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Pandemic report and lessons learned

Outcome of the European Medicines Agency's activities during the 2009 (H1N1) flu pandemic

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1. Introduction

In April 2009 a novel influenza virus strain was identified in Mexico and the United States of America, with potential to trigger a pandemic. The novel strain was identified as an H1N1 strain and the pandemic status confirmed by the World Health Organization (WHO) in June 2009. The European Medicines Agency was one of the key players in the European Union, with regards to the authorisation and supervision of pandemic vaccines and antivirals.

This report summarises the key activities that took place at the European Medicines Agency (EMA) and the lessons learned in the process. It also makes recommendations for improvements based on these findings.

The activities covered in this report took place between 27 April 2009 (the day after the official WHO announcement of the novel virus) and March 2010.

General information on the activities of the Agency during an influenza pandemic, including guidance documents and plans, can be found on the website of the Agency under [Special topics > Pandemic influenza](#).

Information regarding the 2009 pandemic has been published under [Special Topics > Pandemic influenza > 2009 \(H1N1\) influenza pandemic](#).

2. Pre-pandemic activities

Pandemic preparedness work at the Agency commenced in 2003 as part of a Community process, in collaboration with the European Commission (EC), Member States of the European Union and the European Centre for Disease Prevention and Control (ECDC); the later following its establishment in 2005. The Agency's pandemic preparedness focussed on issues falling within its mandate, which is to provide scientific recommendations for the authorisation of vaccines and the monitoring of their benefit/risk during a pandemic.

As part of its preparedness, the Agency also had discussions on pandemic vaccine development with industry over a period of years.

The Agency also reviewed the antivirals for potential use during the pandemic¹

Crisis management plan

In 2006, the Agency put in place its crisis management plan to outline the management structures and detailed procedures to support the processes associated with an influenza pandemic. The plan set up detailed procedures for:

- fast-track approval of pandemic influenza vaccines via the centralised procedure (see below);
- post-authorisation follow-up (including assessment of safety signals) of centrally authorised pandemic influenza vaccines and antivirals;
- assessment of safety signals arising from the use of non-centrally authorised antivirals or from the use of bulk active substance of centrally authorised antivirals.

1

http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000463.jsp&murl=menus/special_topics/special_topics.jsp&mid=WC0b01ac058004bf56##

The plan also set out the two key principles that would guide the Agency's communication activities during the pandemic, and which were further developed in a pandemic crisis communications plan:

- to inform about its specific responsibilities in relation to medicinal products in a pandemic situation, which should not encroach on activities and responsibilities of other European and national partners;
- to tailor its communication activities to fit with its partners to ensure coherent messages across the EU.

Fast-track approval of pandemic vaccines via the centralised procedure

Specific guidance was developed by the Agency and the EC for an assessment procedure for pandemic influenza vaccines. This innovative 'core pandemic dossier' approach, based on decades of experience with seasonal flu vaccines, is designed to speed up the scientific evaluation of pandemic influenza vaccines, in order to be able to authorise a vaccine before the pandemic peak emerges. The procedure involves:

- **Inter-pandemic period:** submission and evaluation of the core pandemic dossier. The information contained in this dossier allows for the authorisation, in advance of a pandemic, of a mock-up vaccine. The mock-up vaccine contains a strain of flu virus to which the majority of the population is naïve but that could potentially cause a pandemic.
The mock-up vaccine mimics the future pandemic influenza vaccine in terms of its composition (antigen content, excipients, and adjuvant system, if used), manufacturing and control. The mock-up vaccine is produced in the same way as is intended for the final pandemic vaccine but it does not contain antigen from the actual pandemic strain.
- **As soon as the pandemic starts:** submission and evaluation of the data for replacing the strain in the mock-up vaccine with the recommended pandemic strain as a variation to the initial marketing authorisation.

This guidance is based on the following principles:

- The immune responses to a mock-up vaccine containing a strain to which subjects are naïve are used to predict responses to the same vaccine containing an alternative strain;
- The safety data generated with a mock-up vaccine in clinical studies is used to predict the safety profile of the same vaccine construct containing an alternative strain.

In practice, safety and immunogenicity data are generated with the respective mock-up vaccine. These data can be extrapolated to the same vaccine containing the pandemic strain. Supplemental clinical trial data with the new strain are then generated and assessed in a 'rolling review' as are supplemental post-authorisation safety data.

Some of the mock-up vaccines contained adjuvants to enhance the immune response thereby allowing lower doses of antigens to be used. This was in accordance with WHO recommendations regarding antigen-sparing formulations in the context of a pandemic when worldwide influenza vaccine production capacity is limited. The experience from the pandemic showed that the use of adjuvants can help to maximise the available vaccine doses for the EU population in case of high demand.

The rationale of authorisation for the pandemic vaccines is explained in detail in documents published on the Agency's website at the time of authorisation of the pandemic H1N1 vaccines.

Between 2004 and the start of the H1N1 pandemic, four mock-up vaccines had received authorisation in the EU via the centralised procedure.

Guidance was also developed to allow fast-track approval of pandemic vaccines after the start of a pandemic. This 'emergency' procedure reduces the timeframe for the evaluation from 210 days to 70 days.

Fast track variations for centrally-authorized antivirals

The Agency developed specific procedures to ensure the rapid assessment of variations for centrally authorised antivirals, together with a fast communication of the outcome of the assessment.

Pharmacovigilance

Preparedness also foresaw specific pharmacovigilance activities to be carried out by marketing authorisation holders for all pandemic vaccines. These were described in the core risk management plan² which was published prior to the pandemic, and included:

- strengthening the spontaneous reporting systems, e.g. by using alternative channels for reporting (web based) and by defining adverse events of special interest to be closely monitored, such as Guillain-Barré syndrome;
- simplified but more frequent periodic safety update reports (sPSUR), providing a monthly review of safety data received by the marketing authorisation holder;
- post-authorisation safety and effectiveness studies, including a compulsory safety study in 9,000 subjects for each vaccine.

The Agency, its Pharmacovigilance Working Party (PhVWP) and the ECDC also had early discussions regarding the benefit-risk monitoring of vaccines, including protocols for safety and effectiveness studies. This resulted in the publication in October 2009 of the "European Strategy on Influenza A/H1N1 vaccines Safety Monitoring"³.

Similarly, discussions also took place regarding the specific pharmacovigilance activities to be carried out by marketing authorisation holders for all antivirals to be used in case of pandemic influenza (oseltamivir, zanamivir, amantadine and rimantadine), to include:

- pandemic safety reports, targeting specific safety issues and providing a bi-weekly or monthly review of safety data received by the marketing authorisation holders;
- centralised coordination of all safety assessments for pandemic influenza antivirals.

Preparedness activities at the level of the National Competent Authorities (NCAs) were also put in place, in particular regarding the need to process a large number of spontaneous adverse reaction reports. In some Member States, teams dedicated to the pandemic were established.

²

http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000246.jsp&murl=menus/special_topics/special_topics.jsp&mid=WC0b01ac058004bf59&jsenabled=true##

³

http://www.ema.europa.eu/ema/index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500044933&murl=menus/document_library/document_library.jsp&mid=WC0b01ac058009a3dc

3. Outcomes of the Agency's activities during the pandemic

The Agency's preparedness activities since 2003 were extremely helpful. The plan and procedures foreseen during preparedness stood the test of the pandemic. They helped to mobilise quickly the right resources throughout the EU as soon as the Agency initiated its pandemic activities on Monday 27 April 2009. At the early stages of the outbreak, the potential severity of the pandemic was difficult to evaluate. The task of the Agency was to ensure that in the event of the worst case scenario the necessary measures were in place in order to ensure that pandemic vaccines would be authorised for use as soon as possible.

Overall the activities of the Agency achieved their objectives. The Agency, with its committees, working parties/groups and experts drawn from the European Member State network successfully facilitated the authorisation of pandemic vaccines within five months of the identification of the novel virus. The European Commission issued the respective Commission Decisions (the authorisations) of these vaccines in days. It is unlikely that shorter timelines for the Agency's review could have been achieved, taking into account the technical aspects of vaccine production at present. This intense activity over a short timeframe represented a major challenge to the European regulatory network in terms of resources, organisation and co-ordination. The Agency and its network showed resilience, in their ability to commit resources to the pandemic for a prolonged period, as well as in their ability to respond to requests for resource-intensive pandemic activities including pharmacovigilance. Throughout this process, the Agency maintained its strict code of conduct and closely safeguarded the independence of the regulatory system in line with its policy on conflicts of interest.

The Agency kept the public informed about all major procedural steps related to the authorisation and supervision process for pandemic vaccines and antivirals.

The Agency worked closely with relevant partner organisations during the pandemic, both at the European and International level including the World Health Organization (WHO).

The fact that the EU medicines system was able to deliver an appropriate response to this public-health crisis was further evidence of its robustness and good functioning. The results achieved under intense pressure were also due to the sustained commitment and cooperation with the national authorities of the Member States, the EC, and the ECDC.

The achievements are as follows:

3.1. Authorisation of pandemic vaccines

- **Five vaccines authorised**

Three mock-up vaccines were converted to pandemic-influenza vaccines once the A/H1N1 flu strain had been identified: Celvapan, Focetria and Pandemrix. They were granted a variation to the marketing authorisation to introduce the pandemic strain on 29 September 2009 (Pandemrix and Focetria) and 6 October 2009 (Celvapan).

In addition, two vaccines were handled using the 'emergency' procedure: Arepanrix and Humenza and received authorisations in March and June 2010 (outside the timelines of this report).

- **Success of the mock-up concept**

The authorisation of 'mock-up' vaccines was particularly useful as it proved to be the fastest route for the authorisation of H1N1 vaccines in the EU. Clinical trial data for the mock up vaccines were available for adults, with some paediatric data made available at the onset of the pandemic. This implied that there were gaps in data for the use of mock-up vaccines in the specific high risk groups identified for this pandemic H1N1 e.g. data in some age ranges in children and data in

pregnant women. These gaps in the data at the time of the authorisation of the variation to replace the strain in the mock-up vaccine with the recommended pandemic strain led to some limitations in the early recommendations for use of the H1N1 pandemic vaccines. Further data were submitted subsequently in a phased manner as part of the 'rolling review' process. This enabled clarification of the conditions of use of the vaccines within a few weeks of authorisation.

- **Interaction with pharmaceutical industry**

The Agency had interacted with the pharmaceutical industry in the preparedness phase to ensure that the necessary requirements were clearly understood in advance so that they could be easily implemented in the event of a pandemic. This ensured that pharmaceutical companies were able to deliver the required information for the variation to convert the mock-up vaccines into pandemic vaccines. This contributed to the successful, timely authorisation of pandemic vaccines. It also ensured that the translations of the product information were available in 23 EU languages in a format suitable for publication within an accelerated timeframe (within a few days of the adoption of an opinion).

- **Effectiveness of the vaccines**

All pandemic vaccines were authorised on the basis that they demonstrated a satisfactory immunological response in clinical trials, which is taken as an indicator of efficacy. The positive efficacy of these vaccines was confirmed during clinical trials following the introduction of the pandemic strain. The benefit-risk profile of the centrally authorised pandemic H1N1 vaccines was adequately assessed, in accordance with procedures agreed years in advance of the pandemic. Effectiveness however, could only be monitored during use of the vaccine. Additionally the independent ECDC-led effectiveness studies (reported after the cut-off dates for this report) confirmed the high level of effectiveness of these products.

3.2. Antivirals

- **Extension of shelf-life for oseltamivir and zanamivir**

In May 2009, the CHMP recommended an extension of the shelf-life for oseltamivir capsules (Tamiflu) from five to seven years. In parallel and in accordance with the Mutual recognition procedure, the shelf-life of zanamivir powder for inhalation (Relenza) was also extended from five to seven years.

- **Use in at-risk populations**

Between May and September 2009, the CHMP issued guidance on the use of oseltamivir in at-risk population such as children under one year of age and pregnant and breast-feeding women. The Committee provided dosage recommendations in children for both treatment and prophylaxis in the pandemic, as well as instructions for the extemporaneous preparation of a suitable oral solution from the capsule formulation. The Committee also reviewed data on the use of oseltamivir in pregnant women and concluded that the medicine could be used in pregnant and breastfeeding women in the context of a novel influenza (H1N1) in a pandemic situation.

- **First EU Compassionate Use procedures**

In early 2010, the CHMP handled the first European Compassionate Use procedures under Article 83(3) of Regulation (EC) No 726/2004 for the use of the intravenous formulations of oseltamivir and zanamivir in critically ill adults and children over one year of age with a life-threatening condition due to suspected or confirmed pandemic H1N1 infection.

3.3. Pharmacovigilance

- The European pharmacovigilance system was effective for monitoring the safety of A/H1N1 vaccines and antivirals. It coped with a sudden increase in the number of spontaneous adverse reaction reports and rapidly provided high quality information to support detection and evaluation of potential safety issues.
- As soon as the vaccines were authorised and used, all manufacturers supplied simplified PSURs as per agreed schedule. Appropriate post-authorisation safety studies were also agreed.
- Spontaneous reports of adverse drug reactions were received in EudraVigilance in a timely manner, and a EudraVigilance Reaction Monitoring Report⁴ was produced by the Agency and transmitted on a weekly basis to all Member States (MSs), providing NCAs with a European perspective for the interpretation of their data.
- A Pandemic Pharmacovigilance Rapid Response Expert Group (PREG) was established to assess safety signals on a weekly basis, respond to concerns of MSs and advise on communication.
- The EU Rapid Alert and Non-Urgent Information systems were used by NCAs to quickly communicate safety concerns based on adverse reactions reported on their own territory. These safety concerns were immediately addressed by the PREG.
- Pharmacovigilance information was published on the Agency's website, including update reports (see below). In addition, many NCAs created a website dedicated to the pandemic, providing information on adverse reactions and links to useful websites.

3.4. Communications

The Agency provided information about its activities with regard to the management of the H1N1 pandemic influenza during all major steps of the process, starting with the posting of the first pandemic-related news item on its website on Wednesday 29 April 2009.

Scientific information about the pandemic and the use of pandemic vaccines and antivirals in the population was initially very limited, but developed rapidly as the situation evolved. During the early stages of the pandemic situation the Agency's communications activities were focused on antiviral medicines. From July 2009 onwards, the assessment of pandemic influenza vaccines took centre stage. New information was provided in the form of explanatory scientific documents⁵, press releases, question-and-answer documents and news items published on the Agency's website.

Dealing with a high degree of uncertainty during the pandemic was a challenge faced by all involved in the management of the pandemic. The Agency operated in a context where there was a great need and an expectation for clear public health recommendations e.g. in relation to the use of these medicines in children and in pregnant women, or to dosing recommendations. At the same time, the nature of the "rolling review" implied that information was submitted and assessed as it became available. Consequently the CHMP had to adopt careful scientific recommendations during early stages of the evaluation process, which did not always fully meet the expectations of stakeholders

- **Micro website**

From 26 September 2009, the Agency had a dedicated micro website, flagged prominently on the

⁴ The Reaction Monitoring Report (RMR) contains frequency tables of all adverse reactions for all A/H1N1 vaccines authorised in the EU via any route of authorisation. In addition, the RMR collects serious suspected unexpected reactions related to the pandemic investigational vaccines. These reactions are included in Individual Case Safety Reports (ICSRs) transmitted to EudraVigilance by NCAs, marketing authorisations holders and sponsors according to their legal obligations.

⁵ http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2009/11/WC500007567.pdf
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500019325.pdf

entry page for the duration of the peak pandemic activities, designed to provide direct access to all of the Agency's news, but also to detailed background information in a public-friendly manner about the role of the Agency in the management of pandemic influenza as well as the regulatory procedures for the authorisation and supervision of vaccines and antivirals. The micro website was well used, with the number of visitors peaking in November 2009 (ca. 50,000 hits on the most popular page).

- **Product information**

The product information for each vaccine, in all official EU languages, was accessible within two clicks from the Agency's home page. The Agency implemented a process for instant publication and continuous update at the time of opinion, ensuring that it remained the point of reference for the most up-to-date product information for doctors and patients throughout the EU. Furthermore changes to the product information following variations were also published at the time of opinion, allowing users of the website to see clearly how the product information was evolving as more data were assessed by the CHMP through the rolling reviews.

In addition, the Agency also accelerated the publication of European Public Assessment Reports (EPARs) for all pandemic medicines to provide continuous information on the scientific rationale of its opinions.

- **Pandemic pharmacovigilance updates**

Between December 2009 and August 2010, the EMA published a pandemic pharmacovigilance update on its website (on a weekly basis, then bi-weekly after March 2010) providing estimates of exposure, a summary of the pharmacovigilance data available in EudraVigilance and conclusions of signal reviews. These documents provided information about adverse drug reaction reports and their assessment by the Agency with an unprecedented level of transparency and openness.

The pharmacovigilance update reports proved to be a very effective tool for the Agency to deal with concerns around the safety of pandemic vaccines and antivirals. Once the reports were made available, almost all safety-related questions received by the Agency could be responded to on the basis of the reports.

- **Early Notification System**

The Agency made efforts to inform its partners in the European Regulatory Network, as well as the European Commission and its international partners in advance of the publication of the communications materials using its internal 'Early Notification System'⁶, normally in the week before the CHMP meetings were held. The Early Notification System included for the purpose of the pandemic: European Commission (DG SANCO, DG ENTR), ECDC, NCAs for medicines regulation, World Health Organization and non-EU Regulatory Authorities such as Swissmedic, US FDA and Health Canada.

⁶ The Early Notification System was introduced by the Agency in 2008 to facilitate the coordination of safety-related information on medicines across the European Medicines Network, it is described in POLICY/0033, available on the Agency's website in [About us > How we work > Policies](#).

4. Lessons learned

The 2009 (H1N1) influenza pandemic tested the preparedness plans previously put in place, and the Agency has learned from its activities.

The key lessons learned are as follows:

Lesson learned 1 – preparedness

The preparedness plan needs to be adjusted. While it was successful in facilitating the availability of pandemic vaccines, there are a number of areas for improvement:

“Mock-up” approach

- The mock-up approach should be reviewed to allow more flexibility so that it does not rely solely on the announcement of WHO pandemic phase 6, but also caters for different pandemic scenarios with different levels of severity (subject to the availability of appropriate severity indicators). The chosen approach should have built-in review mechanisms to facilitate adaptation as more data on the disease, target groups and severity, become available. It is also clear that in the future, the Agency plan should incorporate appropriate trigger points that link to WHO phases (both pre and post pandemic). The Agency plan should also be revised to continue to be complementary to any revised WHO pandemic guidance and any appropriate European guidance, as required.
- The strategy employed should ensure greater availability of data on different potential pandemic influenza strains in all probable target groups for vaccination, with adjuvants as necessary. Although it is accepted that the pandemic vaccine strain would be new, knowledge of the immune response to different strains in various target groups would allow better prediction of the best design for the appropriate vaccine with the pandemic strain thereby facilitating dosage recommendations before clinical trial data using the new strains become available. There is a recognised gap between providing clear and definite messages on the conditions of use and the availability of complete data on the pandemic strain in all target groups. The above measures should reduce this gap and facilitate better recommendations even in this interim phase.
- Mechanisms that can further accelerate authorisation of pandemic vaccines should be implemented targeting in particular better coordination of the supply of strains and reagents; standardisation of clinical trial protocols to ensure timely initiation of trials and earlier data availability; facilitation of ethics approvals, which are locally managed in the EU, particularly for the conduct of studies in children and pregnant women.
During a pandemic, earlier availability of data on the virus strain, disease severity, innate population-based immunity to the new strain and cross-protection of seasonal/ other influenza vaccines is also necessary to direct the choice of vaccine and vaccination strategy. Discussion with ECDC and WHO is necessary to understand more clearly how this may be achieved.

Further to the review of the mock-up approach, the Agency should, with the EC, review the regulatory framework of the proposed strategy to ensure that the legislative provisions for approval of pandemic vaccines can accommodate the necessary changes and still support rapid issuance of authorisations in a transparent manner.

Operational issues

The Agency should review its day-to-day processes during the pandemic, in particular the way the Agency pandemic Task Force and the PREG operate and their link to Agency committees and other

Working Parties, so they can be optimised. The Agency should also review the processes for handling data submissions from marketing authorisation holders and applicants, and for assessing them in a 'rolling review' (the continuous evaluation of new data), so that they can be modified to maximise the use of the available Agency and partner NCA resources.

Lesson learned 2 – working with partners

The respective roles of the various EU partners: the EC, NCAs, EMA, ECDC and national public health agencies (PHAs), needs to be clarified and clearly communicated. Prior to the 2009 (H1N1) pandemic, the Agency had no established links with the public health authorities in the EU MSs and these authorities had not constituted a primary audience for the Agency. During the pandemic, the Agency communicated with the European PHAs via a group co-ordinated by the EC. Discussion with PHAs on choice of vaccine at specific time points- pre, during and post-pandemic and the respective target groups for vaccination are essential in planning a suitable regulatory strategy.

Communication activities need to be better coordinated among the main EU stakeholders. There is also a need for common approaches, such as vaccination strategies and systems for data collection (number of vaccinated people, vaccine effectiveness, pregnancy registries and background incidence rates of diseases).

A greater involvement of key partners such as the European Directorate for the Quality of Medicines (EDQM) will improve handling of issues connected to the batch release of the pandemic vaccines, vaccine potency testing and review of criteria for the evaluation of immune response to pandemic vaccines.

Establishing an information-sharing agreement with WHO will optimise collaboration and safeguard a closer working relationship for the future. Some bottlenecks in the vaccine-production process are the availability of strains and reagents. It should be discussed with WHO how this might be improved in the future.

It is recommended that a high level of communication is maintained between the EU Regulatory Agencies and other international organisations with whom a confidentiality arrangement is in place in order to build on the good information exchange during a pandemic. This might contribute to more harmonised requirements for pandemic vaccines in the long term.

Lesson learned 3 - communications

The Agency's communication activities were directed towards providing the most up-to-date information to healthcare professionals and patients, however it is unclear if this aim was achieved. Except for the product information, all other available communications documents (e.g. press releases, question-and-answer documents, reference documents) were only provided in English. The way health care professionals and patients can get access to this kind of information in the future needs to be addressed.

Healthcare professionals were identified as key to disseminating reliable information about vaccines and antivirals. The Agency should work closely with its working group of healthcare professionals to explore particular needs and concerns of healthcare professionals and to address those in designing future communications programmes.

The Agency received a large amount of requests to participate in media interviews. The Agency should ensure that it has a pool of appropriately trained spokespersons available who can talk on behalf of the Agency to the media and who can explain in simple terms the activities of the Agency.

Lesson learned 4 - research

Research activities are needed ahead of a novel pandemic into areas such as new technologies and serology assays to measure the immune response to influenza vaccines, into influenza disease itself and into methodologies for efficient detection of safety signals during a pandemic. It is recognised that since these are outside of the Agency's remit, further discussion with interested parties including DG Research, will be necessary to progress this aim.

The establishment and funding of European infrastructure (networks, common methods, data-sharing) for industry-independent studies of the safety and effectiveness of vaccines is an element that requires further consideration.

The potential benefits of building a multinational vaccine collaborative network have been highlighted. It could assess the burden of vaccine preventable diseases and the epidemiology of potential adverse outcomes, quickly evaluate safety signals, estimate the utilisation, benefits and risks of vaccines and promptly evaluate the effectiveness of public health measures.

5. Next steps

Taking into account the lessons learned identified in this report, the Agency is suggesting ways for improving its preparedness in the event of another pandemic. These improvements aim at:

- further reducing the time to authorisation of pandemic vaccines;
- ensuring that more information becomes rapidly available on the prevailing disease and on the immune response in various target groups to vaccines containing such strains;
- optimising the numbers of doses available.

This will best direct the usage of these medicines in a future pandemic.

The EMA has also started the review of its pandemic preparedness plan. The finalisation of this review is dependent on the potential revisions to the WHO and EC Community preparedness plans, as it is important to ensure that the Agency plan remains complementary to these key documents. The main next steps for the Agency are as follows:

- Revision of the scientific and procedural guidelines on the fast-track authorisation of pandemic vaccines which will incorporate review of the mock up strategy;
- Review of the Agency pandemic plan and associated work instructions in line with any revised WHO and EU pandemic guidance;
- Improved collaboration with all European stakeholders (EC, Member States, ECDC, EDQM) and international stakeholders (e.g. WHO)
- Review by the Agency and the CHMP Pharmacovigilance Working Party of the core Risk Management Plan for pandemic vaccines;
- Collaboration of the Agency with the ECDC and Member States to revise the "European Strategy on Influenza A/H1N1 vaccines Safety Monitoring" in the context of a future pandemic taking into account the experience of the 2009 pandemic;
- Discussion with the ECDC on the recommendations related to other activities which imply active contribution from Member States (e.g. vaccine coverage data, immunisation registries, etc);
- Update of the Agency's pandemic communication plan to better define the Agency's role and responsibilities in terms of communication in the context of a pandemic alongside its partners and stakeholders.