmacists via the training body. In addition PCRS indicated that a number of patients had been revaccinated by their GP although the number of patients involved could not be confirmed. GPs are not required to report notifications for any private patients nor are they required to report real time notifications for patient eligible under the HSE vaccination service. Therefore having regard to the information received from the training body and from the PCRS, the review group is not in a position to establish the actual number of patients revaccinated following the error. This is of concern to the review group and the group considers these deficiencies in the system should be rectified as a matter of priority.

In addition, as of 25th April the HPSC, the agency responsible for monitoring vaccine uptake had not received any data from PCRS on the number of pharmacist vaccinations in the 2011/2012 season so the impact of the new service on the overall vaccine uptake could not be assessed. The review group considers that data collection to evaluate and monitor the impact of the introduction of any new service should be in place.

The review group considers that the collection, analysis and reporting of information on vaccine uptake are central to effective disease surveillance and control. The review group recommends the implementation of a national immunisation register which would encompass real-time reporting of vaccinations for all healthcare professionals. The primary function of such a register should be public health surveillance of all vaccinations with payment as a secondary arm of the system

In addition the group recommends that there should be collaborative development of IT systems with all stakeholders involved, including the end user of the system implemented, to ensure the system is fit for purpose and will fulfil national requirements.

Recommendations of the review group

Recommendation 1: In relation to the education and training of healthcare professionals for any future development of a similar service, the review group recommends that:

- a) The recognised training body must have access to appropriate internal and external expertise in the subject area, e.g. in this case vaccinations.
- b) It is essential that persons with appropriate knowledge and practice experience participate in all stages of the development, implementation and assessment of such training.
- c) Appropriate governance, clinical and non-clinical, must be in place within the training body to ensure that trainers are formally trained and assessed as competent and that the training is consistent and in line with national and international guidance.

In relation to training for vaccinations generally the review group recommends that:

- a) All healthcare professionals vaccinating should be formally trained to national standards.

In relation to training for pharmacists for any new national service, the review group recommends that:

- a) All guidance and requirements for the service should be in place before any national training is delivered.
- b) Training should be provided for pharmacists and assessed on integrating the new service into pharmacy practice.
- c) The professional and regulatory aspects of the new service should be included in training.
- d) The development and delivery of training for pharmacists should include the participation of pharmacist practitioners to address the above points.
- e) Opportunities for critical reflection should be accommodated into the programme design to allow the pharmacist to consider the information provided and if necessary to challenge and question the instruction or information provided.

Recommendations 2: In relation to the black line markings on the vaccine syringe, the review group recommends that:

- a) The black line mark on the vaccine syringe should be removed as it is now irrelevant following the updated NIAC recommendation that all patients, adult and children, receive a 0.5ml dose.

or

- b) If volume marks are considered necessary to indicate alternative doses, the volumes to which each mark refers to should be indicated and if markings are used on a product to

indicate a half dose then it is important to also indicate on the syringe the full dose of the product.

- c) There should be consistency in dosage markings on all vaccines provided in pre-filled syringes.

Recommendation 3: In relation to product information for the vaccines, the review group recommends that:

- a) The instructions on measuring the correct dose for administration of such products should be included in section 4.2 of the SmPC titled 'Posology and method of administration'. The review group recommends that this recommendation should be brought to the attention of the European Medicines Agency (EMA) for consideration at an early date.
- b) The current NIAC recommendation that the paediatric dose should be 0.5ml (i.e. the same as the adult dose) should be incorporated into the product information for the products placed on the market in this country.

Recommendation 4: For new services being introduced into pharmacy the review group recommends that:

- a) Pharmacists must apply their core knowledge and skills to ensure they are thoroughly familiar with any product they are about to supply and/or administer and must perform an independent double check of the product against the relevant SmPC and other product literature.
- b) Any complexity introduced to the system is kept to the minimum necessary and that where possible, processes should be simplified and streamlined to maintain clarity, accessibility and simplicity.

For the pharmacist vaccination service:

- c) The PSI guidance and IPU SOP templates for the service should be reviewed to ensure that these principles are met.

Recommendation 5: In relation to accreditation and approval of the vaccination training course for pharmacists as required under the regulations, the review group recommends that:

- a) The course of training must be approved by the PSI and the body which is to deliver training and issue the prescribed certificate, must be recognised by the PSI before there is any roll out of training.

- b) A formal process for the recognition of the training body and the approval of the course of training should be in place.
- c) The PSI should designate an appropriate accreditation body which would carry out the necessary accreditation of any training course which it is required to approve.
- d) The accreditation process must be completed before any application for recognition or approval is made to the PSI Council. The accreditation body must include persons with appropriate expertise including both academic expertise and practitioners experienced in the relevant area of practice.

Furthermore:

- e) National standards for the training of all healthcare professionals in vaccination should be developed.

Recommendation 6:

For this project and any future new national health service development projects, the review group recommends that:

- a) The Department of Health designates a lead agency with responsibility for the overall project management of the project, including governance and on-going risk assessment.
- b) Future developments should, where appropriate, also involve a pilot study during development and audit to assess impact on the overall service.
- c) An appropriate lead time should be built into any future initiatives to ensure that the project can progress through the relevant stages in an appropriate sequence so as to minimise risk.

Recommendation 7: In relation to the response to errors within healthcare, the review group recommends that:

- a) Any response to an error should be in line with the principles outlined in the Report of Commission on Patient Safety and Quality Assurance which recommends open communication of errors with patients following the event and a speedy and effective style of communication of errors.
- b) The review group supports the recommendations of the Patient Safety Commission that the dissemination of learning throughout the system is crucial to minimise errors and protect future patients and that a voluntary system of reporting of 'close calls' or 'near-misses' will contribute to further learning and dissemination of best practice. In support of this, the review group recommends that a reporting system for errors within primary

care services, including pharmacy, should be implemented to ensure learning can be visible throughout the system.

- c) A clear incident-response system should be in place from the beginning of a service and should be communicated to all stakeholders
- d) It is essential that the lessons learned in one healthcare establishment are communicated regionally, nationally and internationally.

Recommendation 8: For the notification of vaccinations, the review group recommends that:

- a) An urgent review of the PCRS data be carried out to validate the number of patients who were revaccinated.
- b) In the interest of public health and surveillance, a national immunisation register should be established that will require and receive real-time reporting of vaccinations by all healthcare professionals and that the primary function of this register would be public health surveillance and that the making of payment for services would be a secondary arm of that system.
- c) There should be collaborative development of IT systems with all stakeholders involved, including the end user, to ensure that the system is fit for purpose and that it will fulfil national requirements.
- d) The review group considers that appropriate data collection to evaluate and monitor the impact of the introduction of any new service should be in place.

Report of the review group

1 Introduction and background to the review

For the 2011/2012 seasonal influenza season, pharmacists in Ireland were enabled to participate in the annual national vaccination campaign for the first time. To participate in the vaccination programme it was a requirement that pharmacists undergo certified training in order that they would be appropriately up skilled in the provision of seasonal influenza vaccination.

On the 22nd of November 2011, a superintendent pharmacist noticed a difference between the instructions on measuring the dose of vaccine outlined in an online training video made available by the training company and the instructions provided in the associated product information set out in the summary of product characteristics (SmPC) for the Inactivated Influenza Vaccine (Split virion) BP.

The pharmacist reported his concerns to the Irish Pharmacy Union (IPU) who in turn referred the matter to the training provider, Hibernian Healthcare Ltd to review the instructions provided during training. Hibernian Healthcare confirmed that there was an error in the instructions on measuring the dose of the vaccine provided during training. This error led to the administration of 0.25mls of the vaccine instead of the correct 0.5mls to some patients by their pharmacist.

The IPU and Hibernian Healthcare informed the Pharmaceutical Society of Ireland (PSI), the pharmacy regulatory body, of the error before the opening of business on 23rd November 2011. The training provider commenced contacting each pharmacist trained, to ascertain if the pharmacist was using the correct or incorrect dosing instructions, and to establish how many patients each pharmacist had vaccinated. Through this direct contact, the training provider ascertained that of the 1462 pharmacists trained only 746 were actually vaccinating and of these 203 pharmacists were vaccinating incorrectly. They also established that these 203 pharmacists had vaccinated 1,231 adult patients using the underdose of 0.25mls of the vaccine. Patients who had received this underdose required revaccination with 0.5mls of the vaccine.

On the 1st Dec 2011, following a commitment given to the Minister for Health in an interim report to the Department of Health and to the HSE¹³, the PSI established a Risk Review Group to review and report on the issues around the reported error in patient underdosing with the seasonal influenza vaccine in some pharmacies. The report of this review was to focus on learning and on the changes

³ Interim report from the PSI to the Department of Health and the HSE regarding the underdosing of some patients with seasonal influenza vaccine by pharmacists. Dated 25th November 2011. www.thePSI.ie

that may be required. It was also required to provide advice on any contributory factors and associated issues identified during the course of the review. The review was to be independent, fair, and equitable. The review was to identify factors and/or causes that contributed to the event. The full terms of reference and composition of the review group are given in the following section (Section 2).

2 Composition and Terms of Reference of the Risk Review Group

The following was the composition and agreed terms of reference of the review group:

1. The Purpose of the Review

The PSI risk review group was established to examine and report on the causes of the recent underdosing of some patients with seasonal influenza vaccine by certain pharmacists during the 2011/2012 season. It is intended that the outcome of this review will focus on the learning and changes that may be required, and to advise on any associated issues that may be identified. The review must be fair, equitable and identify factors and/or causes that contributed to the event. It is intended that the review will be independent and will be carried out in an open and 'blame free' manner and it is not intended to apportion blame to a specific person or organisation.

2. The Composition of the Review Group

The following individuals were appointed to the risk review group:

- Professor Peter Weedle (Chair), adjunct Professor of Clinical Pharmacy at the School of Pharmacy in University College Cork, community pharmacist and former member of the PSI Council.
- Mr Raymond Anderson, community pharmacist and pharmacist prescriber, former President of the Pharmaceutical Society of Northern Ireland and current President of the Commonwealth Pharmacists Association.
- Dr Kevin Connolly, Consultant Paediatrician, member of the National Immunisation Advisory Committee (NIAC) and chair of NIAC sub-committee on childhood vaccines, Irish representative on the European Medicines Agency Paediatric Committee and member of Advisory Committee on Human Medicines (IMB).
- Dr Brenda Corcoran, Consultant in Public Health Medicine, HSE National Immunisation Office (NIO) and member of the National Immunisation Advisory Committee (NIAC).
- Ms Mary Culliton former Director of Advocacy with the Quality and Patient Safety Directorate of the HSE and former Head of Consumer Affairs within the HSE.
- Ms Marie McConn, community pharmacist, former member of the PSI Council, the Irish Medicines Board and former President of the Irish Pharmacy Union.
- Mr Stephen McMahon, Chief Executive Officer at Irish Patients Association, a member of Registration and Qualification Recognition Committee of the PSI Council and Chair of the Audit, Risk and Governance Committee of the Health and Social Care Professionals Council (CORU).

- Mr Tom McGuinn, former Chief Pharmacist of the Department of Health, former member of the Advisory Committee on Human Medicines (IMB) and of the GMS Payments Board and currently Pharmacist Policy Advisor to the PSI.

Any additional expertise required by the Group would be provided and funded by the PSI.

3. Terms of Reference of the Review Group

The terms of reference of the risk review group are as follows:

- To examine all the relevant information with a view to establishing the full facts and sequence of events.
- To review the relevant policy and guidance documents.
- To identify the care and service delivery issues, identifying what was well managed and what could have been done better.
- To review the accreditation and training provided, and any other associated services provided to pharmacists by the training organisation and the associated regulation.
- To examine the relevant vaccine products and associated product documentation.
- To review the information with a view to identifying the contributory factors and causes in respect of what went wrong and to identify any issues of concern.
- To identify the actions necessary to prevent a reoccurrence and to advise on how best to implement them.
- To report to the PSI Registrar and Council not later than March 31st 2012. (During the review process, following agreement with the Registrar, this timeline was extended to ensure that adequate time was allocated to examine all relevant matters including meeting with relevant stakeholders and making patient contact).

4. Completion of Review

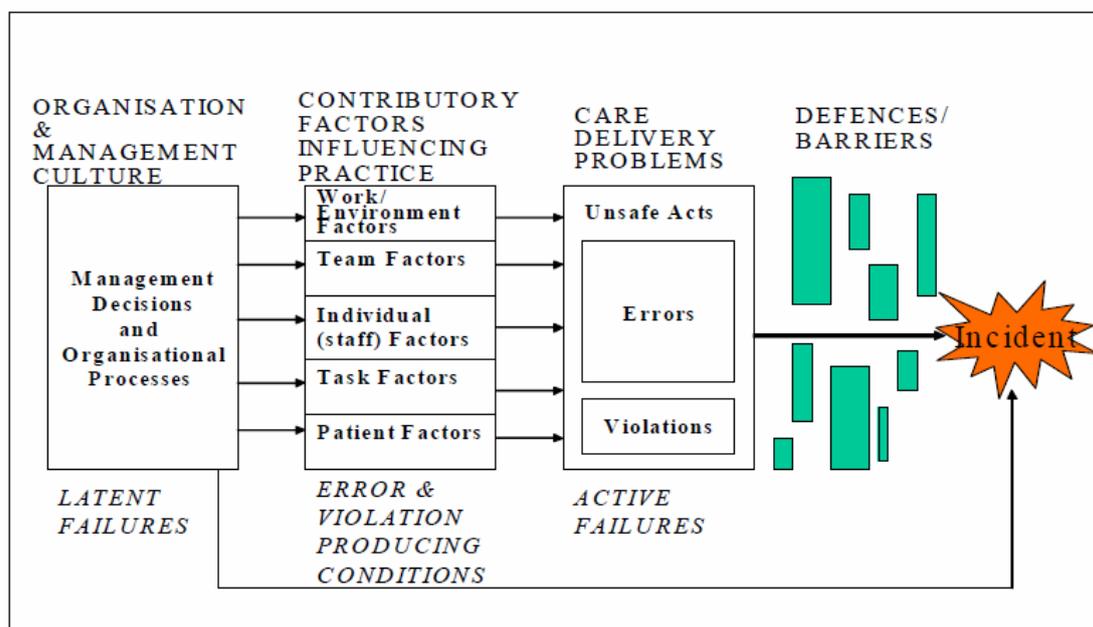
- The purpose and functions of this group will cease upon completion of the review and report outlined above. The report will be available to the Department of Health and all other relevant stakeholders. An interim report will be provided if deemed necessary.

3 Methodology

The Review Group determined that the review itself would use an evidence base to ensure compliance with its terms of reference. ‘Systems analysis of Clinical Incidents-The London protocol’⁴ an internationally recognised protocol for reviewing adverse events in healthcare was selected as the most appropriate model. This protocol outlines a process of investigation and analysis for use by clinicians and others wishing to reflect and learn from clinical incidents.

The method uses ‘systems analysis’ which is a term used to reflect the fact that it is usually a chain of events and a variety of contributory factors that lead to the occurrence of an error in a healthcare setting. The method outlines a systematic and structured study of a system with a view to establishing the **root causes** of and the **contributory factors** to errors or adverse events. The method also aims to identify actions necessary to prevent or mitigate further adverse events and to allow reflection and learning from clinical incidents.

Figure 1: Adapted Organisational Accident Causation Model

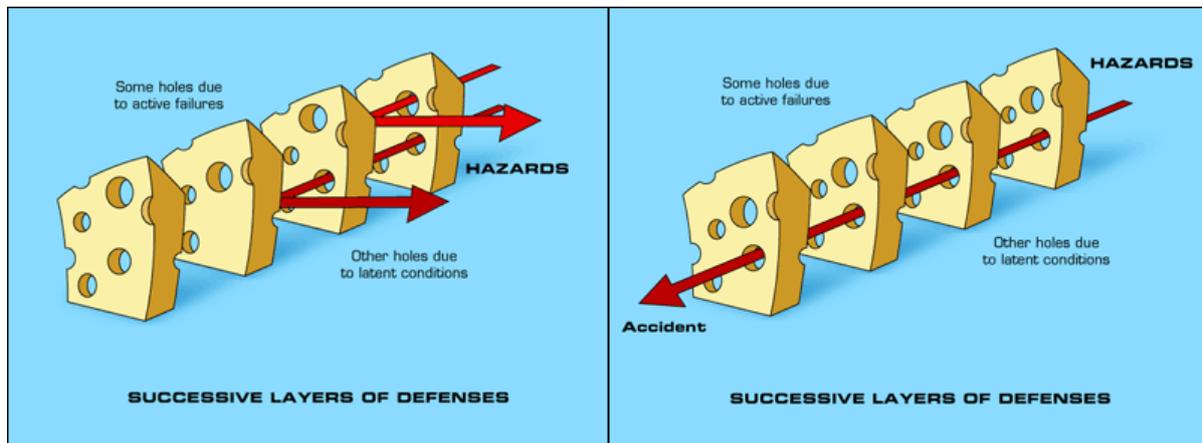


The method is based on James Reason’s Model of organisations accidents (figure 1). Reason describes error as ‘*circumstances in which planned actions fail to achieve the desired outcome*’ and outlined a model to describe how errors can occur, commonly known as the Swiss cheese model

⁴ Systems analysis of clinical incidents-The London Protocol. Sally Taylor-Adams and Charles Vincent 2006

(Figure 2). Within this model each layer is a **defense** or barrier designed to protect against potential error impacting the outcome. Failure of these defences allows an error to go through the system designed to be an accident or clinical incident.

Figure 2 James Reason's model for describing the occurrence of an error
Commonly known as the 'Swiss cheese model for errors'



In undertaking the review, the group sought and examined all information that would inform the following requirements:

- To establish the timeline and sequence of events.
- To review the relevant policy and guidance documents.
- To review the accreditation and training provided, and any other associated services provided to pharmacists by the training organisation and the associated regulation.
- To examine the relevant vaccine products and associated product documentation.

The review group used the following guiding principles, from their terms of reference, in reviewing the above areas and identifying their key findings and recommendations:

- To identify the care and service delivery issues, identifying what was well managed and what could have been done better.
- To review the information with a view to identifying the key causes and contributory factors, in respect of what went wrong and to identify issues of concern.
- To identify the actions necessary to prevent a reoccurrence and to advise on how best to implement them.

Background documentation

The review group reviewed a number of relevant background documents and literature available to them as given in appendix 1.

Written Submissions

Stakeholder analysis identified the following list of relevant stakeholders; Hibernian Healthcare, Irish Pharmacy Union (IPU), Trinity College Dublin (TCD) School of Pharmacy and Pharmaceutical Sciences accreditation group, Health Information and Quality Authority (HIQA), Pharmaceutical Society of Ireland (PSI), Health Service Executive (HSE) Primary Care Reimbursement Service (PCRS), HSE Population Health Directorate, Department of Health (DoH), National Immunisation Advisory Committee (NIAC), Medical Council, An Bord Altranais (ABA), Pre-Hospital Emergency Care Council (PHECC), Boots Pharmacies, Unicare pharmacies, the superintendent pharmacist that reported the error, Irish Medicines Board (IMB) and the Manufacturers of the three available seasonal influenza vaccine products, GlaxoSmithKline, Sanofi Pasteur MSD and Abbott Healthcare Ltd. The identified stakeholders were invited to provide a written submission to the review group. A copy of the letter of invitation is given in appendix 2.

Responses and submissions were received from the following stakeholders; Hibernian Healthcare, IPU, the TCD accreditation group, PSI, HSE PCRS, DoH, NIAC, Medical Council, An Bord Altranais, Boots Pharmacies, Unicare pharmacies, the superintendent pharmacist that reported the error, IMB and the manufacturers of the vaccine products.

Meetings with stakeholders

Following review of the submissions the Risk Review Group invited some of the stakeholders to meet with the group to clarify issues or to provide further information. The group met separately with Hibernian Healthcare, the TCD Accreditation Group, IPU and PSI.

Patient Contact

A sample of patients who received the incorrect dose of the vaccine were interviewed by telephone, by a member of the Review Group who is not a pharmacist and has experience in carrying out such telephone interviews. The aim of this process was to gain insight into patients' experience and gain learning in relation to the occurrence of the error and the response from the point of view of the patient.

4 Influenza and vaccination

Influenza, more commonly known as the 'flu', is a highly infectious acute respiratory illness caused by an influenza virus. Influenza can occur throughout the year but activity usually peaks in winter. This is why it is also known as seasonal influenza^{5,6}. Influenza affects people of all ages and is often self-limiting, with most people recovering in 2-7 days. However, influenza can be severe and can cause serious illness and death, especially in the very young, people aged 65 years and over and people with some chronic medical conditions including chronic heart conditions, chronic respiratory disease, diabetes mellitus and immunosuppression due to disease or treatment. In those with chronic underlying disease, especially the elderly, complications are common and hospitalisation rates high. Pregnant women have also been found to be at increased risk of complications.

Influenza is best prevented by annual vaccination, especially in people who are at high risk of complications. The influenza vaccine is considered a safe, effective way to help prevent infection, avoid hospitalisation and reduce influenza related deaths and illnesses. The best time to be vaccinated is from mid-September to November, i.e. before the influenza season starts; vaccination may be given until April, when virus circulation has almost ceased.

The World Health Organisation (WHO)⁷ and the Council of the European Union⁸ have both issued formal recommendations on seasonal influenza vaccine which include reaching a target of 75% uptake in at-risk persons, including older age groups and people with chronic medical conditions. The European recommendation also includes prioritising the provision of education, training and information exchange on seasonal influenza and vaccination to health care workers, at risk groups and their families, and the removal of obstacles to influenza vaccination uptake.

⁵HSE National Immunisation Office (NIO) <http://www.immunisation.ie/en/AdultImmunisation/FluVaccination/> May 2012

⁶HSE Health Protection Surveillance Centre (HPSC) <http://www.ndsc.ie/hpsc/A-Z/Respiratory/Influenza/SeasonalInfluenza/> May 2012

⁷<http://www.who.int/wer/2005/wer8033.pdf> May 2012

⁸Nicoll A. A new decade, a new seasonal influenza: the Council of the European Union Recommendation on seasonal influenza vaccination. Euro Surveill. 2010;15(1):pii=19458. Available online: <http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19458> May 2012

4.1 Immunisation within Ireland

The development and implementation of an immunisation system is usually a complex process with many stakeholders involved. Figure 1 outlines the multidisciplinary components within an immunisations system.



Figure 1 Multidisciplinary components of an immunisation system⁹

Immunisation policy within Ireland is developed and implemented by a number of different agencies. The role of each agency is outlined below:

The **Department of Health (DoH)** is responsible for making national immunisation policy including any changes to the current immunisation programme

The **National Immunisation Advisory Committee (NIAC)** is an expert committee formed by the Royal College of Physicians of Ireland, to advise the Department of Health on immunisation related

⁹ National Immunisation Office (NIO) www.immunisation.ie May 2012

matters. NIAC prepares the *Immunisation Guidelines for Ireland*¹⁰. These guidelines contain information and recommendations concerning immunisation including seasonal influenza vaccination. The guidelines are updated regularly and in September 2011, NIAC updated their recommendations on the seasonal influenza to recommend vaccination for those aged 6 months and older who are at risk of influenza-related complications and all persons aged 50 years and older.

The **Irish Medicines Board (IMB)** is responsible for the regulation of human and veterinary medical products including the granting of authorisations for vaccines to be marketed in Ireland and to approve the associated product information. The IMB is also responsible for monitoring and evaluation of adverse events following immunisation.

The **Health Service Executive (HSE)** is responsible for the implementation of national immunisation policy and each year a **national seasonal influenza vaccination programme** is run by the HSE. Through this programme from September onwards the seasonal influenza vaccine is made available free of charge for all those aged 65 years and older, those with long term medical conditions who are at risk of influenza-related complications, pregnant women, health care workers and carers. The **HSE National Immunisation Office (NIO)** is responsible for the management of the vaccination programme, including the provision of up-to-date information for the public and health care professionals. This includes communications for health care professionals, producing and supplying factsheets and posters on influenza vaccination for at risk groups and coordinating the procurement and distribution of influenza vaccines. The NIO also publishes *A Practical Guide to Immunisation*¹¹ and maintains the national immunisation website www.immunisation.ie which contains up-to-date information for health care professionals and the general public.

The **Primary Care Reimbursement Service (PCRS)** is also part of the HSE, and is responsible for making payments to healthcare professionals for the free or reduced costs services they provide to the public. Seasonal influenza vaccinations given to those with medical or doctor only cards are recorded by the PCRS who are responsible for payment of the general practitioners (GPs) and pharmacists for their services.

¹⁰ Immunisation Guidelines for Ireland. National Immunisation Advisory Committee, Royal college of Physicians of Ireland 2011 http://www.rcpi.ie/collegestructure/Documents/NIAC_Immunisation%20Guidelines.pdf May 2012

¹¹ A Practical Guide to Immunisation, HSE National Immunisation Office 2008, www.immunisation.ie

The **Health Protection Surveillance Centre (HPSC)** is part of the Health Service Executive (HSE) and is the agency responsible for the surveillance of infectious diseases including seasonal influenza. The HPSC also monitors immunisation uptake data from each HSE area and reports on uptake rates.

Each year an influenza vaccine, as recommended by the World Health Organisation (WHO), is prepared using three virus strains similar to those most likely to circulate in the forthcoming season. These are based on those circulating in the southern hemisphere. For the 2011/2012 influenza season there was no strain change from the vaccine recommended for the northern hemisphere by the World Health Organisation for 2010/2011.

New recommendations for the 2011/2012 seasonal influenza vaccination programme were published by NIAC in September 2011. One of the new recommendations advises a dose of 0.5ml (rather than 0.25ml, as was previously advised) for children aged 6 months to 3 years for whom the vaccine was recommended, based on evidence that the 0.5ml provides a better immune response.

4.2 Participation of pharmacists in the national influenza vaccination programme

On July 18th 2011, the **Minister for Health** indicated his intention to allow community pharmacists to participate in the national seasonal influenza vaccination programme managed by the HSE. This announcement indicated a major change in healthcare policy in Ireland, which is reflected internationally where pharmacist vaccination services have been implemented in other jurisdictions, such as the USA, the UK, Canada, Portugal and most recently New Zealand. This required the DoH to draft and publish legislation to provide pharmacists with the authority to supply and administer the seasonal influenza vaccine to patients without the requirement for a prescription.

The potential for pharmacists' involvement in vaccination had been highlighted in Pharmacy Ireland 2020 (2008), a review of pharmacy services in Ireland, undertaken by the Pharmaceutical Society of Ireland¹². A recommendation of the Pharmacy Ireland 2020 interim report was to develop a strategy for maximising access to vaccines, by utilising the community pharmacy network. This report was

¹² Advancing Clinical Pharmacy Practice to Deliver Better Patient Care and Added Value Services. Pharmacy Ireland 2020 working group Interim Report April 2008
http://thepsi.ie/Libraries/Publications/Interim_Report_of_the_Pharmacy_Ireland_2020_Working_Group.sflb.a.shx

presented to the Minister for Health and Children in 2008. In addition, some pharmacists had experience in providing vaccinations through limited participation in the provision of vaccinations service during the 2010/2011 influenza season when a number of trained pharmacists were involved in providing the flu vaccine to patients within the Boots Pharmacies chain in Ireland under a specific legislative basis termed a Patient Group Direction (PGD) provided by the medical director of the pharmacy group. This resulted in 120 trained pharmacists administering approximately 7,000 doses of the influenza vaccine. Also, since 2009 training in intramuscular injection (IM) technique has become part of the approved curriculum for student pharmacists completing the MPharm degree, the academic qualification which fulfils part of the requirements for professional registration as pharmacists in the State.

The incorporation of pharmacists into the national seasonal flu vaccination programme for 2011/2012 required the input of a number of statutory bodies which had varying roles and responsibilities as outlined below:

The Legislation:

The **Department of Health** was responsible for establishing a legal mechanism by which pharmacists could be permitted to administer seasonal flu vaccinations to patients without the requirement for a prescription. Following a drafting process the Minister for Health signed the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 (S.I. 525 of 2011) on the **14th of October 2011**. These regulations authorised pharmacists in a pharmacy, following certified training approved by the PSI, to supply and administer the seasonal influenza vaccine to patients aged 18 years and over. In addition authority was given to pharmacists to administer epinephrine (adrenaline) 1mg/ml injection for use in the emergency treatment of anaphylactic shock, should it occur as a result of the administration of the vaccine.

The Regulation:

The **Pharmaceutical Society of Ireland (PSI)** is the independent statutory body responsible for the effective regulation of pharmacy services in Ireland, including the registration of pharmacists and pharmacies. The PSI supported the proposal by the Minister for Health to improve public accessibility to the annual influenza vaccination through pharmacies. Under the Regulations signed by the Minister on 14th October 2011, the PSI became responsible for recognising a training body and approving a training course for the purposes of training pharmacists in the administration of the seasonal influenza vaccine. The PSI drafted and published the 'PSI Interim Accreditation Standards

for Seasonal Influenza Vaccination Training Programmes for Pharmacists’. The PSI also drafted and published ‘PSI Guidance on the Provision of Seasonal Influenza Vaccination Services by Pharmacists in Retail Pharmacy businesses’. The PSI requested that all pharmacies providing the vaccination service would notify the PSI of their intention to do so.

The Implementation:

The **Health Service Executive (HSE)** was responsible for integrating pharmacists’ participation into the national influenza vaccination programme. This involved a number of agencies within the HSE, including the **National Immunisation Office (NIO)** and the **Primary Care Reimbursement Service (PCRS)**. These agencies made the administrative supporting arrangements to allow pharmacists participate in the 2011/2012 winter influenza vaccination programme. Pharmacists were incorporated partly into the national seasonal influenza vaccination programme for 2011/2012 to vaccinate certain patient cohorts as outlined below:

Vaccine supply and reimbursement for influenza vaccination by pharmacists and GPs

Risk group	Eligibility	GP		Pharmacist	
		Vaccine supply	Payment for vaccination service	Vaccine supply	Payment for vaccination service
Aged 65 and older	Medical or doctor only card	HSE	HSE	HSE	HSE
	Private	HSE	Private	HSE	Private
Others in at-risk group	Medical or doctor only card	HSE	HSE	Private	Private
	Private	HSE	Private	Private	Private
Not in at risk group	Medical or doctor only card or private	Private	Private	Private	Private

- Patients aged 65 years and older with a medical or doctor only card could receive HSE vaccine free of charge from their pharmacist or GP and the pharmacist or GP were paid by the HSE for vaccinating this cohort of patients.
- Patients aged 65 years and older without a medical card could avail of HSE vaccine free of charge from their pharmacist or GP and pay a private fee for the pharmacist or GP for the vaccination service.

- Patients in the remaining at risk groups could receive HSE vaccine free of charge from their GP who was paid by the HSE for administering the vaccine to those with a medical or doctor only card and paid a private fee by others. These patients, public and private, could also be vaccinated by a pharmacist by paying a private fee for both the vaccine and vaccination service to the pharmacist.
- Patients not in an at-risk group could access the vaccine from either a pharmacist or GP by paying a private fee for both the vaccine and vaccination service.

Under the regulations, pharmacists were required to notify the HSE of all patients vaccinated, both public and private within 7 days of vaccinating. An electronic notification system was developed and implemented by the HSE **Primary Care Reimbursement Service (PCRS)** to facilitate the notification of vaccinations by pharmacists to the HSE.

5 Key findings and recommendations of the review group

Overall conclusion of the review: The review group supports initiatives to maximise seasonal influenza vaccination uptake and concludes that measures to increase this uptake should be strongly encouraged and facilitated, including increased accessibility through pharmacist participation in vaccination campaigns. However, the review group concludes that any such expansion in the scope of practice of a healthcare professional must be accompanied by robust and appropriate training to appropriately upskill the healthcare professional in the professional activity they are about to undertake. This training must be appropriately approved and accredited and must involve trainers with up-to-date knowledge and experience. Robust governance and coordinated management of the overall project must be in place to ensure smooth implementation of such services to ensure that the continuous care and safety of patients is assured.

Following review of the submissions it is clear to the review group that the primary cause of some patients receiving an underdose of the vaccine was that, during training incorrect instruction on measuring the dose of the vaccine for administration was given to some pharmacists.

The review group focussed on discovering the factors that contributed to the error occurring within the training course and also not being detected through the regulatory and governance systems prior to administration of the vaccine to patients.

5.1 Review of the training provided to pharmacists

In order to participate in the vaccination programme it was a requirement of the regulations that pharmacists undergo certified training in seasonal influenza vaccination. A number of stakeholders were involved in the development, roll-out, accreditation and approval of the training course on seasonal influenza vaccination for pharmacists.

Under the Regulations, the PSI became responsible for the recognition of the training body and for the approval of a training course to train pharmacists in the administration of the seasonal influenza vaccine. The School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin accredited the pharmacist vaccination training course.

In anticipation of pharmacists' participation in the seasonal influenza vaccination programme, in mid-August 2011, the Irish Pharmacy Union (IPU) proactively made arrangements with a training provider, Hibernian Healthcare Ltd., that Hibernian Healthcare would develop and deliver a vaccination training programme on seasonal influenza vaccination for pharmacists.

The training provider, Hibernian Healthcare Ltd., is a private provider of a number of medical services including influenza and hepatitis B vaccination services. The company also provides training courses in CPR, Life Saving and First Aid. In 2009 Hibernian Healthcare provided training for some pharmacists in vaccination during the pandemic influenza preparedness planning, and also provided training on seasonal influenza vaccination to some pharmacists in 2010. Neither of these training courses was formally accredited by an external body. The training body had four full time staff members and a pool of 42 trainers consisting of nurses and pre-hospital emergency technicians used for providing training and the delivery of medical services.

In undertaking the review of the training the review group examined the training material provided to pharmacists, received submissions from the training body and other stakeholders and met with the training body, the accreditation group from TCD, IPU and the PSI. In addition, many submissions from other stakeholders provided feedback on the pharmacists and other stakeholders experience of the training provided and received.

The review group made a number of findings in relation to the training:

Between 5th September and 16th November 2011, 1462 pharmacists completed the training course on 20 different dates in 9 separate locations. The training provided was based on a series of lectures, a video and a demonstration of injection technique using an anatomical model arm followed by a practice session for pharmacists. For the demonstration of the injection technique one trainer provided training for a group of 6 pharmacists. Therefore, a large number of trainers was required during the training sessions. This presented a challenge to the training body to assure consistency in quality and content of training delivered across a number of training venues by a number of trainers. The final assessment of the pharmacists for sign-off in competency on the provision of seasonal influenza vaccine was an objective structured clinical examination (OSCE). This is a well-recognised exam format used to test clinical skill performance as well as competence in other non-clinical skills e.g. communication.

From the submissions received and the discussions with the training provider and the other stakeholders, the review group noted that the cause of the error in the training was the misinterpretation of the instructions for measuring the dose of the vaccine. The training body had carried out an internal review as a result of the error and openly shared the outcome of this internal review with the review group. This internal review identified the source and incorporation of the misinterpretation of dosage instructions within the development and delivery of the training in a number of steps as follows:

- The vaccine used during training was the Sanofi Pasteur MSD Inactivated Influenza Vaccine (split viron) BP. This was the vaccine used by the HSE in 2011/2012 season. The vaccine was presented as a pre-filled syringe containing 0.5ml of vaccine. The pre-filled syringe has a black line mark (but no numbers) on the syringe to indicate a 0.25ml dose of vaccine. During development and delivery of training for pharmacists the black line on the vaccine syringe was misinterpreted as indicating the full dose of 0.5ml rather than a 0.25ml dose. Pharmacists were instructed to use this line as ‘a dosage mark’ and to expel vaccine contents to the line. This instruction was incorrect. The correct instruction according to the SmPC for the measurement of the adult dose is to “depress the plunger until droplets appear on the syringe”.
- An Objective Structured Clinical Evaluation (OSCE) was developed by the training company in an effort to standardise the evaluation of the pharmacists during the training course and ensure consistency of trainers and examiners. Towards the end of the development stage of the training materials, the misinterpretation of the dosing instructions by the person reviewing and updating the OSCE resulted in the wording of one of the examination points in the OSCE being changed from the correct SmPC dosage instructions ‘depress plunger until droplets appear on the syringe’ to ‘...pressing the plunger to the marked dosage line’.
- There was no version control on the OSCE therefore this change to the training materials went unnoticed and the change in instruction was not subject to review by quality assurance or by a clinical person.
- A training video was prepared to aid in the training of trainers and pharmacists. The video was based on examination points included in the OSCE. This included showing the incorrect dosing instruction in the video which involved the depression of the plunger on the syringe to the black line mark on the vaccine syringe. This online video was used for training trainers and during training session of pharmacists and was available online to pharmacists as an aide memoire post training. The training video was also used in the training of trainers from the 5th September.

- These two pieces of training and assessment materials (i.e. the OSCE and the video) were the source of the incorrect information for trainers and pharmacists during the training course.
- Some additional factors within the training course compounded this incorrect instruction:
 - During training pharmacists were advised, for health and safety reasons, to only loosen the cap on the syringe needle and to keep the needle of the syringe sheathed with the needle cap. Therefore the volume of liquid being expelled was not as noticeable to the user of the syringe. This instruction therefore contributed to the error in dosing not being noticed as it was in direct conflict with the correct SmPC instructions to prepare the 0.5mls dose which would require the user to have full visibility of the syringe needle tip - “depress the plunger until droplets appear on the syringe”.
 - Pharmacists were trained to administer the influenza vaccine to adult patients only. Therefore no training was provided on immunisation of children including dosage instructions which may have possibly highlighted the error in instruction given.
 - The OSCE used in training course, which contained the incorrect instruction, was subsequently circulated to participating pharmacists in order to assist them in preparing their standing operation procedures (SOPs) for the vaccination service.

However in spite of the above identified issues with training material, the review group noted that of the 1462 pharmacists trained, only 203 pharmacists were vaccinating using the wrong dosing instructions, when contacted by Hibernian Healthcare, after the discovery of the error. This was of concern to the review group as it indicated that many trainers did not adhere to the contents of the training and assessment material in relation to the dosage instructions. In addition, it was reported by pharmacists and other stakeholders that there was a wide variability in whether the correct or incorrect dosing instructions were given during the training sessions. However there is also the possibility that some of the pharmacists ‘self-corrected’ having read the required reading material in full.

It is also of concern to the review group that there was no internal quality assurance of changes to training materials within the training body and no clinical governance of the training materials provided by a person with appropriate, and up-to-date experience in vaccination, including familiarity with the seasonal influenza vaccine products. Due to the large number of trainers involved in the delivery of the training course, the review group considers it was very important that

appropriate and comprehensive clinical governance be in place within the training body, and that formal training of all trainers involved would be carried out in order to be assured of trainer competence. Reliance on the self-declared professional competence of each of the healthcare professionals involved is not considered sufficient.

The review group also notes that the training body, Hibernian Healthcare, did not seek or receive expert input from the national expert bodies on vaccination e.g. NIAC or NIO.

The training body explained that the outcome of their internal review had identified issues with internal governance and overlapping functions, and that the company had undertaken a number of steps to rectify the deficiencies identified including implementation of version control for documents, the formation of an external review group for all training materials, the elimination of overlapping functions and other quality assurance measures.

The review group recognises that once the error was discovered, Hibernian Healthcare, the training provider, acknowledged the error in a very open manner, including apologising for the error and accepting responsibility. The training provider undertook numerous steps to address and rectify the error including individual contact with all pharmacists trained, to ensure that the pharmacists were aware of correct dosing instructions, investigating and reporting the number of patients affected and co-operating fully and proactively with all agencies involved to ensure the error was addressed fully.

In addition to the issues identified within the training material in regards to the instruction provided with the vaccine, the review group notes a number of additional points in regards to training:

- The legislation and therefore the legal basis under which pharmacists had the authority to vaccinate and the requirements of this legislation were not available until after the training course had been delivered.
- The PSI guidance for pharmacists was not available in final form until the legislation was published. Therefore the requirements of this document were also not fully incorporated into the training course. Both of these were required reading after the course.
- The training focussed on training pharmacists in the IM injection technique and the training did not cover the practical aspects of integrating and delivering a vaccination service within a pharmacy practice or the policies and procedures that would be required within a pharmacy practice setting.

- While the training body had informal contact with a number of pharmacists within the IPU there was no formal pharmacist input into the training course content that would be expected to address the professional aspects of delivering the service and to provide training on delivering the service within the pharmacy environment.

The review group considered that this was an important aspect of service delivery and should be addressed during a training course for pharmacists.

Recommendation 1:

In relation to education and training of healthcare professionals for any future development of a similar service, the review group recommends that:

- a) The recognised training body must have access to appropriate internal and external expertise in the subject area e.g. in this case vaccinations.
- b) It is essential that persons with appropriate knowledge and practice experience participate in all stages of development, implementation and assessment of training.
- c) Appropriate governance, clinical and non-clinical, must be in place within the training body to ensure that trainers are formally trained and assessed as competent, and that training is consistent and in line with national and international guidance.

In relation to training for vaccinations generally the review group recommends that:

- a) All healthcare professionals vaccinating should be formally trained to national standards.

In relation to training for pharmacists for any new national service, the review group recommends that:

- a) All guidance and requirements for the service should be in place before any national training is delivered.
- b) Training should be provided for pharmacists and assessed on integrating the new service into pharmacy practice.
- c) The professional and regulatory aspects of the new service should be included in training.
- d) The development and delivery of training for pharmacists should include the participation of pharmacist practitioners to address the above points.
- e) Opportunities for critical reflection should be accommodated into the programme design to allow the pharmacist to consider the information provided and if necessary to challenge and question the instruction or information provided.

5.2 Other Contributory Factors

In addition to the primary cause of the error, the review group considered that there were a number of factors that contributed to the error occurring and its not being detected earlier. These factors were each identified as contributory factors and provided an opportunity to highlight learning and improvement in these areas in the future.

5.2.1 Review of the relevant vaccine products and associated product documentation

At the time there were nine influenza vaccines with valid marketing authorisations in Ireland. However, only three influenza vaccines were effectively available on the Irish market as given in Table 3. These vaccines are all authorised by the IMB through an EU procedure resulting in harmonised products including their SmPCs.

As part of the national influenza vaccination campaign the HSE made available for eligible patients the Inactivated Influenza Vaccine (split virion) BP suspension for injection from Sanofi Pasteur MSD. The other two vaccines were used for private patients - Inluvac sub-unit 2011/2012 suspension for injection from Abbott Healthcare Products Ltd and Fluarix Suspension for injection from GlaxoSmithKline (Ireland) Ltd. These two products were therefore in lower use in Ireland in the 2011/2012 influenza season.

As part of their review the group examined these 3 vaccine products and associated product information (SmPC, package leaflet and labelling) that were available on the Irish market during the 2011/2012 influenza season. In addition the group received submissions from each of the vaccine manufacturers and from the IMB as the licensing authority.

Table 3 Seasonal influenza vaccines available in Ireland during the 2011/2012 influenza season

Product name	Additional dosage measurement line on pre-filled syringe	MA holder
Inactivated influenza vaccine (split virion) BP suspension for injection in prefilled syringe	yes	Sanofi Pasteur MSD
Inluvac sub-unit 2011/2012 suspension for injection in a pre-filled syringe	No	Abbott Healthcare Products Ltd
Fluarix Suspension for injection in a pre-filled syringe	yes	GlaxoSmithKline (Ireland) Ltd

Vaccine syringe marking:

The review group noted a number of findings in relation to syringe marking on the vaccine products available on the market:

- All of the vaccines are presented as pre-filled syringes containing 0.5ml. Two of the vaccines (Sanofi Pasteur vaccine (Fig 5) and Fluarix vaccine (fig 6)) have a black line mark, but no numbers or volume indicator, on the syringe to indicate a 0.25ml dose of vaccine. One vaccine, Abbott Influvac vaccine (fig 7), has instructions to use the 'knurled polypropylene ring' as an indicator for a 0.25ml dose. Therefore there is variability between the products in relation to the markings on the pre-filled syringes.

Figure 5 - Inactivated Influenza Vaccine (split virion) BP - pre-filled syringe



Figure 6 - Fluarix-pre-filled syringe



Figure 7 Influvac-pre-filled syringe



The underdosing of patients occurred in this case with the Sanofi Pasteur vaccine and GSK Fluarix vaccine i.e. the products with a black line mark on the syringe to indicate a 0.25ml dose. Pharmacists reported no dosing errors for the Influvac vaccine.

In addition, in September 2011, NIAC updated its recommendations for the paediatric dose, for the seasonal influenza vaccine, to 0.5ml in Ireland. While this recommendation applies to Ireland, the review group questions the future need for a 0.25ml dose line to be marked on the syringe.

The review group considers it was unclear from the vaccine syringe marking that the black line included on the syringe indicated a 0.25ml dose. The review group therefore considers the marking on the vaccine syringe (i.e. the presence of the unqualified black line mark) was a

contributory factor to the error that occurred. The group therefore concluded that this marking on the syringes should be removed or its purpose clearly identified.

Recommendations 2:

In relation to the black line markings on the vaccine syringe, the review group recommends that:

- a) The black line mark on the vaccine syringe should be removed as it is now irrelevant following the updated NIAC recommendation that all patients, adult and children receive a 0.5ml dose,
- or**
- b) If volume marks are considered necessary to indicate alternative doses, the volumes to which each mark refers should be indicated and if markings are used on a product to indicate a half dose then it is important to also indicate the full dose of the product.
- c) There should be consistency in dosage markings on all vaccines provided in pre-filled syringes.

Product Information

Information on a medicinal product for a healthcare professional is given in the document titled the Summary of Product Characteristics (SmPC). This is the source of the approved licensed information for a product. This information is given in specific sections and includes the authorised indication and use of the product, the correct dosage, the adverse effects and contraindications. The format and content of the SmPC is agreed and harmonised across the EU. There are a number of EU guidelines¹³ on how to present information in the SmPcs. The dosage and the method of administration are given in section 4.2 of the SmPC. The disposal and other handling instructions are given in section 6.6 of the SmPC.

¹³ **EU guidelines** European Commission 'Guideline on Summary of Product Characteristics (SmPC)', September 2009. CMD(h) Annotated QRD template (Version 2.0, 08/2011) - provides guidance on how to present the product information (SmPC, labelling and package leaflet) for all applications for medicinal products authorised through the mutual recognition procedure.

For vaccines, there are specific EU guidelines^{14,15} and a core SmPC for seasonal influenza vaccines¹⁶ which provide guidance on the text to be included in section 4.2 and section 6.6. The core SmPC for seasonal influenza vaccines currently specifies for section 6.6 that ‘where a single dose 0.5ml syringe is to be used for administration of a 0.25ml dose, specific instructions should be added’. The SmPCs of all authorised products are available to the public on the IMB website at www.imb.ie. The extracts of section 4.2 and section 6.6 of the SmPC are given below for each vaccine.

**INACTIVATED INFLUENZA VACCINE BP,
SANOFI PASTEUR (PA 544/34/1)**

Extracts of vaccine SmPC Section 4.2 and Section 6.6

4.2 Posology and method of administration

Adults and children from 36 months: 0.5 ml.

Children from 6 months to 35 months: clinical data are limited. Dosages of 0.25 ml or 0.5 ml have been used.

For children who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

Immunisation should be carried out by intramuscular or deep subcutaneous injection.

For instructions for preparation, *see section 6.6*.

6.6 Special precautions for disposal

The vaccine should be allowed to reach room temperature before use.
Shake before use.

For children, when one dose of 0.25 ml is indicated, push the plunger stopper exactly to the edge of the mark so that the half of the volume is eliminated. The remaining volume should be injected. See also section 4.2.

Any unused product and or waste material should be disposed of in accordance with local requirements

¹⁴ **EU guidelines** Guideline on Clinical Evaluation of New Vaccines, Annex: SPC requirements
EMEA/CHMP/VWP/382702/2006 –

¹⁵ Guideline on Pharmaceutical Aspects of the Product Information for Human Vaccines
EMEA/CPMP/BWP/2758/02

¹⁶ CMD(h) Core SmPC for Trivalent Influenza Vaccines (*CMD(h)/128/2003/rev5 Dec 2011*)

**INFLUVAC SUB-UNIT 2011/2012, SUSPENSION FOR INJECTION
ABBOTT HEALTHCARE PRODUCTS LTD (PA 108/17/1)**

Extracts of vaccine SmPC Section 4.2 and section 6.6

4.2 Posology and method of administration

Adults and children from 36 months: 0.5 ml.

Children from 6 months to 35 months: Clinical data are limited. Dosages of 0.25 ml or 0.5 ml have been used.

For children who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

Immunisation should be carried out by intramuscular or deep subcutaneous injection.

For instructions for preparation, see *section 6.6, Special precautions for disposal of a used medicinal product or waste derived from such medicinal product and other handling of the product.*

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Influvac Sub-unit should be allowed to reach room temperature before use. Shake before use.

For administration of a 0.25 ml dose from a syringe, push the front side of the plunger exactly to the edge of the hub (the knurled polypropylene ring); a reproducible volume of vaccine remains in the syringe, suitable for administration.

see also section 4.2. Posology and method of administration.

Any unused product or waste material should be disposed of in accordance with local requirements.

**FLUARIX SUSPENSION FOR INJECTION,
GLAXO SMITH KLINE (PA 1077/25/1)**

Extracts of vaccine SmPC Section 4.2 and section 6.6

Section 4.2 Posology and method of administration

Adults and children from 36 months: 0.5 ml.

Children from 6 months to 35 months: Clinical data are limited. Dosages of 0.25 ml or 0.5 ml have been used.

For children aged <9 years, who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

Immunisation should be carried out by intramuscular or deep subcutaneous injection. For instructions for preparation, see section 6.6.

Section 6.6 Special precautions for disposal and other handling

The vaccine should be allowed to reach room temperature before use. Shake before use.

When a dose of 0.25 ml is indicated, the prefilled syringe should be held in upright position and half of the volume should be eliminated. The remaining volume should be injected.

Any unused product or waste material should be disposed of in accordance with local requirements

The review group notes that in the vaccine SmPCs the information in relation to the dosage, method of administration and the measuring the dose of the products are given in two separate sections of the SmPC: Section 4.2 entitled 'Posology and method of administration' and Section 6.6 entitled 'Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product' or 'Special precautions for disposal and other handling'. It was also noted that the title used for section 6.6 varies between the SmPC for the various products.

The review group concluded the current location of information on measuring the dosage in Section 6.6 under the heading 'Special precautions for disposal of a used medicinal product or waste

materials derived from such medicinal product and other handling of the product' was not helpful and in fact misleading and identified it as a contributory factor to the error occurring.

Notwithstanding the fact that it would appear that the current relevant guidelines from the competent authorities, including the EMA and the IMB, on the SmPC for medicinal products and vaccines, direct the inclusion of this information, on the measurement of the dose, to be included under the heading of Section 6.6. relating to 'Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product' it is recommended that the positioning of this information should be reviewed and that it should be included under the clinical sections of the SmPC, e.g. in Section 4.2 relating to 'Posology and method of administration'. A busy practitioner upon reading the heading of Section 6.6 may not read further as the content of this section would not appear relevant in the context of administration.

Recommendations 3:

In relation to product information for the vaccines, the review group recommends that:

- a) The instructions on measuring the correct dose of such products should be included in section 4.2 'Posology and method of administration' of the SmPC. The review group recommends that this recommendation should be brought to the attention of the European Medicines Agency for consideration at an early date.
- b) The current NIAC recommendation that the paediatric dose should be 0.5ml (i.e. the same as the adult dose) should be incorporated into the product information for the products placed on the market in this country.

5.2.2 Professional and clinical judgement of pharmacists

The review group notes from the submissions, and discussions with stakeholders, that the error that occurred was wholly unexpected. There was an expectation expressed, by many stakeholders that pharmacists because of their training and experience, would be particularly alert to the importance of giving the correct dose of a medicine and on the need to comply with the requirements of the relevant SmPcs. Because of this confidence, the major focus of the training was on acquiring the new skills required, namely the IM injection technique and the steps to be taken in the event of the occurrence of an anaphylactic reaction. For pharmacists, since this was the first time they were required to administer a medicinal product by injection in the course of their professional practice, their concentration also appeared to be on that part of the procedure and the usual critical examination by the pharmacist of the medicinal product, including the dosage of the product, did not occur in some cases.

Under the regulations, pharmacists were provided with autonomous authority to supply and administer the seasonal influenza vaccine to patients. Pharmacists were therefore required to apply their independent professional and clinical judgment to this service as with all professional services a pharmacist provides. The review group considers that it is extremely important that pharmacists apply their core knowledge and skills to perform their own independent double check to ensure they are thoroughly familiar with any product they are about to administer. The group considers that this independent professional role of the pharmacists should be highlighted and supported during the delivery of training and the requirements for implementation of a new service.

The review group recognises the effect and the strength that an authoritative statement can have, as was provided during training course, despite this statement being invalid. The group recognises the phenomenon of the acceptance of this incorrect information, by people who have the necessary expertise to challenge it.

In addition, the review group notes that after the legislation was published the vaccination service started immediately. There was little time therefore for pharmacists to reflect on the training they had received and on the new legislative requirements that they were then to be subject to in their delivery of the service.

The review group notes that the guidance developed by the PSI and the Standard Operating Procedures (SOP) templates made available by the IPU were both lengthy and complex and there

appeared to be a large focus on process and documentation. The review group considers that it is important that any complexity introduced with a new service be kept to the minimum necessary, as over complexity in a process is recognised as a risk factor for error occurring during a process. The fundamental issue of the service, the safe vaccination of the patient in this case, should not be lost and any documentation required and implemented should support this overall aim. The review group concludes that any guidance and SOPs accompanying the roll-out of a new service should be clear, accessible and simple, to aid safe implementation of the service. These documents should also be formally integrated into the training course content.

Recommendation 4:

For new services being implemented into pharmacy, the review group recommends that:

- a) Pharmacists must apply their core knowledge and skills to ensure they are thoroughly familiar with any product they are about to supply and/or administer and must perform an independent double check of the product against the relevant SmPC and other product literature.
- b) Any complexity introduced to the system be kept to the minimum necessary and that where possible, processes should be simplified and streamlined, to maintain clarity, accessibility and simplicity.

For the pharmacist vaccination service:

- c) The PSI guidance and IPU SOP templates should be reviewed to ensure that these principles are met.

5.2.3 Review of the training accreditation and approval

Under the Regulations, the PSI became responsible for the recognition of the training body and for the approval of a training course to train pharmacists in the administration of the seasonal influenza vaccine. In August 2011, in anticipation of pharmacists' participation in the seasonal influenza vaccination programme, the PSI developed draft 'PSI Interim Accreditation Standards for Seasonal Influenza Vaccination Training Programmes for Pharmacists' and accepted a proposal, made jointly by Hibernian Healthcare and the IPU, that the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin would accredit the pharmacist vaccination training course to be provided by Hibernian Healthcare Ltd.

The School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin (TCD), formed an accreditation group for the purpose of accrediting the vaccination training course for pharmacists. The members of the accreditation group consisted of members of TCD School of Pharmacy staff. In addition as the accreditation progressed some external experts, from the National Immunisation Office and the Pharmaceutical Society of Northern Ireland, were co-opted to the accreditation group at the request of the PSI.

In August 2011, Hibernian Healthcare submitted an application for the accreditation of its vaccination training course for pharmacists to the TCD accreditation group. Following a four week accreditation process by the TCD accreditation group using the PSI Draft accreditation standards, the School of Pharmacy and Pharmaceutical Sciences, TCD provided the PSI with an accreditation report on 20th September that accredited the Hibernian Healthcare course for the 2011/2012 influenza season. This accreditation was conditional upon compliance with a number of recommendations as set out in the accreditation report and the accreditation was to be valid for the period 1st September to 31st August 2012. This accreditation report was approved in principle by the Pharmaceutical Society of Ireland (PSI) Council at its meeting on the 29th September 2011. On that basis, on the 14th October, following the making of the regulations, the PSI formally recognised Hibernian Healthcare as the training body and for the purpose of issuing to pharmacists the certificate prescribed under the regulations. The PSI also approved the course of training to be provided by Hibernian Healthcare on the basis of the accreditation given by the School of Pharmacy and Pharmaceutical Sciences TCD.

The review group noted the following in relation to the accreditation and approval of the training course:

- Internationally many countries have national standards for vaccination training in place for all healthcare professionals involved in vaccinations (e.g. the UK, Canada and New Zealand). In Ireland no such standards exist and it was necessary for the PSI to draft accreditation standards for vaccination training for pharmacists.
- Delivery of the training course to pharmacists started before the accreditation process was completed. This meant that training was run in parallel to the ongoing accreditation process. Therefore any recommendations for improvement in course material arising from the accreditation process required updated material to be given subsequently to the pharmacists who had already undertaken the course, for the purpose of self-study. The review group considers that the roll out of the training prior to the completion of the accreditation process compromised the process and the purpose of the accreditation.
- Some changes were also made to the training materials during the accreditation process which were not seen by the accreditation group. This included changes to the OSCE and to the final version of the training video.
- While the accreditation group had academic expertise and rigour, the group had insufficient input from experienced vaccinating practitioners, which would have been necessary if they were to pick up on the incorrect instruction provided during training.
- The accreditation group outlined the influence that the tight timeframe had on the implementation of the project. This also influenced the occurrence of the parallel processes and limited the availability of additional expertise to the accreditation group.

The review group concluded that the accreditation process undertaken to accredit the training course ought to have been sufficient to detect any error in training material within the training course and found that this did not occur in this case. As outlined, the accreditation process was compromised by a number of factors including the parallel roll out of training and the limited availability of experienced practitioners. Therefore the overall purpose of the process in assuring that the quality of the training course was of an appropriate standard was compromised. This was therefore identified as a contributory factor to the error remaining undetected. The review group makes a number of recommendations to ensure that this process is improved.

Recommendations 5:

In relation to accreditation and approval of the vaccination training course for pharmacists as prescribed under the regulations^{*}, the review group recommends that:

- a) The course of training must be approved by the PSI and the body, which is to deliver training and issue the prescribed certificate, must be recognised by the PSI before there is any roll out of training.
- b) A formal process for the recognition of the training body and for the approval of the course of training should be in place.
- c) The PSI should designate an appropriate accreditation body which would carry out the necessary accreditation of any training course which it is required to approve.
- d) The accreditation process must be completed before any application for recognition or approval is made to the PSI Council. The accreditation body must include persons with appropriate academic expertise and practitioners experienced in the relevant area of practice.

Furthermore

- e) National standards for the training of all healthcare professionals in vaccination should be developed.

^{*} Requirements of regulation 4B(a) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended by the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 (S.I. 525 of 2011).

5.2.4 Project Management and timeframe of the service development and implementation

The timelines for the planning and development of the pharmacists' seasonal flu vaccinations service for 2011/2012 season is outlined in Table 2.

Table 2 Planning and development of pharmacist seasonal Influenza service

Date	Action
PLANNING AND DEVELOPMENT OF THE SERVICE	
18 th July	<ul style="list-style-type: none"> Minister for Health indicated his intention that community pharmacists would be allowed to participate in the national influenza vaccination programme.
15 th August	<ul style="list-style-type: none"> The HSE PCRS requested expressions of interest from community pharmacies to identify potential contractors for the service.
17 th August	<ul style="list-style-type: none"> The PSI Established a Pharmacy Working Group of key stakeholders; the PSI, the IPU, HSE/PCRS, and superintendent pharmacists from the two major pharmacy chains Boots and Unicare.
26 th August	<ul style="list-style-type: none"> The PSI accepted the proposal by Hibernian Healthcare Ltd and the IPU that the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin would accredit the pharmacist vaccination training course being provided by Hibernian Healthcare Ltd. Hibernian Healthcare submitted an application for accreditation of the vaccination training course for pharmacists to TCD accreditation group.
5 th September	<ul style="list-style-type: none"> Training of pharmacists by Hibernian Healthcare commenced.
19 th September	<ul style="list-style-type: none"> The NIO commenced deliveries of vaccine and information booklets for healthcare professionals and leaflets and posters and record cards for at-risk groups to GP and HSE sites.
20 th September	<ul style="list-style-type: none"> TCD accreditation group issued their report on the training programme for pharmacists for the seasonal influenza vaccine (2011-2012) accrediting the training course for the 2011/2012 season.
29 th September	<ul style="list-style-type: none"> PSI Council: <ul style="list-style-type: none"> Approved draft guidance in principle pending publication of the relevant legislation. Approved in principle the interim accreditation standards for seasonal influenza vaccination training programmes for pharmacists. Approved the accreditation report of the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin regarding accreditation of Hibernian Healthcare Ltd/IPU vaccination training programme with a further report being expected from TCD within a number of weeks to include the quality improvement measures undertaken by the course provider to address the issues raised in TCD's accreditation report and feedback from course participants.

IMPLEMENTATION OF THE VACCINATION SERVICE	
14th October	<ul style="list-style-type: none"> • Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 (S.I. 525 of 2011), were signed by the Minister for Health. This allowed pharmacists to supply and administer the seasonal influenza vaccine to patients within a pharmacy. • The PSI's 'Guidance for pharmacists on the provision of seasonal influenza vaccination services by pharmacists in retail pharmacy businesses' was amended to include the requirements of the regulations and was published. • The PSI formally confirmed to the School of Pharmacy and pharmaceutical Sciences, TCD that it was recognised as an accrediting body by the PSI Council for the purpose of accrediting this vaccination training programme. • The training programme provided by Hibernian Healthcare Ltd, in co-operation with the IPU, as accredited by TCD was approved by Council for the purposes of the Regulations. • The PSI formally informed Hibernian Healthcare Ltd that it was recognized by the PSI Council for the purposes of issuing a certificate of training to registered pharmacists as prescribed in the regulations.
16th October	<ul style="list-style-type: none"> • The first vaccination record from a pharmacy was received by the HSE PCRS. (using non-HSE i.e. private vaccine product)
17th October	<ul style="list-style-type: none"> • NIO commenced national seasonal influenza communication campaign with a press release followed by two week national and local radio campaign.
20th October	<ul style="list-style-type: none"> • NIO commenced seasonal influenza vaccine delivery to pharmacists. Deliveries also included seasonal influenza information sheets for the general public and seasonal influenza vaccine record cards.

From all the submissions received and review of the material, the review group appreciates that the development and implementation of the major policy development of including pharmacists, for the first time, in the vaccination service in time for the commencement of the national seasonal flu vaccination campaign in October 2011, was a complex and time-consuming process. This process involved many agencies and stakeholders responsible for different aspects of development and implementation. The timing of the development and introduction of this new service coincided with the start of the influenza season and the national vaccination campaign. This involved a significant and complex workload to be completed within a short period of time.

The review group notes that all stakeholders were committed to timely implementation of the service being achieved. However the group concluded that no one person or body had overall control or a coordinating function; no person/agency was appointed to be responsible for the

management of all aspects of the project. The review group agreed that it was very important that appropriate project management and overall governance, including risk management be in place for such a project to ensure that any risks can be identified and mitigated from the start.

Many stakeholders referred to the effects of timelines, including the difficulties and added pressures that this caused. A major change in policy for agencies and a major change in practice for pharmacists was implemented within a very tight time frame, which coincided with the peak demand for the service. While the review group appreciates the efforts made by all stakeholders involved to ensure that all aspects of the programme were delivered within this timeline, the impact of the tight timeline was evident in the implementation of the new service, especially in the training roll-out and the accreditation process being run in parallel.

The review group considered that the lack of overall project management and governance and the time pressure experienced by those implementing the service was a contributory factor to the error occurring and also to the delayed detection of the error.

The review group acknowledges that many development steps can be taken in parallel, however the group concluded when this occurs it should be done in a planned and controlled manner. The review group consider that having strategic project management in place, would address or mitigate the risks involved in a tight timeframe for implementation. This would also allow for formal risk assessment at the project start and on-going management review during the development and implementation stages. The project plan should acknowledge and highlight any overlapping developmental steps and the risks involved.

The review group concludes that these aspects should be addressed for any future development projects in the healthcare system and that good governance is of foremost importance for the implementation of any new project to ensure that the risk of error is minimised within the system.

Recommendation 6:

For this project and any future new national health service development projects, the review group recommends that:

- a) The Department of Health designates a lead agency with responsibility for the overall project management of the project including governance, and on-going risk assessment.
- b) Future developments should, where appropriate, also involve a pilot study during development and audit to assess impact on the overall service.
- c) An appropriate lead time should be built into any future initiatives to ensure that the project can progress through the relevant stages in an appropriate sequence so as to minimise risk.

5.3 Associated issues identified

In performing the review of the vaccinations service, the review group noticed a number of associated issues, not directly related to the error that occurred, but that ought to be addressed or would warrant further investigation. These associated issues are outlined below:

5.3.1 Response to the error

The discovery of the error and the steps taken by the individuals and agencies involved are outlined in Table 3.

Table 3 Discovery of the error and subsequent response

Date	Action
22 nd November	<ul style="list-style-type: none"> • A pharmacist contacted the IPU offices after close of business to point out that he noticed a difference between training instruction given in an online training video and the SmPC for the Inactivated Influenza vaccine (Split virion) BP. • IPU contacted the training provider with the above information to investigate further. • The training provider confirmed to the IPU that there had been an error in the information provided to pharmacists on measuring the dosage of the vaccine during training and in the training support video.
23 rd November	<ul style="list-style-type: none"> • The training provider and the IPU informed the PSI of the error. This notification was also copied to the IMB, NIO, HSE and TCD accreditation group. • The training provider e-mailed all pharmacists who had attended the training course with the correct instructions for measuring the dose of the vaccine and contacted Sanofi Pasteur MSD to ascertain the consequences of administering a 0.25ml of seasonal influenza vaccine to adults. Sanofi Pasteur MSD referred Hibernian Healthcare to the NIO. • The NIO confirmed that they would seek advice from Sanofi Pasteur MSD and also from the National Immunisation Advisory Committee (NIAC). • The training provider commenced contacting all pharmacists who had attended training to ensure they were aware of the correct guidance for administering the vaccine, to identify how many patients were affected by the error and to ensure that, from that date, all vaccinations were being administered correctly. • According to the HSE PCRS database, a total of 6744 patients had been vaccinated by 484 pharmacies by this date.
24 th November	<ul style="list-style-type: none"> • The NIO wrote to the PSI, the training provider and the IPU stating that NIAC advised that patients who had received an underdose of vaccine be revaccinated with a full 0.5ml dose and that no time interval was necessary before revaccination. NIAC also confirmed that there were no additional safety issues for patients who had received an inadequate dose or with any revaccination.

	<ul style="list-style-type: none"> • The PSI contacted all pharmacists via email outlining the nature of the error and informing them of the advice on revaccinations from the NIO and NIAC. The PSI also informed pharmacists that the IMB had advised that the error need not be notified to the IMB as an adverse event¹⁷. The PSI also advised pharmacists regarding a full review of the service within their pharmacy and of the need to keep appropriate records of revaccinations. • The IPU also contacted all members advising that pharmacists should recall relevant patients for revaccination. • The training provider provided an update to the PSI and IPU outlining the telephone contacts they had made with pharmacists to date. • The PSI also requested the School of Pharmacy and Pharmaceutical Sciences, TCD to review matters in light of the error. • Later, on the 24th November, the PSI was informed by a superintendent pharmacist in a large chain of pharmacies that the underdosing error had also occurred with a second vaccine (Fluarix) which was being administered to private patients. This related to a very small number of patients. This vaccine also had a black line on the vaccine syringe as an indication of a 0.25ml dose. • It was confirmed to the public on the National News by the IPU that pharmacists should recall all affected patients for revaccination.
25 th November	<ul style="list-style-type: none"> • The PSI delivered a report mandated by the Minister for Health, setting out the actions taken and on-going, to identify all pharmacists, pharmacies and patients affected by the error, and to manage the on-going and developing situation. • The training provider made an interim report to the PSI outlining the actions taken to date and confirming the number of pharmacists spoken to and the number of incorrect doses administered. • The President of the IPU spoke on RTE's Morning Ireland to reiterate advice to patients regarding revaccination. The advice was also carried in the national newspapers. • The IPU put information for patients on the public section of its website. • The IPU wrote to the Minister for Health, outlining the actions it had taken since the error had been brought to light. • PSI advised all key stakeholders that the underdosing error had also occurred, for a very small number of patients, with a second vaccine (Fluarix) which was being administered to private patients. • The PSI placed a public notice on its website advising members of the public to contact their pharmacy if they had any concerns, but also offering that the PSI was contactable either by telephone on an 1850 number or by email. • The PSI issued a public statement stating that in light of the assurances received from and on behalf of the profession to comply with PSI guidance, it was satisfied that vaccination services could continue to be provided in pharmacies and that the public could continue to have confidence in this service. • The PSI also published its report to the Minister on its website and dealt with

¹⁷ While the error did not need to be reported to the IMB as an adverse event any suspected adverse reaction associated with the error must be reported to the IMB.

	<p>several media queries on the issue.</p> <ul style="list-style-type: none"> • The PSI issued a communication to all superintendent pharmacists by email asking that a full review of the vaccination service be carried out in their pharmacies to ensure compliance with PSI guidance, and in particular to ensure that the identification and follow-up of all affected patients was being managed appropriately. • Superintendent pharmacists were also reminded that should any further issues arise during their reviews, that the vaccination service be suspended until the issues had been appropriately clarified and rectified as necessary. • The NIO wrote to Hibernian Healthcare, IPU and PSI stating that the correct dose (0.5mls) of influenza vaccine can be given in the same arm as the first dose of vaccine to patients that required revaccination.
27th November	<ul style="list-style-type: none"> • The training provider made a second interim report to the PSI and sent a further e-mail to all pharmacists.
28th November	<ul style="list-style-type: none"> • The training provider emailed all pharmacists who had attended the training to reconfirm the correct instructions for measurement of the dose for all flu vaccines.
29th November	<ul style="list-style-type: none"> • The IPU included a note in their eNewsletter advising pharmacists that the PCRS browser would now accept notification of revaccinations and that pharmacists should input all such information.
30th November	<ul style="list-style-type: none"> • The PSI sent a further communication to all superintendent pharmacists requesting a formal notification be sent to the PSI confirming that a full review of the vaccination service had been carried out and that the service was being provided in accordance with the requirements of the regulations and with the PSI guidance. • The School of Pharmacy and Pharmaceutical Sciences, TCD accreditation group submitted an additional report to the PSI regarding its review of the training programme for pharmacists for the seasonal Influenza vaccine (2011-2012) in light of the error.
1st December	<ul style="list-style-type: none"> • The PSI met with the accreditation group of the School of Pharmacy and Pharmaceutical Sciences, TCD, the IPU and the training provider to discuss the error, the adequacy of the response and on-going steps • The Risk Review Group was established by the PSI.
6th Dec	<ul style="list-style-type: none"> • The training provider provided a report to the PSI which outlined that from their contact with pharmacists they estimated that 80% of patients had been revaccinated, or scheduled to be revaccinated, with the full 0.5ml dose.
12th Dec	<ul style="list-style-type: none"> • The IPU and training provider met with the accreditation group at TCD to review the events and try to identify lessons that should be learned to prevent a reoccurrence in any future healthcare training programmes that may be provided.
	<ul style="list-style-type: none"> • The PSI has not received any formal complaints from patients or members of the public in respect of this matter.

Patient perspective: In addition, a small number of patients were contacted to gain insight into their experience on how the error was handled. It was noted that for most patients their initial source of knowledge on the issue was contact from their pharmacist. All those interviewed reported that they were either satisfied or very satisfied with the information received and with the action of the pharmacists. All those interviewed stated that they would continue to attend their pharmacist for vaccination and no patient reported that their confidence in their pharmacist was diminished. One person reported being upset when she first heard of the issue and was disappointed that having put her trust in the process she was let down. However, she believed that the issue was handled openly and honestly and that therefore she would continue to attend the pharmacy for vaccination in the future.

Therefore while the error had the potential to impact on patients' confidence in receiving vaccinations from pharmacists, the review group noted that from the small sample of patients interviewed that this had not occurred. The review group concluded that it is of primary importance for any changes in the health service and movement of services that patient care be maintained at the highest level and that patients can be assured of the same level of patient care and patient confidence in the health system and that their care throughout these changes is fully maintained.

The review group concluded overall that following discovery of the error the response was timely and well handled. The review group noted that it was a pharmacist that discovered the error and who immediately brought the error to the attention of the relevant bodies. The governance system within pharmacies worked well to co-ordinate and manage the response.

The review group considered the response to the error once identified was very open by all the stakeholders involved. The actions taken by agencies in responding to the error was rapid and many agencies worked together to ensure that the correct advice on rectifying the error was ascertained.

The review group considered that the response to this error was in line with the principles outlined in the Report of the Commission on Patient Safety and Quality Assurance¹⁷ which recommends open communication of errors with patients following the event and a speedy and effective style of communication of errors.

However, the review group noted that the vaccination service was underway for six weeks before the error was detected and this is of concern. In addition this error was not required to be reported to or recorded by the IMB as an adverse event nor was it captured in any other national system. Some manufacturers of the vaccine products indicated that they had reports on their vigilance systems of underdosing with the seasonal influenza vaccine albeit in low numbers compared to the overall use of the product. The review group considered that it is important that a 'no blame' reporting system be in place to report and detect such errors. This would facilitate early detection of errors and disseminate learning throughout the system. The review group therefore supports the recommendations of the Report of Commission on Patient Safety and Quality Assurance¹⁸ that the dissemination of learning throughout the system is crucial to minimise error and protect future patients and that a voluntary system of reporting of 'close calls' or 'near-misses' will contribute to further learning and dissemination of best practice. In support of this, the review group recommends that a reporting system for errors within primary care services, including pharmacy, should be implemented to ensure learning can be visible throughout the system.

Recommendation 7:

In relation to the response to errors within healthcare the review group recommends that:

- a) Any response to an error should be in line with the principles outlined in the Report of the Commission on Patient Safety and Quality Assurance¹⁸ which recommends open communication of errors with patients following the event and a speedy and effective style of communication of errors.
- b) The review group supports the recommendations of the Commission on Patient Safety and Quality Assurance that the dissemination of learning throughout the system is crucial to minimise error and protect future patients and that a voluntary system of reporting of close calls or near-misses will contribute to further learning and dissemination of best practice. In support of this, the review group recommends that a reporting system for errors within primary care services, including pharmacy, should be implemented to ensure learning can be visible throughout the system.
- c) A clear incident-response system should be in place from the beginning of a service and should be communicated to all stakeholders.
- d) It is essential that the lessons learned in one healthcare establishment are communicated regionally, nationally and internationally.

¹⁸ Building a Culture of Patient Safety - Report of the Commission on Patient Safety and Quality Assurance. 2008 http://www.dohc.ie/publications/pdf/en_patientsafety.pdf

5.3.2 Reporting and notification of vaccinations:

Under the regulations, a number of requirements on record keeping for vaccinations were introduced for pharmacists. Under these, pharmacists were obliged to keep individual records for each patient vaccinated in the pharmacy and also to notify the HSE of all public and private patients within 7 days of the vaccination. For this purpose the PCRS set up an electronic notification system to facilitate these notifications and also to pay pharmacists for their services to eligible patients.

Pharmacists are also obliged to notify the patient's GP of the vaccination where the patient makes that information available.

Those patients who had received an underdose of vaccine required a second vaccination with the full 0.5ml dose of the vaccine and pharmacists were required to notify these revaccinations to the PCRS. Initially the PCRS had incorporated a validation check on their IT notification system to allow only one record/claim to be made for each patient. In order to enable the revaccination notification to be made this validation check had to be removed. There was therefore an initial lag time until November 29th before a revaccination record could be accepted.

The data provided by Hibernian Healthcare indicated that 203 pharmacists had incorrectly vaccinated 1231 patients. As of the 6th December, Hibernian Healthcare indicated that pharmacists had reported that 80% of these patients had been either revaccinated or had scheduled an appointment for revaccination.

The PCRS reported in February 2012, that 9904 vaccination records had been received from 484 pharmacies which included 454 records of revaccinations.

The number of revaccinations in the PCRS database was therefore significantly lower than the figures reported by the training body.

The review group are concerned with the discrepancy in figures between the two reporting systems. A number of submissions received by the review group described difficulties encountered with the IT notification system. Some pharmacists indicated that they were unable to submit notifications of revaccinations electronically and had therefore sent these to the PCRS by fax. The PCRS indicated that while they had received some faxed notifications, these were not recognised by the PCRS as

notifications. The PCRS did not provide a figure for the number of revaccinations notifications received by fax.

In April 2012, the PCRS undertook some further validation work with the IT notification system and issued a further communication to pharmacists to request notification of revaccination following updating of the notification system.

The PCRS reported that as of 25th April 2012, 583 records of revaccinations notifications had been received giving a revaccination rate of 47% (583/1231) which is still significantly less than the 80% reported by the training body.

In addition, the PCRS indicated that a number of patients had been revaccinated by their GP although the number of patients involved could not be confirmed. GPs are not required to provide notifications for any private patients nor are they required to report real time notifications for those patients eligible under the HSE vaccination programme.

Therefore having regard to the information provided by the training body and the PCRS, the review group are not in a position to establish the actual number of patients revaccinated following the error. This is of significant concern to the review group and the group considers that this deficiency in the system should be rectified as a matter of priority.

As of 25th April 2012, the HPSC, the agency responsible for monitoring vaccine uptake had not received any data from the PCRS on the number vaccinations provided by pharmacists during the 2011/2012 season. Therefore the impact of the new service on the overall vaccine uptake could not be established. The review group considers that appropriate data collection to evaluate and monitor the impact of the introduction of any new service should be in place.

Overall the review group noted a number of issues with the notifications arrangements for the vaccinations:

- Notification of vaccination of all patients (i.e. public and private) is not a requirement for other healthcare professionals.

- Real time reporting is not in place for other healthcare professionals therefore vaccine uptake data is only available at the end of the season and is only for those patients holding a medical or doctor only card.
- Stakeholders, including end users, reported many difficulties in using the PCRS notifications system. This included the notification of the initial vaccinations and subsequently when using the system to notify revaccinations.
- The electronic PCRS notification system is a dual purpose system which is primarily concerned with the payment of pharmacists for their services.
- There is no national immunisation register to allow easy access to vaccination uptake data.

The review group was of the view that the collection, analysis and reporting of information on vaccine uptake are central to the effective disease surveillance, control and management within the healthcare service.

Recommendation 8:

For the notification of vaccinations, the review group recommends that:

- a) An urgent review of the PCRS data be carried out to validate the number of patients that were revaccinated.
- b) In the interest of public health and surveillance, a national immunisation register should be established that will require and receive real-time reporting of vaccinations from all healthcare professionals and that the primary function of this register would be public health surveillance and that the making of payment for services would be a secondary arm of that system.
- c) There should be collaborative development of IT systems with all stakeholders involved, including the end user, to ensure that the system is fit for purpose and that it will fulfil national requirements.
- d) The review group considers that appropriate data collection to evaluate and monitor the impact of the introduction of any new service should be in place.

Appendix 1 Documents reviewed by the risk review group as background and reference material

1. Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 [S.I. 525 of 2011].
2. PSI Guidance on the Provision of Seasonal Influenza Vaccination Services by Pharmacists in Retail Pharmacy businesses.
3. PSI Interim Accreditation Standards for Seasonal Influenza Vaccination Training Programmes for Pharmacists.
4. Accreditation Report from School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin regarding the accrediting of Hibernian Healthcare- Irish Pharmacy Union Vaccination Training Programme for Pharmacists for the seasonal Influenza Vaccine (2011-2012 season)- 20th September 2011.
5. Letter from PSI to Hibernian Healthcare Ltd. recognising Hibernian Healthcare for the purposes of issuing a certificate of training to registered pharmacists under the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 [S.I. 525 of 2011] - 14th October 2011.
6. Letter from PSI to School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin recognising the school of pharmacy as an accrediting body by the PSI Council - 14th October 2011.
7. Interim Report from the PSI to the Minister for Health and HSE regarding the underdosing of some patients with seasonal influenza vaccine by pharmacists - 25th November 2011.
8. Report to PSI Council regarding the underdosing of some patients with seasonal influenza vaccine by pharmacists - 6th December 2011.
9. Additional report from School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin regarding the programme for Pharmacists for the Seasonal Influenza vaccine (2011-2012 season) – 30th November 2011.
10. The Immunisation Guidelines for Ireland 2008 Ed (updated online September 2011) - Royal College of Physicians of Ireland-National Immunisation Advisory Committee (NIAC).
11. HSE National Immunisation Office - A Practical Guide to Immunisation-selected chapters relevant to immunisation and influenza.
12. Summary of product characteristics and the patient information leaflet for the influenza vaccine Influvac from Abbott Healthcare.

13. Summary of product characteristics and the patient information leaflet for the influenza vaccine Fluarix from GlaxoSmithKline.
14. Summary of product characteristics and the patient information leaflet for the influenza vaccine Inactivated Influenza Vaccine (split viron) BP from Sanofi Pasteur MSD Ltd.

Appendix 2 Letter of invitation for submissions sent to identified stakeholders

«Title» «Forename» «Surname»

«Work_Title»

«Address_1»

«Address_2»

«Address_3»

«Address_4»

«Address_5»

19th December 2011

Re: Risk Review Group request for written submissions

Dear «Title» «Surname»,

The PSI has established an independent Risk Review Group to examine and report on the causes of the recent underdosing of some patients with seasonal influenza vaccine by certain pharmacists. It is intended that the outcome of this review will focus on the learning and changes that may be required and to advise on any associated issues that may be identified. The composition and terms of reference of the Risk Review Group are enclosed for your information.

I am writing to you, as Chairman of this Independent Risk Review Group, to invite you to provide a written submission for consideration by the Group. In your submission it is suggested that you would provide any material and/or information, that you would deem relevant having regard to the Terms of Reference of the Group, and which you would wish to be taken into consideration by the Group in its deliberations.

All submissions, preferably in electronic format, should be sent to cora.nestor@thePSI.ie or alternatively a hard copy can be forwarded to Dr. Cora Nestor, Risk Review Group Secretariat, 18 Shrewsbury Rd., Dublin 4. I request that all written submissions be forwarded by **Friday 20th January 2012**.

Please note that should any further clarifications and/or explanations be required, the Review Group may invite parties to make a supplementary oral presentation, in the course of which any

necessary clarifications and/or explanations may be provided to the Group. The date for this would be Thursday 9th February 2012.

I would also like on behalf of the Risk Review Group to extend, in advance, its gratitude to those bodies and individuals who make submissions to it and who assist and co-operate with the undertaking and completion of the Review.

Yours Sincerely,

Prof. Peter Weedle

Chairman of Risk Review Group

Appendix 3 Letter of invitation for submissions sent to patients

4th April 2012

Dear Patient,

We are inviting patients who would be interested to participate in a review of the pharmacy vaccination service this year.

An independent Review Group has been established to examine the reasons why some patients received an underdose of the 'flu' vaccine from their pharmacist. This group is focusing on how this event occurred, what can be learned from what happened and what we need to do to ensure that such errors do not happen in future. As a patient who received an underdose and needed a second vaccination, the Review Group would like to hear about your experience and your opinion of the service you received. The Review Group are also interested in your opinion as to how errors are best responded to in any healthcare setting.

If you agree to participate, you will be asked to give your pharmacist your name and contact telephone number. A random sample of patients will be then contacted by Ms Mary Culliton, a member of the Independent Review Group, to carry out a short, confidential telephone interview to discuss your experience. Mary is the former Director of Advocacy with the Quality and Patient Safety Directorate of the HSE and former Head of Consumer Affairs within the HSE. Mary is not a pharmacist and will ensure all information given to her will be confidential and anonymised.

All patients randomly selected will be contacted before the end of April 2012.

If contacted, the information collected will be anonymous and your name or details will not be published. Your personal information (name and contact details) will not be used for any other purpose or given to any other parties.

If you would like any further information on this process before you decide on participation, please contact Cora Nestor, Pharmaceutical Society of Ireland, 18 Shrewsbury Rd, Dublin 4 on 01 2184009.

Your views are important to us and I would like to thank you in advance for your time and your valuable input into this review

Yours Sincerely,

Prof. Peter Weedle

Chairman of Risk Review Group

Appendix 4

Telephone questionnaire for patients in relation to receiving an underdose of the 'flu' vaccine from pharmacists

Introduction outline

Thank you for your time participating in this process.

Outline of purpose and process: We are inviting patients who would be interested to participate in a review of the pharmacy vaccination service this year.

An independent Review Group has been established to examine the reasons why some patients received an underdose of the 'flu' vaccine from their pharmacist. This group is focusing on how this event occurred, what can be learned from what happened and what we need to do to ensure that such errors do not happen in future.

As a patient who received an underdose and needed a second vaccination, the Review Group would like to hear about your experience and your opinion of the service you received.

The Review Group are also interested in your opinion as to how errors are best responded to in any healthcare setting.

The group will be issuing a report on their findings in May. All patient responses are confidential and will be anonymised

Questions

1. How did you first hear about the issue of the under-dosing of flu vaccine?

2. How were you contacted by your pharmacy?

3. How soon after were you contacted?

4. Who contacted you and What were you advised ?

5. How did you feel when you were contacted?

very unconcerned *unconcerned* *Neither concerned nor unconcerned* *Concerned* *Very Concerned*

6. What did you think of the information you were given?

Very satisfied *satisfied* *Neither satisfied nor unsatisfied* *unsatisfied* *very unsatisfied*

7. If unsatisfied , what further information would you liked to have received?

8. From the all the information you heard and received-what did you perceive was the error?

9. Have you had the flu vaccine other years?

10. Has this experience affected your confidence in vaccination by Pharmacists? (Yes/No)

11. Would you attend a pharmacist again for a vaccination?

12. Any other comments you would like to make on your experience?

Are you a medical card holder or a private patient? _____

Appendix 5 Abbreviations Used in the Report

ABA	An Bord Altranais –the Nursing Board
CPR	Cardiopulmonary resuscitation
DoH	Department of Health
GMS	General Medical Services
GP	General Practitioner
HIQA	Health Information and Quality Authority
HPSC	Health Protection Surveillance Centre
HSE	Health Service Executive
IM (injection)	Intra muscular (injection)
IMB	Irish Medicines Board
IPU	Irish Pharmacy Union
NIAC	National Immunisation Advisory Committee
NIO	National Immunisation Office
OSCE	Objective Structured Clinical Examination
PCRS	Primary Care Reimbursement Service
PHECC	Pre-Hospital Emergency Care Council
PSI	Pharmaceutical Society of Ireland- the Pharmacy Regulator
RCPI	Royal College of Physicians of Ireland
SmPC	Summary of Product Characteristics
SOP	Standard Operating Procedure
TCD	Trinity College Dublin
WHO	World Health Organisation
