



Review of Switzerland's H1N1 immunization strategy

Final Report

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Abstract

In response to recommendations from international bodies the Swiss health authorities had to take a number of actions concerning a possible spread of a high disease severity arising from the H1N1 virus ("swine flu"). The Head of the Pandemic Task Force ("Sonderstab") commissioned an international expert panel in collaboration with Ernst & Young to undertake an evaluation of the preparation and implementation of the Swiss immunization strategy. The review's main aim was to assess vaccination planning, purchase, approval, delivery, distribution, execution and re-utilisation / removal. In particular, implications resulting from the current legal framework, namely the Epidemic Law which is currently in a revision phase, needed to be taken into account. The evaluators were expected to make a contribution to the revision of the law providing recommendations on the basis of their findings. First, it could be observed that the cantonal pandemic plans were not standardized and harmonized. Our review suggests that in the pre-pandemic period the planning, distribution and transportation of pandemic influenza vaccine is exercised on a regular basis and federal responsibilities are strengthened in all these areas. The FOPH should have control over a standardized distribution process from central storage to the Cantons. When procuring vaccines in the future we recommend that the ease of the regulatory pathway should be considered to a greater extent. Furthermore, in order to prevent public confusion a communication strategy should be defined and integrated into the overall pandemic plan assigning a Head of Communication to take the leadership over all communication and coordinate with all stakeholders. Despite some difficulties encountered the Swiss authorities undoubtedly did a good job in handling the events, particularly since neighbouring countries also reported similar difficulties in mastering a situation of uncertainty.

Key words

Evaluation, disease, H1N1 virus, Pandemic Task Force, vaccination strategy, planning, purchase, approval, delivery, execution, Epidemic Law, Federal responsibilities, communication, situation of uncertainty

Mots clés

évaluation, maladie, H1N1 virus, cellule spéciale, stratégie d'immunisation, plan, achat, approvisionnement, exécution, livraison, loi sur les épidémies, compétences fédérales, communication, situation d'incertitude

Schlüsselwörter

Evaluation, Krankheit, H1N1 Virus, Sonderstab Pandemie, Impfstrategie, Planung, Kauf, Zulassung, Lieferung, Durchführung, Epidemiengesetz, Bundeskompetenzen, Kommunikation, Situation der Unsicherheit

Management Summary

Following the declaration of a new pandemic influenza virus H1N1, and based on data coming out of Mexico, international health authorities advised that they could not exclude the likelihood of the spread of a high disease severity arising from the H1N1 virus. It was against this background that Switzerland's health authorities had to take a number of management decisions in response. Faced with the likelihood of the global spread of the H1N1 virus ("swine flu"), Switzerland, as did indeed many other countries around the world, had to take a number of actions to prepare and protect its resident population. Preparations had to be made on the basis of the worst scenario even though at the time the likely degree of severity was unknown. It was only after June 2009 that sufficient data was available to indicate that the disease caused by the H1N1 pandemic virus would be mild in H1N1 infected persons.

The H1N1 virus was present in Switzerland from spring 2009 to early 2010. In response to questions from the Federal Assembly with regard to pandemic preparedness and planning, the General Secretariat of the Federal Department of Home Affairs established a mandate for an evaluation of events. A review of the immunization strategy and its implementation was therefore commissioned by the General Secretary, who was also Head of the Pandemic Task Force. An international panel of experts was constituted to conduct the evaluation in collaboration with Ernst and Young, an international firm based in Switzerland with experience in the evaluation of public measures. The review was asked to focus on issues relating to vaccination planning, purchase, approval, delivery, distribution, execution and re-utilisation / removal. In particular, the aim of the study was to consider how the current legal framework and the proposed revisions to the now out-of-date Epidemic Law helped or hindered the preparation and implementation of the immunization strategy. Timing was imperative as the law had recently been re-drafted and was part-way through the consultation phase. It was therefore expected that on the basis of the review and its findings, recommendations on the proposed revisions could be made and taken into account in final drafting. The contract was signed in January 2010 and a final report was expected by mid April 2010.

The organization and delivery of health services in Switzerland is shaped by its federal political system which is characterized by federal structures comprising three different political levels: the Confederation, the Cantons (26) and Communes. The Federal Office of Public Health is attached to the Federal Department of Home Affairs and is the national authority on public health matters. Responsibility for public health is shared between the Confederation and Cantons; essentially, however, the Cantons are autonomous for the provision and delivery of health services. In the case of an epidemic and in the consequent declared state of emergency, the federal authorities have the legal authority to command and control the medical response (Art. 10 of the current Epidemic Law). This legal framework was obviously one of the factors that influenced Switzerland's response to the H1N1 influenza pandemic.

In hindsight the Federal Council's decision to manage the issues related to the purchase or use of a pandemic vaccine and any ensuing criticisms and difficulties was framed not only because of uncertainties concerning the pandemic's likely severity, but also because the response was dictated by the previous planning and preparations that had taken place before the appearance of the H1N1 virus in

Switzerland. Indeed the limited capacity for producing a pandemic influenza vaccine shaped the planning and purchase policies of many of those countries which had sufficient resources to implement an immunization strategy. As a general lesson it can be concluded that the formulation of an immunization strategy for responding to an influenza pandemic has to take account of a number of factors, but has only a narrow window of time in which to react. Identification of the virus, and ultimately dealing within a timeframe dictated by the requirements of vaccine production, approval, delivery and distribution will always be a race against the speed of the virus's spread.

Because of the threat posed by H5N1 ("bird flu"), the Federal Health Authorities as well as, those of each of the 26 Cantons had established pandemic plans in order to be prepared for the next pandemic. It became obvious during 2009 that these plans were not standardized and harmonized. Logistics issues, especially concerning the packing and re-packing of the vaccines and their distribution from central storage to the Cantons, as well as, strategy plan for the vaccinations at "mass" centres or at the practices of the general practitioners, (GPs) were not adequately understood nor reviewed. Concerning the lack of uniformity of the cantonal plans it can be stated that different plans may be seen as entirely acceptable, as long as they are compatible. At present, a framework is missing in Switzerland that would assure that even if different plans are allowed, all plans should meet certain minimum standards or requirements for interoperability.

Switzerland decided to buy in 13 million doses of vaccines from two suppliers in order to be able to vaccinate 80 % of the population with two doses, as was expected necessary in the beginning of the pandemic. This strategy turned out to be correct, even if only a small quantity was used at the end. The approval of the vaccines bought created major difficulties. The approval of Pandemrix® - the first vaccine available - by Swissmedic, the Swiss regulator, was four weeks late compared to the European regulator (EMA) and diverged concerning the age and other risk groups. This caused a conflict of responsibilities between the three actors involved: Swissmedic, the Federal Commission of Vaccination Issues (EKIF) and the Federal Office of Public Health (FOPH). In the future the approval process for vaccines should get more attention. Thereby, differences between the different actors - FOPH, Swissmedic and EKIF - should be anticipated. In summary, despite the good rational, arguments and management and resulting actions, room for improvement in the area of vaccine purchase could be identified. While making a choice for procuring a vaccine in the future, we recommend that the ease of the regulatory pathway should be considered to a greater extent.

The pharmaceutical companies delivered the vaccine to the central storages of two private companies from where the Cantons could place their orders. The ordering and delivering processes to the Cantons turned out to be a major issue; it lacked central management and coordination. Whereas the FOPH mainly planned with vaccination centres, the Cantons used a heterogeneous system involving mass centres, hospitals, as well as GPs. Communication to the GPs within such a system turned out to be a major challenge. Many actors criticized the FOPH for adhering to their plan to vaccinate in centres for much too long, and for failing to recognize that this discrepancy between Federal and Cantonal planning was crucial. This heterogeneous situation also meant that Pandemrix® needed to be re-packaged, consequently causing further delay.

The review recommends standardization in the distribution process from central storage to the Cantons. It is the FOPH who should have control of this process and

not private firms. For the vaccinations the report recommends a stronger involvement of the general practitioners, as well as an intensified communication between them and the FOPH. As a general recommendation, important elements of the pandemic plan should be exercised on a regular basis.

As a result of the epidemic following a milder course than originally expected and to the low demand for vaccine on a national scale, stock levels both in the Federal and Cantonal reserves remained high. Parts of the unused vaccine doses were renounced, others were provided to developing countries following an initiative launched by the president of the United States, Barack Obama. In addition, Switzerland also signed a contract with Iran to deliver 900'000 doses. The low demand but also limited validity of the vaccine doses (especially Celtura® from Novartis) meant that Switzerland currently has little option other than to discard all remaining doses in the upcoming months.

In order to raise public awareness, it was decided to adopt a communication strategy based on a worst case scenario. In line with WHO's reports on the escalation of the pandemic (phase 2/3/4/5/6), this strategy was justifiably the right choice. But due to the lack of coordination between the various stakeholders, within a relatively short time the messages became confused. The delay in the delivery of the vaccine and the extensive academic discussions which took place about "which vaccine for whom?" were at the heart of this confusion. To complicate matters even further, the escalation phase then turned into a de-escalation phase; clear, credible communication became close to impossible. In the future, a communication strategy should be defined and integrated into the overall pandemic plan assigning a figurehead who should take the leadership over all communication (e.g. chief communication officer of the Pandemic Task Force) and coordinate with all stakeholders. Communication has to think ahead, but never to act ahead of the facts. Therefore, planning has to consider three levels: mild, medium and severe.

With regard to the legal framework, our review recommends strengthening federal responsibilities for planning, distribution, and transportation of a pandemic influenza vaccine and the oversight of how best to provide vaccination services to the public. This should happen within the pre-pandemic period. The Federal Agencies must be given the authority to set and assure standardization of essential elements of pandemic plans and implementation throughout the country.

An international comparison of the challenges and events encountered in the UK, Germany and France completed the analysis. Due to uncertainty about virus severity, most European countries (including Switzerland) justifiably decided to set the amount of vaccines purchased based on a worst case scenario. Similar problems to those noted in Switzerland with regard to the management of the vaccination strategy were also observed in these three countries, irrespective of their differing political systems or organization of public health. In particular, all countries reported difficulties in planning and taking decisions as well as in managing communication in a situation of uncertainty.

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Index of abbreviations

Art.	Article
cf.	compare
Dept.	Department
e.g.	for example
EDI	see "FDHA"
EKIF	Federal Commission of Immunization Issues
EMA	European Medicines Agency
EpiG	see "EpiL"
EpiL	Epidemic Law
FDA	Food and Drug Administration
FDHA	Federal Department of Home Affairs
FOPH	Federal Office of Public Health
GDK	Cantonal health directors' conference
GP	General practitioner
GS EDI	General Secretariat of the Federal Department of Home Affairs
H1N1	Pandemic influenza subtype / "swine flu"
H5N1	Pandemic influenza subtype / "bird flu"
HMG	Heilmittelgesetz, „law of therapeutic products"
JCVI	Joint Committee on Vaccination and Immunization
M	million(s)
N	number
NHS	National Health Service
PEI	Paul-Ehrlich-Institute
UK	United Kingdom
WHO	World Health Organization
SANKO	Sanitätsdienstliches Koordinationsgremium (Health Service Coordination Group)
Sonderstab	Pandemic Task force

1 Introduction

1.1 Mandate and scope of the project

Principal / Trigger of evaluation	<p>The presence of the H1N1 influenza pandemic in Switzerland from spring 2009 till the beginning of 2010 posed an enormous challenge to both federal and cantonal authorities. In order to gain a clear understanding of the strengths and weaknesses of the immunization strategy, and in response to a number of questions raised earlier in the Federal Assembly, in early December 2009 the General Secretariat of the Federal Department of Home Affairs (FDHA) mandated an evaluation of the H1N1 immunization strategy. The study was consequently commissioned by the General Secretary, who also presided over the Pandemic Task Force (Sonderstab Pandemie, GS EDI) and in agreement with the Cantonal Health Directors' Conference (GDK). The Evaluation Unit at the Swiss Federal Office of Public Health was charged with developing the evaluation's terms of reference, assuring the study's scientific quality and managing the contract. It reported directly to the head of the Pandemic Task Force on all matters concerned with this mandate.</p> <p>The evaluation's main objective was to assess the preparation and implementation of the immunization strategy, as an integral part of overall pandemic preparedness, with a view to gaining recommendations for improvements. In particular, given that revisions to the now outdated Federal Law on Epidemics were in hand, it was hoped that the evaluation would highlight any gaps and/or needed modifications to the drafted revision.</p>
Agent	<p>A panel of international specialists was constituted and charged with leading the technical aspects of the evaluation in collaboration with Ernst & Young, a Swiss based international consultancy firm, experienced in the evaluation of public actions.</p>
Scope	<p>Due to time restrictions and in line with the specifications from the principal the evaluation pragmatically focused on the following main areas:</p> <ul style="list-style-type: none">• How is the planning and implementation of the H1N1 immunization strategy in Switzerland assessed under the current conditions (such as Epidemic Law, federal system) from different actors and experts?• What implications can be derived regarding an optimization of the vaccination strategy and its implementation?• What went well, what went worse, what could be done better and what could not have been foreseen?• The following areas are in the spotlight: Communication to the public, purchase and financing of the vaccine, efficiency of approval process, storage and distribution of the vaccine; segregation of roles and responsibilities, as well as, communication between all actors involved.
Methodology	<p>The evaluation methodology used both quantitative and qualitative data in its documentary analysis, interviews and case studies of 5 cantons. Also included was a comparative analysis of Switzerland's immunization strategy and its implementation with that of a selected number of neighbouring countries.</p>

1.2 Project organization

Project management and field work were performed by Ernst & Young. Members of the international expert panel provided technical direction and input to the study, and were closely involved in all the relevant project phases, (c.f. chapter 1.4). Their main tasks included

- taking part in key interviews together with Ernst & Young to gain better understanding of the methods used to collect information on the structures and processes that formed the basis of the Swiss response to the H1N1 influenza pandemic
- guiding areas of further inquiry
- reviewing technical and programmatic aspects
- framing conclusions and recommendations

The contractual partner, the Evaluation Unit of the Federal Office of Public Health, was available as a resource to the evaluation team throughout. Members of the evaluation team consisted of the following eight persons:

Evaluation team		
Expert panel	Prof. Jonathan Van-Tam:	Professor of Health Protection (Communicable Disease Control), University of Nottingham, United Kingdom
	Prof. Paul-Henri Lambert:	Retired professor associated with the Centre of Vaccinology in the Department of Pathology and Immunology at University of Geneva, Switzerland
	Peter Carrasco:	Policy Advisor Expanded Program on Immunization World Health Organization (WHO)
	Beatrice Tschanz:	Communication expert, e.g. Former head of Communication, SwissAir Group
	Dr. Kimmo Leppo:	Former Director-General, Health Department, Ministry of Social Affairs and Health, Finland
Ernst & Young	Christian Sauter:	External project leader, Senior Manager at Advisory Public Services, Ernst & Young Switzerland
	Petra Beck:	Member of project team, Ernst & Young Switzerland
	Lauri Meier:	Member of project team, Ernst & Young Switzerland
Client representatives		
Evaluation unit, Swiss Federal Office of Public Health	Dr. Marlène Läubli-Loud:	Responsible for the project, Head of the Evaluation Unit
	Eva Bruhin:	Research associate, Evaluation Unit

Table 1: Composition of evaluation team and involved members from the Federal Office of Public Health

1.3 Project phases

The project was divided into the four phases: project preparation, analysis of current status / country comparison, development of options / areas for improvement and last but not least, the writing of this report. The phases spread over the period from early December 2009 until April 2010 (c.f. Figure 1):

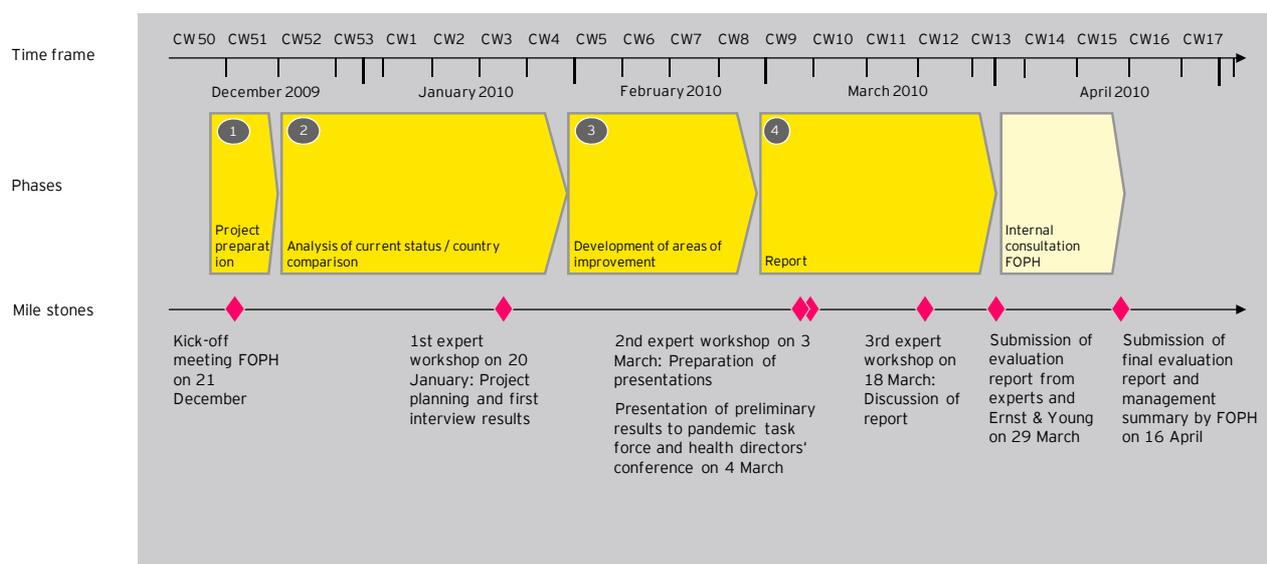


Figure 1: Project phases

The individual phases encompassed the following:

Project preparation

After contract signature, a 'kick-off' meeting was organized by the contractual partners, the Evaluation Unit, to discuss and agree the overall project structure, time frame, roles and responsibilities, organizational issues as well as the next steps.

A workshop was convened in the middle of January at which time the panel of experts met for the first time with the Ernst & Young team. Discussions centred around project planning, the chronology of events in Switzerland, as well as first interview results.

Analysis of current status / country comparison

The current situation with regard to the Swiss H1N1 immunization strategy was evaluated by an initial review of key documents followed by a round of interviews with a selection of key informants. Semi-structured interviews (cf. pro forma interview schedule appended to report as Appendix 2) were then carried out with a number of key persons (N=38) as shown in the table below^{1,2}:

¹ The list of interviewees was defined by the pandemic task force (Pandemie-Sonderstab). The numbers in brackets indicate how many interviews were conducted with members of the corresponding actors.

Federal Department of Home Affairs (2)	
Federal Office of Public Health (12)	<ul style="list-style-type: none"> - Directors - Divisional management - Epidemic law professionals - FOPH Legal advisory Office - Communication
Cantons (11)	<ul style="list-style-type: none"> - Cantonal doctors - Members from Cantonal governments - Cantonal pharmacists - Swiss conference of Cantonal health directors
Swissmedic (2) / EKIF (1)	
Distributors (2)	<ul style="list-style-type: none"> - Alloga - Voigt
Pharmaceutical industry (2)	<ul style="list-style-type: none"> - Novartis - GlaxoSmithKline
Associations (3)	<ul style="list-style-type: none"> - Pharmasuisse - Santésuisse - Swiss Medical Association
Swiss army (2)	<ul style="list-style-type: none"> - Military surgeon - Swiss army pharmacy
Federal chancellery (1)	

Table 2: Interview partners

Development of recommendations and areas for improvement

This analysis was later completed by a more in-depth review of immunization planning, delivery and distribution, packaging and execution in five cantons Zurich, Vaud, Basle City, Tessin and Glarus (case studies, see chapter 4). These five cantons were selected on the basis of several criteria; size, rural/urban and good/difficult experiences. A comparison of the same issues between Switzerland and the experiences in three European countries with similar (federalist) and differing (centralist) political systems (Germany, France and United Kingdom) (c.f. chapter 5) was made to complete the analysis. Members of the international expert panel led the process, took part in a number of key interviews and, based on the data collected, drew conclusions and framed the final recommendations. In particular, during a second workshop between Ernst and Young and the expert panel, recommendations regarding the revision of the Federal Epidemic Law were proposed by the expert panel members and agreed by the team.

Report writing

The preliminary results were presented and discussed with members of the Pandemic Task Force and the Executive Committee of the Cantonal Health Directors' Conference on March 4th 2010. The conclusions and recommendations were then refined thereby permitting Ernst & Young to begin writing up the first draft of the

² "Current" means the level of preparedness in late March 2009 and actions taken since that date up until the end of 2009.

final report. A third and final workshop of the evaluation team was held in mid March for the purpose of reviewing the first draft report, agreeing revisions, and any extra details needed to finalize matters. Before submitting the final version of the report, a draft was submitted to members of the Pandemic Task Force to ensure accuracy of the events presented in the report.

2 Context and legal framework

2.1 Landscape of key actors

Network of actors and supply chain of vaccines

The complexity in the management of the H1N1 immunization strategy arose partly from the high number of actors involved at both federal and cantonal levels. The following graphic shows a simplified picture focusing on the main public and private actors involved, as well as the supply chain of H1N1 vaccines in Switzerland:

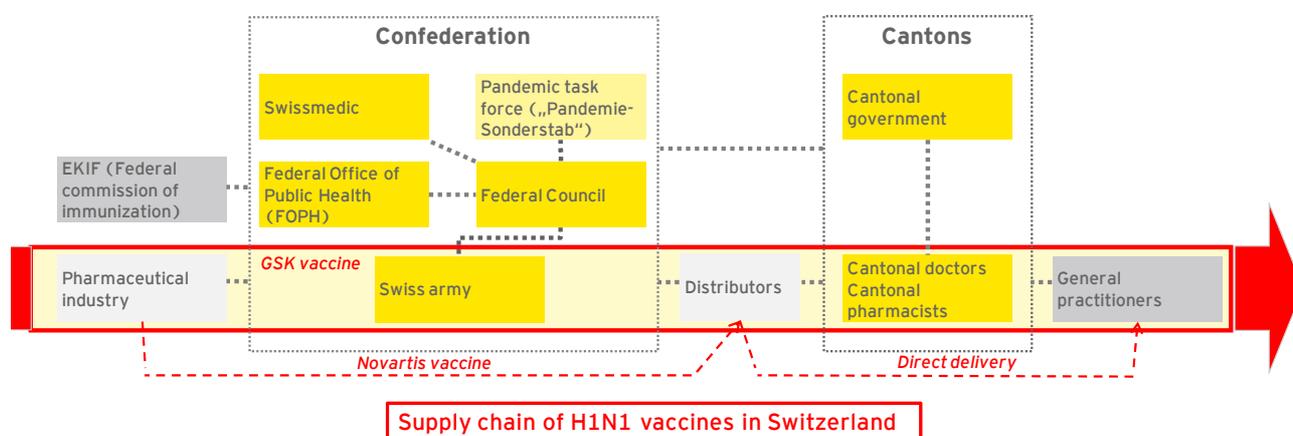


Figure 2: Landscape of key actors and supply chain H1N1 vaccines

Segregation of roles and responsibilities between Federation and Cantons

The Federal political system and structures are a key influential factor in shaping health policy and practice in Switzerland. Consequently this had a strong influence on how the H1N1 pandemic would be and was managed. Based on the current epidemic law, Cantons are responsible for taking the necessary measures to fight a pandemic (cf. art. 11 EpiG) unless Switzerland finds itself in “extraordinary circumstances” in which case the Federal Council can order “other necessary measures” (cf. Art. 10 EpiG). Apart from article 10 of the current epidemic law, the Confederation has to supervise the implementation of the law by the Cantons and coordinate their measures, if necessary. In the case of an influenza pandemic, a special task force (“Pandemie-Sonderstab”) is established to advise the Confederation through the Federal Council.

At cantonal level, cantonal doctors (medical officers) are responsible for implementing the necessary public health measures (cf. art. 12 EpiG) in collaboration with cantonal pharmacists on one side, and general practitioners (GPs) on the other.

Swissmedic / EKIF

The roles of both Swissmedic and EKIF (in German: Eidgenössische Kommission für Impffragen, in English “Federal Commission of Vaccination Issues” also need to be taken into consideration: Whilst Swissmedic is charged with the responsibility for the authorization (licensure) and post-marketing supervision of therapeutic products in Switzerland (including vaccines) by the Confederation, the EKIF)

has been established as an independent, expert panel with responsibility for advising (Federal) authorities on its scientific recommendations concerning immunization (target groups). Private actors (health service providers) are also involved in the implementation of the immunization strategy together with the pharmaceutical industry and private distributors.

2.2 Technical and legislative background

Technical and legislative background

In the planning and implementation of an influenza pandemic preparedness strategy, there are a number of external conditions that will inevitably play a part in shaping a country's response. Whilst these factors are very difficult to influence or control, they must never be ignored.

For example, whereas the planning and implementation of logistics maybe integrated into exercises on federal level, vaccine production cannot be made faster via simulations and trainings. Furthermore, it can only start after a virus has already occurred somewhere in the world. The development of appropriate vaccines or antigens can only take place if the virus is identified. Following on from this, the time required for vaccine production takes several (approximately six) months from the start until the availability of a vaccine; in addition, the time needed for the approval process and licensing of the vaccine, can be significant and must also be taken into account. The approval and licensing processes are complex and many requirements need to be met, especially, for example, adequate clinical testing. In addition there is limited global capacity in place to produce a pandemic influenza vaccine, and because of the nature of the influenza vaccine production process, being mainly egg-based, the number of actual doses is never assured until later on. In short, due to such external factors, all decisions, for example with regard to purchasing or ordering, must be taken in an environment of uncertainty.

In view of the above, therefore, however much an influenza pandemic develops in terms of its severity and spread, it is always a race against time to be able to react promptly, especially with regard to vaccine availability.

3 Key questions: Conclusions and recommendations

Introduction and overview

Many countries including Switzerland started to implement their immunization strategy against H1N1 in spring 2009. Afterwards, suppliers were selected, vaccine was purchased, approved and distributed for immunization throughout the country. Over the course of these actions the pandemic virus started to spread throughout in Switzerland and reached its peak in the first week of December with the highest number of laboratory confirmed cases per week (N=2362). At the same time immunization of large parts of the population took place, but only after the pandemic reached its peak, and markedly later than countries in the European Union.

The findings around the pandemic response will be treated in this chapter process by process. As an overview the following graph should give a first impression on the events in connection with the definition and implementation of the H1N1 vaccination strategy (cf. table below).

The epidemic curve in Switzerland as outlined at the bottom of the graph shows both the number of confirmed cases per week (cf. columns) and the cumulated number of cases (cf. line) in Switzerland.³ The timeline of vaccine purchase and start of vaccination both in Switzerland and in Europe is outlined in the middle part of the graph. On the top, it is illustrated when recommendations of public authorities of Switzerland and other countries respectively WHO were published. For Switzerland, it has to be differentiated between recommendations of EKIF, FOPH and Swissmedic.

³ It should be noted that the epidemic curve in Switzerland differed from the epidemic curves in other European countries. As an example, the first and largest wave in the UK was in June/July 2009, which was well before vaccine was available.

Definition and Implementation of immunization strategies against H1N1 in Switzerland

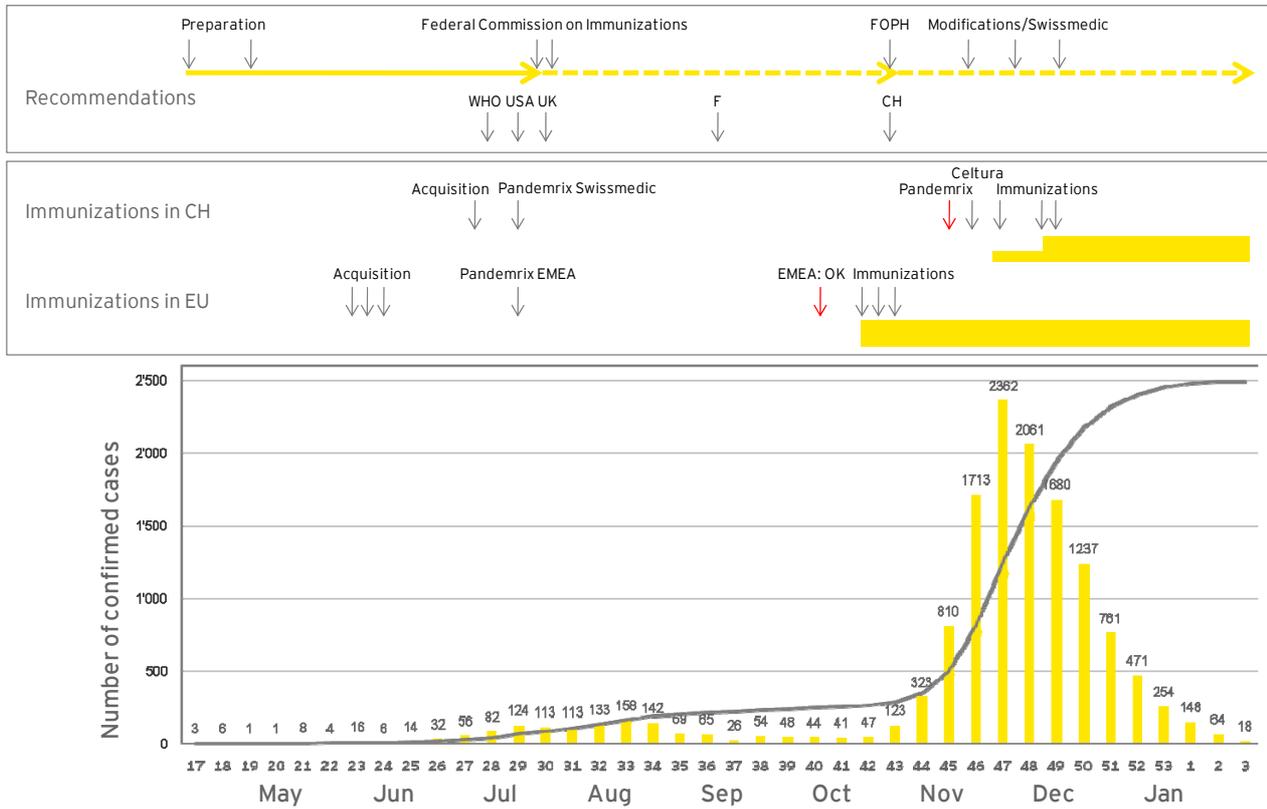


Figure 3: Definition and implementation immunization strategies against H1N1 in Switzerland

Data collection from interviewing key actors

Members from key actor groups were interviewed by using a standardized set of questions. Depending on the role and involvement of a specific actor the interview was further customized to highlight his or her specific function, but room was still left for the interviewee to develop statements about phases and actions in which s/he had less direct involvement.

The first step was to narrow down our research. Six main processes were identified for developing the questionnaire to document the vaccine response by Swiss authorities to the H1N1 pandemic. In addition, important cross-cutting themes were also integrated into the interview plan; therefore, next to the coordination between the Swiss Confederation and the Cantons which was a continuous evaluation theme, emphasis was placed on the fields of communication and the legal environment. A matter of key interest was the nature and quality of communication from the Federal authorities to the public on the one hand, but also to institutional stakeholders on the other hand. As raised before the legal environment has also had important implications on some decisions and processes, e.g. in the context of the segregation of roles and responsibilities between Federation and Cantons. These cross-cutting themes are given separate subchapters in this report (see graphic below). All processes were also examined with a view to developing useful revisions to modify the epidemic law, which will be addressed in chapter 6.

Six main processes and 2 cross-cutting themes were covered in interviews

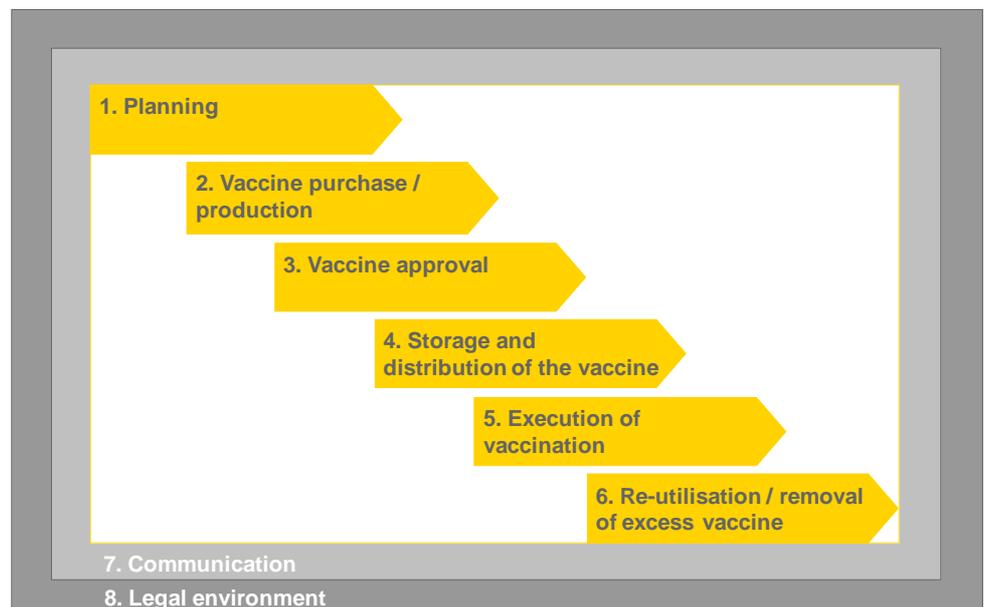


Figure 4: Main processes and cross-cutting themes

Key questions

The following subchapters summarize the evidence found for each phase of the chronology of events during the H1N1 pandemic. A key question was developed for each process.

3.1 Planning

Key Question - Planning: What was the state of planning with regards to vaccination in March 2009?

State of play

Based on available scientific data, the WHO Global Influenza Preparedness Plan, 5/2005 and the International Health Regulations (IHR, 2005) and taking into account the experience made with the H5N1 bird flu virus, the *Swiss Influenza Pandemic Plan* was developed. In general, two phases were integrated. Measures in an early phase focus on identification, characterization and prevention of a new subtype of the influenza virus from spreading. At a later stage, when the virus cannot be contained despite other intervention, the main aim is to limit morbidity and mortality in the population.

At the end of 2008 pandemic plans existed both on Federal and Cantonal levels. The Federal plan was formulated on the basis of the scenario that the H5N1 bird flu virus would be the next pandemic. The Plan consisted of three main parts:

- **General background information and introduction to subject:** Current state of knowledge about microbiological, medical and epidemiological aspects of an influenza pandemic, working hypotheses, pandemic phases according to WHO definitions and possible impacts for Switzerland in the areas of preparing for and controlling an influenza pandemic.
- **Assumptions and derived settings:** Overview on objectives and strategies for each of the six pandemic phases regarding planning and coordination, influenza monitoring, measures relating to health service, use of antiviral drugs and vaccines, communication between authorities and population, as well as, responsibilities.
- **Measures:** Description of preparedness level in early 2009 for central issues such as influenza monitoring, certain aspects of the health system, antiviral drugs and vaccines and communication, as well as, ethics.

The phases in the Swiss plan were formulated on the basis of the six phases defined by the WHO:

- Phase 1/2: Inter-pandemic period
- Phase 3,4,5: Pandemic alert period
- Phase 6: Pandemic period

The Federal plan also provided the basis for the Cantonal pandemic plans, which were then adapted to local circumstances. Planning processes at Cantonal level have to be looked at in the context of the Swiss system of federalism: According to the current Epidemic law, the Federation is charged with the purchase of the vaccines but the Cantons are responsible for ordering from nominated distributors and organizing the distribution within their own territories, using whatever system they consider to be the best solution.

Management / handling of situation

The organization (e.g. of logistics) did not result in much consistency because of Cantonal autonomy and the fact that their plans reflected local circumstances, which vary considerably. For example, in a major Canton this could mean that vaccination centres would be put in place; whereas in some smaller Cantons it had been decided to go with existing structures and use general practitioners (GPs) to perform the immunizations because of financial reasons (high set-up

costs to build vaccination centres). However, small did not necessarily mean “no vaccination centres” as was seen in the example of Basle-City (c.f. case study in chapter 4). This leads to the next point: Some Cantons did not have plans for different scenarios in their “drawers” while others did. Again in Basle-City the two aspects - whether or not to plan with vaccination centres and whether or not to calculate with scenarios - were linked to each other. In an enhanced severity scenario vaccination centres would have opened. Otherwise one would have - and this is what actually happened - stuck to immunizations by GPs. As a further example, different roles and responsibilities of the same functions could be detected: In a small Canton the task of “Cantonal doctor” was in one case fulfilled by a retired GP, whereas in larger Cantons this function typically constitutes a full-time job. However, the differences in planning concern all subsequent processes and will therefore be outlined in more detail in the following subchapters and also in the case studies (c.f. chapter 4).

In this context, it has to be mentioned that the Confederation respectively the Federal Council is authorized to order necessary measures to (all) Cantons in case of extraordinary circumstances (cf. art. 10 epidemic law). However, applying art. 10 of the current epidemic law was not taken into consideration during the H1N1 pandemic because the decision makers determined that the circumstances (the severity of disease and disruption) were not considered as extraordinary, thereby obviating the need to invoke this article. This one decision (which was not taken) had huge ramifications for what happened next.

Conclusions

At the end of 2008 pandemic plans were in place, both on Federal and on Cantonal level based on the experience with H5N1.

For supporting all activities in connection with pandemic planning and response sufficient funds were allocated. For this reason the analysis will not outline this aspect in further detail.

Quality and completeness of the plans differed. Some Cantons - to avoid naming them explicitly at this point (cf. chapter 4: case studies in Cantons) - clearly stipulated different measures as response to different scenarios of severity. For example in terms of prioritization: In case of high vaccine demand first risk groups would be served and then vaccination centres would open for a wider public. Others including the Federation basically planned for the worst case meaning a severe pandemic with a fatal course resulting in many cases of death among the population. The basic idea behind this was “If the worst case can be mastered, so can a mild course”. This assumption did not prove to be totally correct in this case.

The problem was not the fact that the Cantonal plans diverged when compared to each other and to the Federal plan but the implications of the differences in cantonal plans affected the interplay in many areas between them and federal level; this should not be surprising as this is inherent in a federalist system. The problems encountered in processes following the planning phase e.g. in the distribution, may rather be seen as a consequence of a lack of standardization and harmonization of the individual plans. Different plans are acceptable as long as they are compatible. A framework is missing in Switzerland that would assure that even if different plans are allowed, all plans should meet certain minimum standards or requirements for inter-operability. For example Cantons could be forced to guarantee that their plans, whatever they look like, ensure that vaccines can be delivered to doctors responsible for immunizing patients within 24 hours upon arrival of the vaccines in the Canton. The missing Federal authority to coordinate such or other sub-national logistic issues led to a lack of a master distribution

plan (cf. chapter 3.4). In fact at an executive-operational level, an institution (SANKO⁴) exists which could have been assigned to coordinate measures between the Cantons in order to react to the pandemic. In a conference on 19 August 2009 held by SANKO, representatives from the Cantons were asked about a need for coordination but the offer was clearly rejected. The belief was that the vaccination campaign would be mastered by Cantonal authorities without any difficulties.

Further, our research showed that there are varying perceptions on the quality of planning with regard to content and logistics. Content-wise there was a uniform belief that the preparation done by the Swiss Federation was well done. With reference to logistics there is room for considerable improvement.

In summary, there was first a lack of standardization and coordination between the federal and the 26 cantonal pandemic plans (variable quality and completeness). Second, there was no uniform planning for different severity scenarios on Federal and Cantonal level. Thirdly, inter-operability of the various plans had not been adequately tested. The following chapters will discuss these conclusions divided into the main processes vaccine purchase, approval, delivery and distribution, as well as, execution of the vaccination.

Conclusions

- ▶ At the end of 2008 pandemic plans existed both on Federal and Cantonal level based on H5N1 experience
- ▶ Sufficient funds were allocated to support all activities
- ▶ There was a lack of standardization and coordination between the federal and the 26 cantonal pandemic plans (variable quality and completeness)
- ▶ SANKO, a body for coordinating Cantonal measures in fighting the pandemic, was not used by the Cantons
- ▶ Federal authorities lacked the authority and responsibility to manage sub-national logistic issues. This led to a lack of a master distribution plan
- ▶ There was no uniform planning for different severity scenarios on Federal and Cantonal level

Recommendations

From these observations the following recommendations are put forward. Without breaching the system boundaries of the Swiss federalist political system it appears appropriate to strengthen the federal role. We do not say that all decision making concerning pandemic planning should be centralized, however, the Federal authorities must be authorized to set and assure standardization and inter-operability of essential elements of pandemic plans and implementation throughout Switzerland. The actual law allows the Federation to dictate to the Cantons how to organize themselves only if the situation is declared as "extraordinary" such as a crisis (Art. 10 Epidemic law). This may be considered prob-

⁴ SANKO: German abbreviation for "Sanitätsdienstliches Koordinationsgremium". In English no official translation does exist. It might be named "Coordination board for medical services". It is an executive institution of the Delegate of the Federal Council for coordinated medical services.

lematic in two ways. First, the Federation can only do that once the crisis breaks out and not before, meaning in the preparation of it. Second, Article 10 may not be applied in a mild pandemic. In the context of the revision of the Epidemic law, Federal authorities should therefore be given the authority to order / coordinate measures and set standards at Cantonal level even in the case of a mild pandemic and to do so not only at the outbreak of a pandemic but already before in the preparation / planning stage (in effect at all times). Given the low level of severity, the Cantons did not see the need to engage SANKO. However, as a general lesson it should be noted that coordinating measures between Cantons is important irrespective of the level of disease severity. Giving SANKO a more active role even in this mild pandemic could therefore have eased some difficulties related to coordination.

Recommendations
<ul style="list-style-type: none"> ▶ The Federal agencies must be given the authority to set and assure standardization of essential elements of pandemic plans and implementation throughout the country from the planning stage onwards ▶ In the future SANKO, as a coordinating body on Federal level, should be used more actively, even if disease severity is low ▶ Establish scenarios in the pandemic plan in relation to disease severity and how this would impact on vaccine distribution and by public acceptance ▶ Exercise essential parts of pandemic plan (e.g. distribution and communication) concentrating on inter-operability

3.2 Vaccine purchase

Key Question - Vaccine purchase: Did the Swiss Government buy the right amount and the right kind of vaccine for a reasonable price?

State of play

The Swiss Federation knew that prevention measures would have to be strengthened and considered the purchase of vaccines when first H1N1 cases of death were reported from Mexico / North America. Decisions about the timing and the amount of vaccine purchase had to be made in a situation when severity about the course of the pandemic was still uncertain (early summer 2009). That 'time' as a factor can be crucial was a lesson learned from the influenza pandemic of 1918. The so-called "Spanish flu" of the subtype H1N1 initially developed mild (in Spring 1918) and then suddenly changed its course drastically (in Autumn 1918) bringing millions of people to their deaths.

As for the selection of vaccine producers, Switzerland had had a contractual relationship with GSK already before April 2009 concerning H5N1 bird flu vaccines.

Management / handling of situation

Swiss government purchased the following three types of vaccines.

- ▶ Pandemrix®: produced by GSK, egg-based vaccine
- ▶ Celtura®: produced by Novartis, cell-based vaccine
- ▶ Focetria®: produced by Novartis, egg-based vaccine

Taking into account the time factor and effecting an insurance policy against the worst case, it was decided to set the amount of vaccines purchased in such a way that 80% of the Swiss population could be vaccinated with two doses, which meant purchasing a total amount of 13M vaccines.

Regarding the selection of vaccine producers, the first task was to clarify whether the existing H5N1 contract with GSK would also apply to the swine flu (H1N1). A situation with another and milder pandemic had not been discussed as a scenario three years earlier when this contract was signed. On the one hand, it can be argued that Switzerland would have been forced to buy 7.5 m vaccines (antigen and adjuvants) from GSK if contracts were interpreted literally. On the other hand Switzerland and GSK faced a situation that a mild pandemic was simply not dealt with explicitly in the contract arrangements. In the framework of negotiations another option emerged. Since army facilities still held adjuvants on stock which had been purchased by Switzerland in the context of H5N1, it seemed attractive to only buy H1N1 antigen. The reason was that H1N1 antigen from GSK could be used together with the adjuvants already on stock from GSK in order to constitute a H1N1 vaccine. In the end, Switzerland and GSK agreed on the purchase of "only" 8M doses of H1N1 antigen - an offer that was very favourable to Switzerland compared to other countries.

As In the original H5N1 contract, a Swissmedic approval was a set condition by FOPH to purchase the vaccine. However, GSK could not guarantee the effectiveness of its vaccine Pandemrix® at the point of the conclusion of the contract, though was confident because of its previous experience with the H5N1 vaccine.

In addition to the 8M vaccines from GSK, 5 m of vaccines were still needed in order to reach a total amount of 13M. Since it had been decided (sensibly) to reduce the risk of dependency on one supplier, a second source of vaccine had to be secured. In this context, attention has to be drawn to the fact that global demand for vaccines was much higher than supply and therefore very few possible suppliers existed on the market. These considerations led the FOPH to invite Novartis to make an offer. Negotiations led to an agreement that the Swiss Federation would buy 5M single doses of Celtura®. No bidding process was set up. Celtura® was but one of two products on offer from Novartis; and there were other options within Europe (e.g. from Baxter AG).

Conclusions

In summary, we concluded that the dual supplier strategy was correct and given the initial uncertainty on the severity of the development of the pandemic the timing and amount of vaccine purchased was correct.

It is also important to mention that the decision to buy adjuvanted vaccine was - next to the fact that adjuvants had already been on stock - scientifically important. Firstly, because - based on H5N1 data - a better general effectiveness could be expected. Second, these data were available for children below 5 years, people over 65 years and immune-compromised patients. Last, but not least, less antigen is needed and therefore the required amount can be produced faster. This approach was also supported by EMEA and WHO which recommended the use of antigen-saving vaccine formulations.

Given the fact that Celtura® had been submitted for licensure in only a small number of countries (compared with EU central approval for some other products) it might have been anticipated that Celtura® had a greater probability of encountering regulatory difficulties than some other products. This eventually came to pass.

Conclusions

- ▶ Dual supplier strategy was correct
- ▶ Given initial uncertainty on severity:
 - Timing of vaccine purchase was correct
 - Amount of vaccine procured was correct
- ▶ It was a good decision to buy adjuvanted vaccine
 - Better effectiveness expected based on H5N1 data
 - Better effectiveness for children < 5 years , people > 65 years and immune-compromised patients
 - Less antigen needed
- ▶ Regulatory delays might have been anticipated with regard to one of the two initially ordered products (Celtura®) because it had been submitted for licensure in only a small number of other countries

Recommendations

Despite the good rational, arguments and management and resulting actions just described, there is room for improvement in the areas of vaccine purchase. This applies in particular to regulatory aspects. Novartis submitted its product Celtura® in only a small number of other countries for licensure. Thus, experiences with approval processes and outcomes with foreign regulatory bodies were not numerous. Regulatory delays might therefore have been anticipated with regard to this vaccine. While making a choice for procuring a vaccine in the future, we therefore recommend that the ease of the regulatory pathway should be considered to a greater extent. Swissmedic, as the agency for the authorization and supervision of therapeutic products, should be integrated more closely in the decision making for providing advice when selecting potential suppliers and prod-

ucts to decrease the probability of unexpected delays arising in the approval process.

Recommendations
<ul style="list-style-type: none"> ▶ In the future choice of vaccines should be influenced by greater consideration of the ease of the regulatory pathway ▶ Swissmedic should be consulted when selecting potential suppliers and products

3.3 Vaccine approval

Key Question - Vaccine approval: Were the Swiss approval procedures for the vaccine adequate to the situation?

State of play

Swissmedic operates on the legal foundation set in the law of therapeutic products (Heilmittelgesetz, "HMG"). The institute endeavours to ensure that authorized therapeutic products are of high quality, effective and safe. A request for approval should assure that these requirements are fulfilled by providing Swissmedic with adequate results from clinical tests.

The current legal framework does allow Swissmedic to adopt an approval decision from foreign regulatory agencies with similar pharmaceutical product controls (Art. 13 HMG), however this is only true, if at the same time Swissmedic is not itself reviewing the same product for approval.

Management / handling of situation

In view of the decisions of Swissmedic and the European regulatory body EMEA, marked disparities were apparent between the time lines for licensure and product indications (for pregnant women and by age), as outlined in the table below:

	Pandemrix®		Focetria®		Celtura®	
	EMA	S'medic	EMA	S'medic	PEI	S'medic
Coverage	≥ 6 months incl. pregnant women	18 - 60 years, without pregnant women	≥ 6 months incl. pregnant women	≥ 6 months incl. pregnant women	≥ 6 months incl. pregnant women, 2 doses	≥ 3 years incl. pregnant women, 2 doses ≥40 years
Submission of application	31 Jul 09	31 Jul 09	31 Jul 09	No submission	n/a	n/a
Date of approval	30 Sep 09	30 Oct 09	30 Sep 09	30 Oct 09 (article 13)	2 Nov 09	13 Nov 09
Amendments		18 Nov 09: OK ≥ 60 years				
		19 Nov 09: Warning for auto immune diseases		20 Jan 10: Warning for auto immune diseases		11 Jan 10: Warning for auto immune diseases
		14 Dec 09: OK ≥ 6 months				

Table 3: Approval decisions in comparison

During the month of October, it became clear that Swissmedic would approve Pandemrix® only for people of 18 - 60 years without pregnant women. In addition, approval of Celtura® took longer than expected. As a result, there was no vaccine for children and pregnant women available at the end of October. FOPH was therefore forced to look for an additional vaccine that could be used for both of these groups and that would be available immediately. It was decided to purchase the vaccine Focetria® produced by Novartis and to apply an accelerated approval proceeding based on Art. 13 of HMG.

The review of information focused attention on the coordination of policy statements regarding vaccine usage between institutions within Switzerland. Specifically it must be mentioned that the FOPH and its advisory body EKIF (Federal commission on vaccination issues) reached different judgments and communicated different recommendations than Swissmedic, which caused confusion of the public.

Conclusions

Although - in contrast to the usual procedure - Swissmedic accepted a rolling submission for the H1N1 pandemic vaccines the licensure as a whole took too long. In spite of this chronology of events, Swissmedic's way of proceeding and its decision making were seen to be complying with the law. An additional observation which caused some confusion, is the fact that an accelerated approval process was not applied for Pandemrix® and Celtura® products, but was to the Focetria® vaccine from Novartis. In addition, no data sharing agreements with larger regulatory bodies, such as EMEA, exists at present which Swissmedic could make use of.

Conclusions
<ul style="list-style-type: none"> ▶ Marked disparity between Swiss and EU time lines for licensure (4 week delay) ▶ Different indications of vaccine use compared to the EU (pregnancy and age) necessitated further purchase of a third vaccine (Focetria®) and caused handling problems (auto immune disease) ▶ Swissmedic lacked experience and anticipation for emergency licensure of pandemic vaccines, this was compounded by an unhelpful legal framework ▶ Lack of established data sharing agreements with larger regulatory agencies ▶ Swissmedic vs. EKIF / FOPH used different considerations in recommending usage of the pandemic vaccines (safety vs. risk-benefit ratio)

Recommendations

In an emergency situation, Swissmedic's licensure procedure as experience during H1N1 might easily be too slow in our view. We therefore recommend that Swissmedic acquires access to expertise and procedures for developing the capacity to regulate and approve the use of pandemic influenza vaccines in emergency situations faster than at present (e.g. rolling submission).

Furthermore, Swissmedic does not have established data sharing agreements with larger regulatory agencies such as EMEA. Such contracts would allow them

to start a dialog at an early stage and would possibly contribute to a faster decision-making process.

As for Swissmedic and FOPH / EKIF, differences between these institutions could have been better foreseen. Swissmedic should therefore improve planning and communication with the FOPH to anticipate national needs particularly related to special indications (e.g. pregnancy and age groups) and identify potential gaps at an earlier - meaning pre-licensure - stage in the vaccine approval process.

If an approval decision is not made in due course and off-label use is expected (auto immune disease, age groups) public communication should only be done by the FOPH and not by Swissmedic. This procedure would relieve doctors from liability especially if doctors are expected to do large-scale vaccinations 'off-label'. Only after relatively time-consuming negotiations did the Swiss authorities choose this strategy.

It should be possible for Swissmedic in a severe crisis to accept the decisions on licensure of a pandemic influenza vaccine by foreign approving bodies, such as EMEA, even if an ongoing approval process is taking place within Swissmedic, and no Swissmedic decision has yet been made. Very recently, on 24 March 2010, the Federal Council decided to change the relevant Therapeutic Products Act. The adaptation ensures a more efficient acceptance process for therapeutic products that are already approved in foreign countries with similar requirements. A new clause regulates the preconditions and the process in the case of simultaneous submissions in Switzerland and abroad. Hence, the initial position with a view to a next pandemic might be different than it had been before the H1N1 pandemic of 2009/2010.

Recommendations

- ▶ Swissmedic should develop (access to) expertise and procedures for emergency cases (e.g. rolling submission)
- ▶ Swissmedic must put in place data sharing agreements with key regulatory partners (EMEA)
- ▶ Swissmedic should improve planning and communication with FOPH to anticipate national needs particularly related to special indications (e.g. pregnancy and age groups) and identify potential gaps at an earlier (pre-licensure) stage
- ▶ When off-label use is expected (auto immune disease, age groups) public communication should be done by FOPH and not by Swissmedic
- ▶ In case of pandemic crisis Swissmedic should be in the position to accept EMEA licensure when FOPH decision to provide vaccination is taken (probably eased by recent decision of Federal Council on the change of Therapeutic Products Act 13 (Art. 13 HMG))

3.4 Vaccine delivery and distribution

Key Question - Vaccine delivery: Did the companies deliver vaccines to Switzerland as contracted?

The two selected vaccine producers GSK and Novartis delivered the vaccine supplies as stipulated in the contracts. Compared to other European countries the delivery was neither faster nor slower in Switzerland.

Key Question - Vaccine delivery and distribution: Did the distribution of the vaccines both from central storage to the cantons and within the cantons work well?

State of play	In contrast to many other countries the Swiss Confederation does not have an operational arm apart from the army. As a consequence, the Federation was not involved in logistics. There was no national distribution plan and Cantons were highly autonomous to organize their ordering, delivery and distribution. Due to this situation the efficient functioning of the supply chain was impeded at some points, as described in the following sections.
Management / handling of the situation	<p>Depending on the delivery system a Canton chose either that GPs ordered directly from the distributor(s) or there were one or more central delivery points in a Canton from where a physician could request vaccine. Hybrid models such as situations where Cantons collaborated with hospitals or wholesalers were equally encountered. According to their own statements, the distributors reported that the various delivery systems in the end was not a large problem, however, they would have preferred to deliver to centralized points rather than to general practitioners individually.</p> <p>The underlying approach used to manage the supply chain was to avoid treating some Cantons in favour of others. Since every Cantonal pharmacist had to order separately not all Cantons or wholesalers could be supplied at exactly the same time. However, our research showed that for Cantons which had in general ordered quickly as they were told the contingents were treated equally by the distributors. Alloga and Voigt tried to suit the needs of all Cantons by preventing a situation where one Canton was supplied with the whole delivery amount first whilst a second needed to wait. Their approach was to supply the Cantons equally with a first shipments and then deliver little by little according to Cantonal situation and orders.</p> <p>Responsibility for the process of distribution from central storage to the Cantons was poorly defined by the Swiss authorities. As a result, the actual responsibility for logistics and distribution on national level was <i>de facto</i> transferred to two private companies.</p>
Conclusions	<p>The Federal plan had foreseen a joint start of the vaccinations in all Cantons: On 9 November for all health personnel and on 16 November for those persons belonging to a risk group. A problem emerged when some Cantons started vaccinating people right after receiving the vaccines not waiting until the official start, which put Cantons adhering to the official start of vaccination under massive pressure (cf. figure p. 40). Questions were raised in the public why a certain (other) Canton would already offer vaccinations, whereas the "home" Canton did not. As a result, "vaccine tourism" - whereby residents from one Canton seek their vaccination from another Canton that was offering vaccination before their home Canton did - developed, which cannot be a desirable state. Given this situation, a strengthened Federal role leading to binding agreements would help to reduce a "vaccine chaos".</p> <p>In addition, delivery was delayed due to the necessity of repacking the GSK vac-</p>

cine Pandemrix® which the vaccine producer delivered in packages of 500 doses or 100 vials (this was common in all European countries using the GSK product). These relatively big lots (Celtura® and Focetria® from Novartis were delivered in lots of 10) would have perfectly suited the needs in case of vaccination centres, however, they were quite impractical facing the situation of a mild pandemic where the use of the routine health providers or structures - namely vaccinations by general practitioners (cf. chapter 3.5) - was the main objective. An often quoted statement from Cantonal representatives was that the necessity of repacking was already known and communicated to the FOPH early, however, this was not considered to be serious a problem early in the planning phase by them. Effort and resources required to repack Pandemrix® into smaller lots were not taken into account and necessary steps not taken in due time. Apart from lost time there was another consequence resulting from repacking. The new, smaller lot needed a new approval by Swissmedic for assuring that all small shipments could be tracked by lot and manufacturer.

Conclusions

- ▶ FOPH did not have a national distribution plan. As a result, not all Cantons / wholesalers were supplied and could start vaccinating at the same time
- ▶ 26 different systems for ordering, delivery and distribution of vaccines impeded the efficiency of the supply chain
- ▶ The responsibility for equitable distribution was ultimately vested in two private companies
- ▶ The effort and resources required to repackage GSK product (Pandemrix®) into smaller lots were not taken into account and therefore there were delays in delivering at all levels
- ▶ Lack of exercising logistic and distribution operations did not permit the authorities at all levels to foresee the complications that could arise from all facets in managing the supply chain

Recommendations

For the future the Swiss pandemic plan should specify that a standardized plan for allocation and distribution is prepared and exercised. Regular training on logistics and distribution operations will allow authorities to foresee complications that could arise from all facets in the managing the supply chain. Exercising any allocation and distribution plan should consider changes in vaccine technology, vaccination strategies and tactics, changes in staff over time (training issues) and changes in authorities, key people and structural changes over time.

Recommendations

- ▶ The revision of the Swiss pandemic plan must specify that a standardized plan for allocation and distribution is prepared and exercised
- ▶ Any allocation and distribution plan should be regularly exercised based

on

- changes in vaccine technology
- changes in vaccination strategies and tactics
- changes in staff over time (training issues)
- ▶ changes in authorities, key people and structural changes over time

3.5 Execution of the vaccination

Key Question - Execution of the vaccination: Impact of differing cantonal strategies?

State of play	<p>As outlined in chapter 3.1 the Swiss Confederation wanted to assure that it would be properly prepared for the worst case, that a severe influenza pandemic would affect Switzerland.</p> <p>Measures taken and the organizational preparation were designed to master this situation. This included the planning to establish the capacity to vaccinate many people in a short time frame. Therefore the establishment of vaccination centres would support the goal of a mass vaccination scenario.</p>
Management / handling of situation	<p>In contrast to what was foreseen in the Federal plan according to the pandemic handbook, some Cantons did not incorporate vaccination centres into their plans. Most Cantons planned to offer vaccinations using both centres and general practitioners. Many actors criticized FOPH for adhering to their plan to vaccinate in centres for much too long, and for failing to recognize that this discrepancy between Federal and Cantonal planning was crucial.</p> <p>In the middle of October, FOPH published official recommendations about who should be vaccinated. First of all, risk groups including health personnel, pregnant women and people in charge of children under six months should be vaccinated. Second, other people willing to be vaccinated should do so under the condition that sufficient vaccines were available. An overall policy of mass vaccination was not recommended (the same as in many other countries).</p>
Conclusions	<p>As for the question if vaccination should take place at vaccination centres or at GPs, both methods have pros and cons. If vaccinations are performed in doctor's practices public confidence and credibility tend to increase. In addition, using the existing channels would help avoid the establishment of extra structures and hence the costs associated with it. Additional personnel would not need to be recruited for providing vaccinations. Recruiting personnel for vaccination centres would have been costly since it would draw health workers from their normal places of work leaving a void at the doctor's practices. Finally it can be argued that when targeted vaccination is intended (identification of high-risk patients) GPs, who know their patients best, are best placed to do this.</p> <p>It was concluded, that in order to be able to respond to a severe pandemic with vaccination centres an emphasis should be placed on the management of surge capacity. Pandemic plans should systematically integrate this topic. In future planning and exercises the use of vaccination centres will legitimize the public acceptance of them as providers of vaccinations. The use of vaccination centres to support a mass vaccination scenario should not be underestimated because of</p>

the ability to provide many vaccinations, more quickly and at a lower unit cost. Centralized points of medical supply would ease the logistic challenge. Furthermore, repacking of large vaccine units, meaning Pandemrix®, would not have been necessary had vaccination centres constituted the only points where patients could obtain an injection. The latter caused handling problems anyway. As GPs preferred single doses, vaccination centres needed larger quantities: Celtura® was packed into single doses and Pandemrix® into multiple vials (10 doses per unit after repacking). Whereas multiple vials would suit the needs of a vaccination centre, general practitioners faced a practical problem. Once a multiple vial of Pandemrix® was opened it had to be used within 24 hours. In some situations this meant a big effort for GPs to find 10 people wanting to get the vaccine in this time frame.

Furthermore, FOPH predicted that there would be a need to offer vaccine in phased priority order as supplies became available, as mentioned above. Our analysis has shown that not all Cantons followed this plan. As in the Canton of Zug for example, all people could get their dose at the same time while in other Cantons the question was raised why this would not be possible here. Therefore, failure to adhere to the phased priority order set by FOPH, caused more confusion.

Conclusions

- ▶ All groups of service providers and pharmacists were not adequately consulted in the preparation of a cantonal pandemic plan to vaccinate the population
- ▶ Surge capacity for mass vaccination was insufficiently planned for at all levels
- ▶ Regular exercising of mass vaccination of the public was not carried out

Recommendations

Members of Cantonal government, as well as, Cantonal doctors and -pharmacists, highlighted the importance of operating within normal structures as long as possible if a pandemic showed a moderate course. Their perception was that “mass vaccination planning was perceived as culturally inappropriate for Switzerland”, in the case of a mild pandemic.

In the present legal framework where Cantons elaborate and organize their own method of vaccinating target groups themselves, it seems meaningful to listen to all groups of service providers and pharmacists in the preparation of a Cantonal pandemic plan for vaccinating their population. There was clear-cut unanimity that the involvement of all stakeholders is crucial to the success of any plan for reaching its goal.

Recommendations

- ▶ The Federal government should lead the development of coordinated Cantonal plans for both mass vaccination (centres) and population vaccination via existing primary care services

- ▶ In both cases relevant groups of service providers and pharmacists should be consulted in the preparation of these plans
- ▶ Surge capacity for vaccination should be planned for at all levels using both systems (GPs and mass vaccination centres)
- ▶ Regular exercising of population level vaccination should be carried out (both systems)
- ▶ In a given crisis situation there should be defined criteria to obtain greater consistency about which model (centres, primary care or both) is best suited to the characteristics of a Canton (e.g. urban vs. rural)
- ▶ In the future, to avoid public confusion, Cantons should not deviate from the vaccination policy of phased priority targeting as set by Federal recommendations

3.6 Re-utilisation / removal of excess vaccine

Key Question - Re-utilisation / removal of excess vaccine: Had Switzerland over-ordered?

State of play	As indicated at the beginning of this chapter, the Swiss Confederation wanted to assure the supply of 80% of the population with two doses of vaccine and therefore purchased 13 M doses in total (cf. chapter 3.2).
Management / handling of situation	<p>What actually happened - or will happen - with the excess vials is as follows:</p> <ul style="list-style-type: none"> • GSK has agreed not to deliver the remaining 1.5 M (Pandemrix®) to the Swiss health authorities • In support of the Obama initiative (cf. Appendix 1, 1.5 M (Pandemrix®) will be delivered by GSK directly to the WHO on behalf of Switzerland • The Confederation still holds a stock level of around 6.8 M • The Cantons are still in possession of some 1.3 M of unused doses • It is estimated that GPs hold a stock of some 500'000 doses • A contract was signed with the Islamic Republic of Iran on 26 January 2010 providing for a donation of 150'000 units (Celtura®) and a sale of 750'000 units (Celtura®).
Conclusions	<p>Resources amounting to CHF 84 M were approved by the Swiss parliament (cf. Appendix 1) in order to purchase the desired quantity of vaccine. As the epidemic turned out to be milder than expected inevitably there was growing public concern about the possible oversupply of the vaccine. Had Switzerland over ordered? However, we should not forget that Switzerland's health authorities had to "insure" its population against the epidemic. The fact that it had to "file a partial claim" in the end was a bonus.</p> <p>Many other developed countries found themselves in the same situation, that is being left with a surplus supply. At this point in time therefore, the possibility of Switzerland's selling off the remaining stock to third parties in the immediate future seems improbable.</p>

To what degree excess vaccine stocks can be sold or passed on is also subject to the validity of the different vaccine types. All Celtura® doses, which are part of the Swiss stock, will have lost their validity by 30 April 2010. An application for prolonging the validity twice, each time for three months, is still subject to approval by Swissmedic. Focetria® expires at the end of 2010, whereas Pandemrix® from GSK is valid for 24 months. But even if a new wave of H1N1 reaches the country next winter current stocks will not have to be used because the future seasonal flu vaccine will also protect against H1N1.

As a consequence of the low uptake and limited validity of the vaccine (especially Celtura® from Novartis), Switzerland currently has no other option than to discard all remaining doses in the upcoming months.

Conclusions

- ▶ High stock levels could not be averted given a decline in demand on a national and global level
- ▶ Validity of the different vaccine types was not an issue during the pandemic. However due to the limited validity of the vaccines and to low uptake, Switzerland has no other option than to discard all remaining doses
- ▶ By supporting the Obama initiative, Switzerland showed solidarity with developing countries

Recommendations

Given a similar situation of uncertainty in the future, we can only recommend that the Swiss Federal Authorities follow the same path as was taken in 2009 - that is ordering in sufficient vaccine doses to protect against a severe pandemic. The risk of people dying because not enough vaccine can be made available weighs much heavier than the possible financial loss of procuring excess vaccine.

Recommendation

- ▶ In a situation of uncertainty, sufficient vaccine doses should be ordered on the basis of a severe pandemic to ensure the population's protection.

3.7 Communication

Key Question - Communication: Was there overall a comprehensive and coherent strategy?

State of play

Several communication aspects were integrated into the Swiss influenza pandemic plan (cf. chapter 3.1)

Management / handling of situation

Initially, communication was consistent, clear and fact oriented. A tremendous effort was made to get the following main message to the public: the H1N1 virus will inevitably come to Switzerland and could lead to a pandemic with severe consequences. Therefore, risk groups can and will need to be protected by vaccina-

Conclusions

tion, and the public needs to take a number of hygiene precautions as a first step.

In order to raise public awareness, it was decided to adopt a communication strategy based on a worst case scenario. In line with WHO's reports on the escalation of the pandemic (phase 2/3/4/5/6), this strategy was justifiably the right choice. But due to the lack of coordination between the various stakeholders, within a relatively short time the messages became confused. Every day the public was confronted with different messages via the TV news and in print media, and from different messengers. Instead of keeping control over what was being communicated, the messages changed from being active and fact oriented to becoming defensive and speculative. "There will be dozens of dead" was one of the official statements - in a phase where at the same time people were being told "to wash their hands properly" (in the national, humorous TV spots).

The delay in the delivery of the vaccine and the extensive academic discussions which took place about "which vaccine for whom?" were at the heart of this confusion. To complicate matters even further, the escalation phase then turned into a de-escalation phase wherein clear, credible communication became close to impossible.

Conclusions

- ▶ Crisis onset: there were impressive communication efforts which raised high awareness among the public
- ▶ Acceleration phase: Lack of overall communication strategy with all the stakeholders involved
- ▶ Pandemic Peak: Loss of credibility in the „Crisis“ phase (e.g. lack of communication coordination between Swissmedic, EKIF and FOPH)
- ▶ Post pandemic peak: Public was confused due to diversity of messages and messengers - loss of motivation for vaccination uptake

Recommendations

A communication plan has to consider various scenarios (escalation/de-escalation) and be broken down into different levels with precise definitions of the respective roles, their tasks and responsibilities.

The safest way to keep the direction and control over communication is to keep to facts only. Speculations are unavoidable, but should be restricted to the domain of the media. Those responsible for communication have to think ahead, but should never act ahead of the facts.

In every crisis there are unforeseen events which in turn pose specific challenges to communication operations. However, with sound planning, sound exercising and well orchestrated coordination, crisis communication can be managed successfully.

A pandemic communication plan has to be established before knowing the likely gravity of the pandemic. Therefore, planning should take into account three levels: mild, medium and severe. Crisis communication planning, however, has to be based on a severe pandemic scenario, thus making coordination with all stakeholders a key element. The strategy should be defined as fast, transparent and simply as possible. Credibility is essential. There is no room for jokes, humour or

fantasy in any of the communication elements.

The lessons learned in and from this H1N1 pandemic can be summarized, as follows: The absence of a comprehensive and coherent communication strategy created confusion resulting in the loss of credibility with respect to the immunization strategy amongst the stakeholders and public alike. To raise awareness about the severity of the problem and gain public confidence in the vaccination strategy, communication needs to be active and never defensive.

Recommendations	
▶	Current influenza pandemic preparedness plan should define a communication strategy as part of the overall pandemic plan. It should:
○	Define the communication hierarchy
○	Nominate the figurehead who should take the leadership over all communication (e.g. chief communication officer of the Pandemic Task Force) and coordinate with all stakeholders
○	Establish a tool for communication between all the various stakeholders (e.g. Cantonal doctors, GPs and pharmacists)
▶	Exercise the communication plan with all stakeholders

3.8 General legal implications

Key Question - General legal implications: Does the current legal framework allow an efficient and effective combat of transmissible diseases?

State of play	The Federal law of 18 December 1970 describes how disease control activities are to be put in place for combating transmissible diseases of humans. This “Epidemic law” is presented and discussed in chapter 6.
Management / handling of the situation	The actual epidemic law is based on combating contagions in the 19th century. In June 2006 the Federal Council commissioned a review of the current epidemic law. The preliminary draft was well received according to feedback from the consultation process. However, the current legal framework ultimately had implications on the events of the H1N1 pandemic.
Conclusions	As it has been touched on in chapter 3.1 the current epidemic law (cf. chapter 6) does not provide the Federal agencies with the legal basis for preparing and overseeing a coordinated and coherent response to a pandemic influenza until it has reached a critical stage. The Federation is not entitled to intervene at an earlier stage where overall pandemic preparedness may easily be suboptimal. We therefore strongly recommend that provisions are made in a manner that Federal agencies are empowered to command, control and coordinate certain aspects of pandemic preparedness at a stage where they can influence the planning and response at all levels. This may affect processes such as vaccine fast track approval, allocation, distribution and communication.

Conclusions

- ▶ Current epidemic law does not provide the Federal agencies with the legal basis for preparing and overseeing a coordinated and coherent response to a pandemic influenza until it has reached a critical stage → This is too late

Recommendations

It is also possible that the authorities at the federal level can influence other areas of the response to an influenza pandemic. As described in chapter 3.4 the Swiss Confederation was not involved in the logistic part of this pandemic. Not least with regard to a severe pandemic in which case it might be advantageous to standardize the delivery of vaccines from a central level to the Cantons. In order to be able to respond to geographical circumstances, Cantons should still be authorized to organize their distribution themselves, but according to agreed national standards. However, transportation of vaccines and related items up to Cantonal borders should be arranged by the Confederation in a consistent manner to maximize efficiency.

In addition, Federal authorities should invest more into pandemic planning before the next pandemic arrives.

Recommendations

- ▶ The Federal Council should make provisions to ensure that Federal agencies are empowered to command, control or coordinate certain aspects of pandemic preparedness (vaccine fast track approval, allocation, distribution and communication) at an earlier stage than currently permitted by the law.

4 Case studies: Cantons

4.1 Overview

Vaccination start

Patients and people wanting to get an H1N1 vaccination were confronted with different start dates depending on the Canton of residence. In the majority of the Cantons health personnel could be vaccinated beginning from 8 to 10 November and individuals from other priority groups / risk groups in week 46 starting on 9 November. For the general population the situation was even more heterogeneous. The difference between the first and last start date is three weeks (cf. table below)

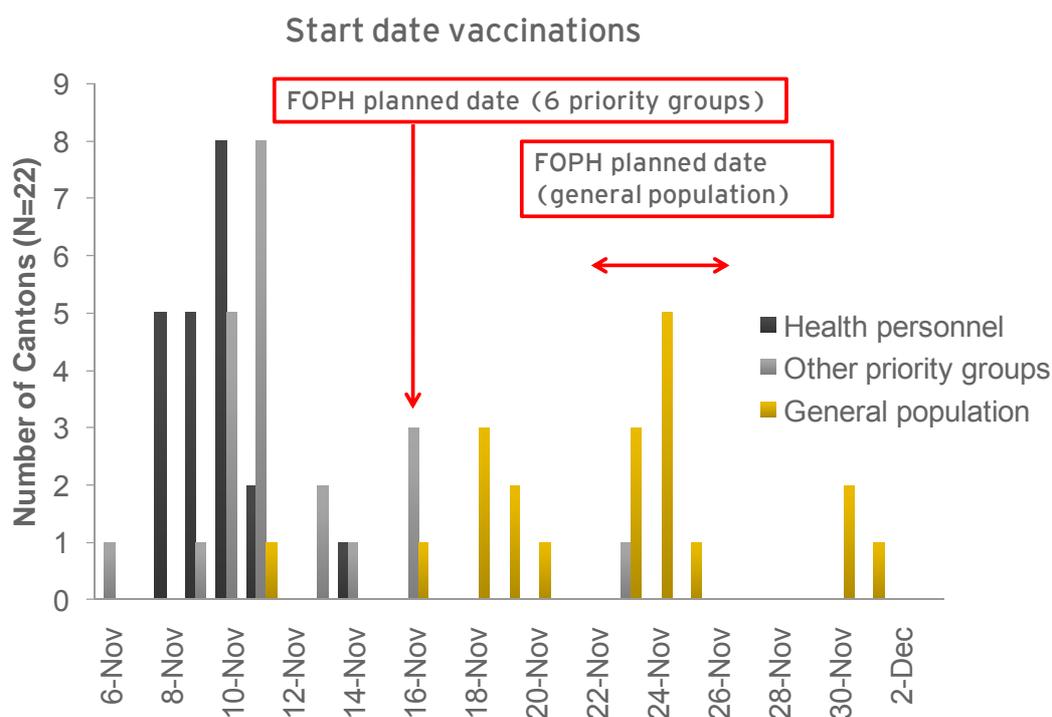


Figure 5: Start of vaccinations

Sample Cantons

In the following section, the responses to the H1N1 pandemic of the five case-study Cantons of Zurich, Waadt/Vaud, Basle City, Tessin and Glarus are examined in more depth. The aim is to highlight the similarities and/or differences in the planning, organization, ordering/delivery and execution phases of the Cantonal plans in Switzerland.

4.2 Case studies

	Canton of Zurich	Canton of Vaud/Waadt	Canton of Basel-City	Canton of Tessin	Canton of Glarus (rural Canton of central Switzerland)
Planning: Scenario planning in place?	Yes. Both mild and worst case scenarios were planned, especially in view of execution of vaccination (GPs and existing vaccination centres in mild case vs. establishing additional vaccination centres in worst case).	Yes. Starting point of planning was a worst case scenario, but the plan consisted of different modules that could be activated according to the severity of the pandemic.	Yes. Vaccinations offered by hospitals, GPs and pediatricians to cover risk groups. Vaccination centres would have been opened if risk groups had already been vaccinated and public demand would have been high enough.	No scenario planning in place (only worst case), which caused problems during H1N1 as the plan had to be adapted to mild influenza pandemic.	No scenario planning. Due to the size and population of the Canton every approach other than keeping normal structures meaning vaccinations done by GPs would not have proved reasonable.

<p>Delivery and distribution: Delivery to GPs, central points or mixed form?</p>	<p>Direct delivery to all GPs and hospitals by distributor</p>	<p>Delivery to both hospitals (respectively to corresponding pharmacies) and two wholesalers (= ordinary system for distribution)</p>	<p>One central delivery point only (University hospital Basle).</p>	<p>One central delivery point only (cantonal pharmacy)</p>	<p>Delivery to six largest wholesalers that were identified by Cantonal pharmacist.</p>
<p>Repacking of Pandemrix® into smaller lots: Done by themselves or by distributor</p>	<p>Done by distributor</p>	<p>Done by distributor and hospital pharmacies</p>	<p>Done by themselves.</p>	<p>Done by themselves as repacking by distributor considered as too expensive</p>	<p>Took place at distributor since too expensive, no adequate cold storage room capacity and personnel difficult to recruit.</p>

Execution of the vaccination: Vaccination centres, GPs or both?	Execution of vaccination within existing structures, which means by GPs and at existing vaccination centres (e.g. university hospital).	Mainly by GPs, but also some vaccination centres were opened.	By GPs only. However, vaccination centres would have opened if demand and severity would have been high enough.	Mainly by GPs. In addition, 2 vaccinations centres for public sector personnel (health personnel, police, administration) were opened.	By GPs only.
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Major findings

A closer look at the situation in the Cantons of Zürich, Vaud/Waadt, Basel-City, Tessin and Glarus highlights the heterogeneous picture already mentioned in section 3. One main difference was the existence or non-existence of scenario planning: Some Cantons took into account different scenarios in relation to disease severity while other Cantons - like the Confederation - only planned for the worst case. As the latter turned out to be inappropriate given the mildness of the epidemic, future pandemic planning should consider different scenarios as well as their impact on vaccine distribution and execution (cf. recommendations key question 3.1). As for delivery and distribution, various systems were used, though only part of the differences can be explained by specific Cantonal requirements. As a result, the efficiency of the supply chain was impeded. A standardized plan and criteria for the allocation and distribution of vaccines is recommended. The problem of repacking the vaccine Pandemrix® was also solved in different ways by Cantons: depending on local capacities and cost considerations, repacking was partly done by Cantons themselves and partly by the distributor. Due to the low severity of the influenza pandemic, vaccination was mainly done by GPs in most Cantons. But there is a consensus among Cantons that also in case of a severe pandemic, GPs must be involved in the delivery of vaccinations and that this should not be limited to vaccination centres only (in particular in view of risk groups).

5 International comparison

In the limited time available for the overall review, the main aim of this part of the analysis was to obtain an overview of the different countries' experience compared with that of Switzerland. A comparison of the main issues addressed in the review of Switzerland's immunisation strategy was therefore made by contacting key persons with a sound overview of events and experiences in each of the reviewed countries. Naturally, the UK description and analysis is much richer and more detailed given that the author is, of course, a member of the expert panel: It places events in context by providing background information on the health system and vaccination policy.

5.1 Case study: Germany

When were the Advance Purchase Agreements (APAs) signed and activated?	<p>The Advanced Purchase Agreements (APAs) were signed in December 2007 with GlaxoSmithKline (GSK) and in May 2009 (Novartis)</p> <p>July 2009: The Health Directors' Conference ("Gesundheitsdirektorenkonferenz") decided to activate the APA with GSK for 30% of the population (50 Mio. Doses)</p> <p>October 2009: Decision to buy vaccines without adjuvants for pregnant women</p> <p>December 2009: Contracts signed with CSL Biotherapies (CSL H1N1 Pandemic Influenza Vaccine)</p>
When were the licences granted?	<p>Pandemrix® by the European Commission on 1 October 2009</p> <p>CSL H1N1 Pandemic Influenza Vaccine by the Paul-Ehrlich-Institute on 25 November 2009</p>
When did the first stocks arrive in Germany?	<p>Calendar week 43 (19 October 2009): Pandemrix®</p> <p>Calendar week 51 (14 December 2009): CSL H1N1 Pandemic Influenza Vaccine</p>
When did Phase 1 start?	<p>Calendar week 44 (26 October 2009): The vaccination program against swine flu begins.</p> <p>Calendar week 51 (14 December 2009): Pregnant women</p>
When did Phase 2 start?	<p><i>Cf. above</i></p> <p>12 October 2009 (Phase 1): Vaccination recommended for 1) Health personnel, 2) People at high health risk, 3) pregnant women</p> <p>3 December 2009 (Phase 2): Vaccination also recommended for children and young adults from 6 months up to 24 years</p> <p>In general, the whole population (children above 6 months) should have the possibility to be vaccinated.</p>

What were the main challenges encountered? (*Official evaluation still in process at the time of writing*)

Lessons learned (*Official evaluation still in process*)

5.2 Case study: France

When were the Advance Purchase Agreements (APAs) signed and activated?	On 15 July 2009 the Health Minister ordered 94 million vaccines from GSK, Sanofi and Novartis.
When were the licences granted?	Pandemrix® and Focetria® were approved on 25 September, Celvapan® on 6 October and finally Panenza® on 16 November.
When did the first stocks arrive in France?	On 27 August 12 000 doses of Celvapan® were provided (under embargo). More than two months later - on 9 October - France received its first doses of Pandemrix®.
When did Phase 1 start?	Vaccinations for health personnel were launched on 20 October 2009. Vaccination centres opened their doors for immunizing the general population on 9 November.
When did Phase 2 start?	As a result of a very high demand for vaccination, on 30 November 2009 the French government increased its efforts to offer vaccination On 1 December 2009, the French Prime Minister held a press conference to stress the government's commitment to reinforcing vaccination deployment.
When did the <i>Comité technique des vaccinations</i> make their Phase 1 and Phase 2 recommendations?	Health care professionals at risk were advised on 7 September. On 28 October it was communicated that one dose would be sufficient in general. At the same time different categories of patients, such as pregnant women, young children, the immune suppressed patients etc. were given specific recommendations. The recommendations were supplemented on 27 November by specific advice for the allergic- and haemophiliac patients.

What were the main challenges encountered?

- ▶ Decisions had to be taken in a situation of uncertainty, forcing authorities to adjust their response; however the consequences of these adjustments were not well understood. The fact that official predictions regarding the severity of the epidemic were not ultimately confirmed resulted in undermining the health authorities' credibility.
- ▶ The fact that vaccine availability was incremental over time required priority setting. Given the uncertainty of the severity of the ongoing pandemic, priorities had to be determined based on epidemiological data. However, priority setting, which meant identifying and contacting the priority groups, gave rise to a number of logistical problems.
- ▶ Availability of the vaccines, the capacity to vaccinate (due to supply) and willingness to be vaccinated (level of demand) varied over time and in different ways. As a result, vaccination centres were overcrowded at first and empty in a second phase.
- ▶ The decision to organize the delivery of this vaccination outside the structures normally used for more than 80% of vaccinations made it difficult to engage medical staff in this public health activity.
- ▶ Given the uncertainties over the vaccines, their effectiveness and tolerance, experts / public health authorities were reticent to comment. This communication void left the space for traditional opponents of vaccination to fill the gap and dominate the field, using mainly online communication channels.

Lessons learned

- ▶ A communication strategy has to be planned ahead, and particularly for dealing with fluid situations, must include:
 - Ensuring that political decision makers and experts are communicating with the public and the stakeholders in the right place and at the right time
 - Identifying measures and messages for responding to experts who provide contradictory information
 - Monitoring the internet and identifying how, and when to respond to disinformation
- ▶ The role of expertise in an emergency situation has to be considered: A balance between the need for recommendations based on scientific evidence (which is often lacking in such situations) and the putting into practice of feasible measures has to be established.
- ▶ Planning for a mass vaccination campaign has to be revised. A rigid system relying only on one single modality not changing over time may not be appropriate.
- ▶ The position of GPs as the link between measures recommended by public health authorities and public acceptance seems crucial. No large public health intervention can be put into place without the concurrence of the medical community. An analysis has to be made about the reasons of GPs' current distrust towards recommendations of public health authorities and about elements that could encourage general practitioners to

commit themselves to accept public health activities.

5.3 Case study: UK⁵

Context

The UK has a centrally coordinated health system although GPs are in fact private (self-employed) doctors who contract with the government to provide General Medical Services to the population. Financing is almost entirely via central taxation with very few charges indeed for end-users, and generally limited to around (CHF 20) per medicine prescribed. Vaccination policy at all ages is always determined centrally based on recommendations from the Joint Committee on Vaccination and Immunization (JCVI) - analogous to EKIF in Switzerland, which are subsequently endorsed in almost all cases by the UK Department of Health and the Secretary of State for Health (central government), subject to finances being available. Once ratified at this level, all such vaccines are then totally free to UK residents under National Health Service arrangements (excepting travel vaccines which are usually paid for by the patient). Childhood vaccines are centrally purchased by the Department of Health, stored in state warehouses and distributed to GPs and clinics by a single (private) distributor. GPs are then paid by government for giving the vaccine and for meeting set uptake targets. In practice, very few GPs actually give vaccines personally and this task is devolved to vaccine trained nurses who are employed in every GP surgery.

Paradoxically, adult (elderly) and travel vaccines, e.g. seasonal influenza vaccine are not subject to these arrangements. Instead, GPs purchase these privately from manufacturers or distributors and upon administration to the patient may claim back from the Government the cost of the vaccine, plus fees for handling and administration.

Thus, influenza vaccines are normally purchased privately by GPs using non-centralised mechanisms (followed by central reimbursement); but during the pandemic of 2009 the arrangements normally used for childhood vaccines were also used for pandemic vaccine, e.g. direct government bulk purchase of specified products, and government controlled distribution to end users.

The UK pandemic plan discussed the use of both mass vaccination centres and GPs for delivery of pandemic vaccine. Primary Care Trusts (the nearest equivalent to Cantons) were requested to ensure that adequate local arrangements were in place to enact vaccination. The potential role of both centres (staffed by GPs and related staff) and GPs (working from their own premises) is explicitly mentioned in the plan without there being a firm commitment to one system.

This context means that the UK is well used to centrally organized and controlled vaccination programmes (for children at least). It has previously undertaken several mass vaccination campaigns (in children, e.g. Hib catch-up campaign, Meningococcal group C catch-up campaign, HPV catch-up) via GPs and so this type of response is well tested, although never before for influenza. In particular the meningococcal group C vaccination campaign of 1999/2000, delivered to young children entirely by GPs and their staff is a particularly strong example of an urgent targeted mass vaccination campaign being planned and delivered very rapidly by central government. The context then was a huge rise in meningococcal group C deaths in babies, children and teenagers. Thus the UK had some recent rehearsals for mass vaccination, undertaken via the GP system.

Pandemic vaccination in the UK needs to be placed in the context of its very large

⁵ The views and opinions expressed in this section are those of the expert contributor, Prof J Van-Tam, and not necessarily those of the UK Government.

stockpile of antiviral drugs, available in March 2009, and a centralized (telephone-based) system for treating all persons with influenza symptoms.

When were the Advance Purchase Agreements (APAs) signed and activated?	<p>The Advanced Purchase Agreements (APAs) were signed in July 2007. They were activated in June 2009 upon declaration of the pandemic.</p> <p>Agreements were signed on 15 May between the UK Government and vaccine manufacturers to secure supplies of up to 90 million doses of pre-pandemic H1N1 vaccine.</p> <p>Contracts signed with Baxter Healthcare Ltd and GlaxoSmithKline (GSK) on 26 June to supply sufficient H1N1 swine flu vaccine for the population of the UK.</p> <p>The UK had already reviewed the available H5N1 vaccines and decided to purchase from Baxter and GSK. These two providers offered 'identical' H1N1 products (as per the EMEA rapid approval system) and were therefore chosen for the UK contracts.</p>
When were the licences granted?	<p>Pandemrix® was licensed by the European Commission on 1 October, and Celvapan® on 8 October.</p>
When did the first stocks arrive in the UK?	<p>Pandemrix® was first received in the UK on 9 October 2009. There were stocks of licensed Celvapan® from 8 October (in stock but unlicensed a short while before this date).</p>
When did Phase 1 start?	<p>An announcement was made on 15 October 2009 that vaccine supplies were in the NHS distribution network and that the vaccination programme would begin from 21 October:</p> <ul style="list-style-type: none">▶ From 21 October 2009 supplies went to NHS Acute Trusts for frontline staff and patients in at-risk groups in hospital.▶ From 26 October 2009, supplies went to general practices for people in the at-risk groups.▶ Those targeted were Health Care Workers; patients in high-risk groups for seasonal influenza (but with greater emphasis on the young than the over 65s); household contacts of immune-suppressed patients; and pregnant women.⁶▶ The GSK vaccine was deliberately preferred as the best choice for pregnant women (despite adjuvant and thiomersal) because of its rapid immunogenicity after just one dose. However either product could be given.▶ Very extensive briefing materials were provided to health professionals and the public.
When did Phase 2 start?	<p>Phase 2 (children aged 6mth to 5yrs) was announced by the Chief Medical Officer on 19 November 2009. The vaccination of healthy children between 6 months and under 5 years of age began in early December, however there was some local variation. This decision was driven by emerging evidence of a high hospitalisation</p>

⁶ A decision was never made to vaccinate the whole population irrespective of risk conditions although there was enough vaccine purchased to do this.

rate in children ≤ 5 years.

When did the JCVI make their Phase 1 and Phase 2 recommendations? The JCVI made a statement on the initial priority groups for vaccination on 7 August 2009. The recommendation for Phase 2 was made in a statement of 17 November 2009.

What were the main challenges encountered? Relatively few major challenges were encountered because the UK (health professionals and public) is well used to centrally driven vaccine policy. Vaccine arrived on time and was distributed using a system in almost everyday use (in 'peacetime') for childhood vaccinations. Payments for GPs were negotiated in advance by the government.

- ▶ The UK's large first wave occurred in June/July 2009, well before vaccine was available.
- ▶ Public perception of the pandemic was that it was mild and so vaccine acceptance was not as high as anticipated and considered unnecessary by some patients. Some GPs were also rather lukewarm in their support as they had seen mainly mild disease in the first wave.
- ▶ The risk assessment made by JCVI defined priority groups for vaccination as opposed to whole population coverage; so less vaccine was needed than purchased in contracts. This has led to criticism of over-ordering of vaccines, when in fact - like Switzerland - there was no contract flexibility; it was a 'sellers market'.
- ▶ Despite a major effort on the communication front enthusiasm for the 'new' vaccines was not overwhelming because they were still seen as 'untested' and 'rushed through' by some groups in society and by some individual health professionals. In particular, some midwives wrongly advised pregnant women not to receive vaccine.
- ▶ The pandemic crisis unfolded in the UK at a time when it was not certain if seasonal vaccine would also be needed. Since this had already been ordered and had mainly been produced by manufacturers, a policy decision (based on JCVI advice) was made to give the elderly both products concomitantly.
- ▶ Despite a major effort on communications, there was still some suspicion of an adjuvant by the public and even (on occasions) confusion between the preservative (thiomersal) and the adjuvant (AS03).
- ▶ No head to head comparison data (between the GSK and Baxter products) were available so decisions were made based on indirectly comparable immunogenicity data provided by each manufacturer.

5.4 International comparison: Conclusion

Challenges encountered during H1N1 pandemic were rather similar in the UK, Germany, France and Switzerland: To plan and take decisions in a situation of uncertainty and to manage communication in such a situation caused difficulties in all countries reviewed. At the same time, there were some country specific difficulties resulting from different public health systems. For instance, federal structures as in Germany and Switzerland partly turned out to be a handicap for an effi-

cient management of H1N1 pandemic. But the example of France shows that a centralized system per se does not constitute a guarantee for a better result.

As for the purchase of vaccines, UK was slightly ahead of Germany, France and Switzerland. However, this did not cause any problems for Switzerland with regard to vaccine supply. Due to uncertainty about virus severity and to expected demand, most European countries (including Switzerland) decided to set the amount of vaccines purchased based on a worst case scenario.

While vaccines (Pandemrix®) were submitted for approval to regulatory authorities at the same time both in Switzerland and Europe (EMA), the approval process in Switzerland took considerably longer. This delay as well as difficulties concerning repackaging and distribution delayed the start of vaccination in Switzerland compared to other European countries. But once vaccinations started, Switzerland was able to regain lost time.⁷

⁷ Until mid of April 2010, no assured data about immunization rate in the examined countries were available.

6 Recommendations for the revision of the Swiss Epidemic Law

Preliminary note: Our evaluation and recommendations are focusing explicitly on the area of immunization, which should be considered as special issue within the overall pandemic handling. As immunization issues (vaccine development / production, purchase, licensure) always have to be handled within a limited and pre-determined time frame (time for development and production of vaccines), different processes and allocation of authorities might be needed than for other measures of pandemic handling. This raises the question if there should be a special section about immunization in the epidemic law.

Loi sur les épidémies (EpiL) et Ordonnance sur la pandémie d'influenza (IPV) ⁸	Révision / projet de loi sur les épidémies (version de la consultation)	Evaluation and recommendations
Objectifs et stratégies		
	<p>Art. 3 Objectifs et stratégies Après avoir consulté les cantons, la Confédération détermine les objectifs et les stratégies nationaux de dépistage, de prévention et de contrôle des maladies transmissibles et veille à la coordination internationale en la matière.</p>	Cf. article 71
Compétences confédération - cantons		
<p>Art. 10 Circonstances exceptionnelles (EpiL) 1) Si des circonstances exceptionnelles le requièrent le Conseil fédéral peut ordonner les mesures nécessaires, applicables à la totalité ou à certaines parties du pays. 2) Il peut charger les cantons d'exécuter ces mesures.</p> <p>Art. 11 Principe (EpiL) Les cantons prennent les mesures propres à lutter contre les maladies transmissibles. L'Art. 10 est réservé.</p>	<p>Art. 5 Situation particulière 1) Il y a situation particulière lorsque: a. les organes d'exécution ordinaires ne sont pas en mesure de prévenir et de combattre l'apparition et la propagation de maladies transmissibles et: 1. s'il existe un risque élevé d'infection et de propagation; 2. s'il existe un risque spécifique pour la santé publique; ou 3. si l'économie ou d'autres secteurs vitaux risquent de subir de graves répercussions;</p>	The current epidemic law differentiates between an "ordinary" and an "extraordinary situation". In case of an "extraordinary situation", the Confederation is given the authority to refer to emergency legislation. This escalation concept has proved to be insufficient because it doesn't take into account the case of a pandemic of minor severity or extension in which some centralized authority is needed but applying Art. 10 cannot

⁸ Les informations de l'ordonnance sur la pandémie d'influenza (IPV) sont en italique.

	<p>b. l'Organisation mondiale de la santé (OMS), se fondant sur le Règlement sanitaire international (2005)³, a constaté la présence d'une urgence sanitaire de portée internationale menaçant la santé de la population en Suisse.</p> <p>2) Le Conseil fédéral décrète que la Suisse se trouve en présence d'une situation particulière.</p> <p>3) En cas de situation particulière, il peut ordonner les mesures nécessaires, notamment:</p> <p>a. édicter des mesures visant la population; b. édicter des mesures visant des individus;</p> <p>b. édicter des mesures visant à assurer l'approvisionnement de produits thérapeutiques, en particulier pour limiter ou interdire leur exportation;</p> <p>c. astreindre les professionnels de la santé à participer à la lutte contre les maladies transmissibles.</p> <p>Art. 6 Situation exceptionnelle Si une situation exceptionnelle l'exige, le Conseil fédéral peut édicter les mesures qui s'imposent pour l'ensemble ou certaines parties du territoire.</p>	<p>be justified.</p> <p>Against this background, the introduction of an intermediary phase called "particular situation" (cf. Art. 5 draft law) is approved: According to the draft law, confederation has the authority to order measures (cf. paragraph 3) in case of a "particular situation". However, confederation will still mandate cantons to execute these measures.</p> <p>In order to successfully handle a "particular situation", it is crucial that confederation is also given the authority to order / coordinate corresponding preparation measures (cf. recommendations at Art. 71).</p>
Exécution (dt. Vollzug) et surveillance / coordination		
<p>Art. 9 Haute surveillance, coordination (EpiL) La Confédération exerce la haute surveillance sur l'exécution de la loi et coordonne, s'il est nécessaire, les mesures incombant aux cantons.</p> <p>Ordonnance sur la pandémie d'influenza (IPV) Art. 7 Plan en cas de pandémie 1) Un groupe d'experts institué par le départe-</p>	<p>Cantons Art. 69 Principe Les cantons exécutent la présente loi pour autant que la Confédération ne soit pas compétente.</p> <p>Art. 70 Rapport Les cantons adressent régulièrement au DFI un rapport sur l'exécution de la loi. Le Conseil fédéral</p>	<p>Remark: principle of Art. 69 is already implicitly contained in the current law.</p>

ment élabore et met à jour régulièrement un rapport formulant des recommandations sur les mesures à prendre en cas de pandémie (plan en cas de pandémie). Ce groupe d'experts est composé notamment de représentants de la Confédération et des cantons, ainsi que de spécialistes du corps médical, du Centre national Influenza et de l'économie.

2) Le plan en cas de pandémie comprend en particulier:

- c. un état de la situation actuelle concernant la surveillance et la prévention de l'influenza en Suisse, ainsi que la lutte menée contre elle;
- d. des recommandations sur les mesures de prévention générale contre l'influenza;
- e. des recommandations en matière d'information de la population;
- f. des recommandations sur les mesures relatives à l'approvisionnement de la population en vaccins contre l'influenza (vaccins), en médicaments ayant une action spécifique contre l'influenza (médicaments antiviraux) et autres médicaments appropriés contre l'influenza et à la constitution de réserves;
- g. des critères permettant d'établir un ordre de priorité des personnes auxquelles les vaccins, les médicaments antiviraux et autres médicaments appropriés contre l'influenza sont distribués en cas de problèmes d'approvisionnement;
- h. des recommandations sur les mesures concernant la vaccination de la population et l'administration de médicaments antiviraux et autres médicaments appropriés contre l'influenza, en cas de pandémie;
- i. des recommandations sur les mesures de san-

règle la forme et le contenu de ce document.

Confédération

Art. 71 Surveillance et coordination

- 1) La Confédération surveille l'application de la présente loi par les cantons.
- 2) Le Conseil fédéral coordonne les mesures d'exécution des cantons s'il y a un intérêt à une exécution uniforme. A cet effet, il peut notamment charger les cantons:
 - a. de prendre des mesures d'exécution spécifiques;
 - b. de contrôler l'efficacité des mesures d'exécution ;
 - c. de l'informer sur les mesures d'exécution qu'ils ont prises.

Differences in execution respectively a lack of coordination of execution measures has proved out to be one of the main problems concerning H1N1 vaccination strategy. It is therefore strongly supported that confederation is given the authority to ensure coordination among cantons and thus to encourage a harmonized execution.

Based on H1N1 experience, Art. 71 should however be completed as follows in order to ensure a harmonized execution respectively a better coordination:

- On the one hand, the Confederation must be given the authority to already intervene in the planning phase, which means before Switzerland finds itself in a „particular“ or „extraordinary“ situation. Confederation must be able to ensure that necessary preparation measures are taken.

Proposed addition: „Confederation is responsible that required preparation measures are taken.“

- On the other hand, better coordination of execution measures also requires better coordination of

té publique à prendre en vue d'empêcher l'introduction, la propagation et la réapparition de l'influenza pandémique.

3) *Le plan en cas de pandémie est publié sous une forme appropriée.*

Art. 8 Mesures (IPV)

Le département établit, en se fondant sur le plan en cas de pandémie, des mesures à prendre en vue d'une menace de pandémie ou d'une pandémie.

federal and cantonal pandemic plans and a similar quality level of cantonal plans.

Proposed addition: „Confederation sets quality goals / standards for cantonal pandemic plans. Cantonal plans have to be approved by confederation.“

Approvisionnement en produits thérapeutiques

Art. 6 Approvisionnement en produits thérapeutiques (EpiL)

Le Conseil fédéral veille à ce que la population soit suffisamment approvisionnée en produits thérapeutiques les plus importants pour lutter contre les maladies transmissibles dans la mesure où cet approvisionnement ne peut être assuré au moyen des mesures prévues par la loi fédérale du 8 octobre 1982 sur l'approvisionnement du pays.

Art. 12 Ordre de priorité (IPV)

1) Le département peut, en cas de pénurie, régler l'attribution des vaccins, des médicaments antiviraux ou d'autres médicaments appropriés contre l'influenza, selon la menace et en utilisant un ordre de priorité et une clé de distribution. A cet effet, il travaille en collaboration avec les cantons et tient compte dans la mesure du possible de leurs desiderata.

2) L'attribution vise à assurer le plus grand bénéfice pour la santé de la population; en particulier,

Art. 44 Approvisionnement en produits thérapeutiques

Le Conseil fédéral veille à ce que la population soit suffisamment approvisionnée en produits thérapeutiques les plus importants pour lutter contre les maladies transmissibles dans la mesure où cet approvisionnement ne peut être assuré au moyen des mesures prévues par la loi fédérale du 8 octobre 1982 sur l'approvisionnement du pays.

According to both current and draft legislation, purchasing vaccines is the confederation's responsibility whereas cantons are responsible for the distribution within the cantons. Based on Art. 12 IPV, confederation is authorized to steer vaccine distribution by setting priorities in case of supply bottleneck.

The H1N1 evaluation has shown that responsibility for distribution from central storage to the cantons is not defined clearly enough. This respectively the lack of a centralized coordination and control (dt. Steuerung) of vaccine distribution has caused many difficulties during H1N1 pandemic. Therefore, the following additions are proposed:

- **In case of a "particular" or "extraordinary" situation, the Con-**

des soins de santé adéquats et le fonctionnement de services essentiels doivent être maintenus. Notamment les catégories suivantes de personnes peuvent être prioritaires pour l'attribution:

- a. *le personnel médical et soignant;*
- b. *les personnes travaillant au sein de services publics importants, comme la sécurité intérieure et extérieure, les transports, les communications, ainsi que l'approvisionnement en énergie, en eau potable et en denrées alimentaires;*
- c. *les personnes présentant un risque de mortalité élevé en cas d'influenza.*

3) Au demeurant, l'attribution s'applique selon des critères médicaux et éthiques reconnus. Les besoins économiques doivent être pris en considération.

federation has to control and supervise vaccine distribution from central storage to the Cantons (including definition of delivery amounts to each canton).

- **For the cantons, confederation defines binding quality goals / standards for vaccine distribution within the cantons. Confederation is authorized to mandate cantons with corresponding preparation measures (cf. explanations at Art. 71).**

Organisation

Art. 12 Personnel specialize (EpiL)

- 1) Chaque canton doit charger un médecin ayant les aptitudes nécessaires (médecin cantonal) de diriger les mesures à prendre contre les maladies transmissibles. Ce médecin devra être formé et parfaire ses connaissances en vue de cette activité.
- 2) Les cantons peuvent convenir d'engager conjointement du personnel spécialisé.

Art. 4 Cellule spéciale (IPV)

Art. 53 Médecins cantonaux

- 1) Chaque canton désigne un médecin cantonal. Les cantons peuvent désigner conjointement un médecin cantonal.
- 2) Le médecin cantonal assure la coordination des activités exercées par l'ensemble des autorités et des institutions qui participent à la lutte contre les maladies transmissibles.
- 3) Le Conseil fédéral fixe les conditions spécifiques auxquelles doit satisfaire le médecin cantonal pour l'exécution des tâches requises.

Art. 54 Organe de coordination

- 1) La Confédération et les cantons instituent un organe visant à promouvoir la coordination (organe de coordination).

Cantonal doctor

Differences in the level of competency of cantonal doctors have caused difficulties during H1N1 pandemic. Art. 53 of draft legislation that proposes to harmonize technical requirements for assuming the function of a cantonal doctor is therefore approved (cf. paragraph 3).

Coordination body

The fact that procedures and processes between the Confederation and

1) Pendant la durée d'une menace de pandémie ou d'une pandémie, le Conseil fédéral met en place, sur proposition du département, une cellule spéciale chargée de le conseiller et de soutenir la Confédération et les cantons dans la coordination des mesures d'exécution. La cellule spéciale est dirigée par le département.

2) La cellule spéciale est composée de représentants des départements, de la Chancellerie fédérale, des cantons et de l'économie ainsi que, selon les besoins, d'autres personnes compétentes.

2) L'organe de coordination est composé de représentants de la Confédération et des cantons. En cas de besoin, l'organe de coordination peut être complété par d'autres experts.

3) Il est notamment chargé des tâches suivantes:

- a. identification et évaluation des problèmes ainsi qu'élaboration de solutions;
- b. coordination des mesures de dépistage, de protection et de lutte contre les maladies;
- c. garantie d'une mise en oeuvre uniforme des mesures;
- d. coordination des activités d'information et de communication;
- e. soutien au Conseil fédéral, dans le cadre de la gestion de crise, lors de situations particulières ou exceptionnelles

4) Le Conseil fédéral règle la convocation et la direction de l'organe de coordination.

Art. 55 Comité de crise

1) En cas de besoin, notamment lors d'une situation particulière ou exceptionnelle, le Conseil fédéral met en place, sur demande du Département fédéral de l'intérieur (DFI), un comité de crise chargé de le conseiller et de soutenir la Confédération et les cantons dans la coordination des mesures à prendre. Le comité est dirigé par le DFI.

2) Le comité de crise est composé de représentants des départements, de la Chancellerie fédérale, des cantons et de l'économie ainsi que, selon les besoins, d'autres spécialistes.

cantons were not well-rehearsed was another problem during H1N1 pandemic. The initiation of a permanent coordination body (cf. Art. 54 draft legislation) is approved as it enables to rehearse cooperation in ordinary situations for the case of a pandemic. But the role and responsibilities of this body have to be precisely defined in order to prevent conflicts of competence between the coordination body and other existing bodies (e.g. Cantonal Health Directors' Conference).

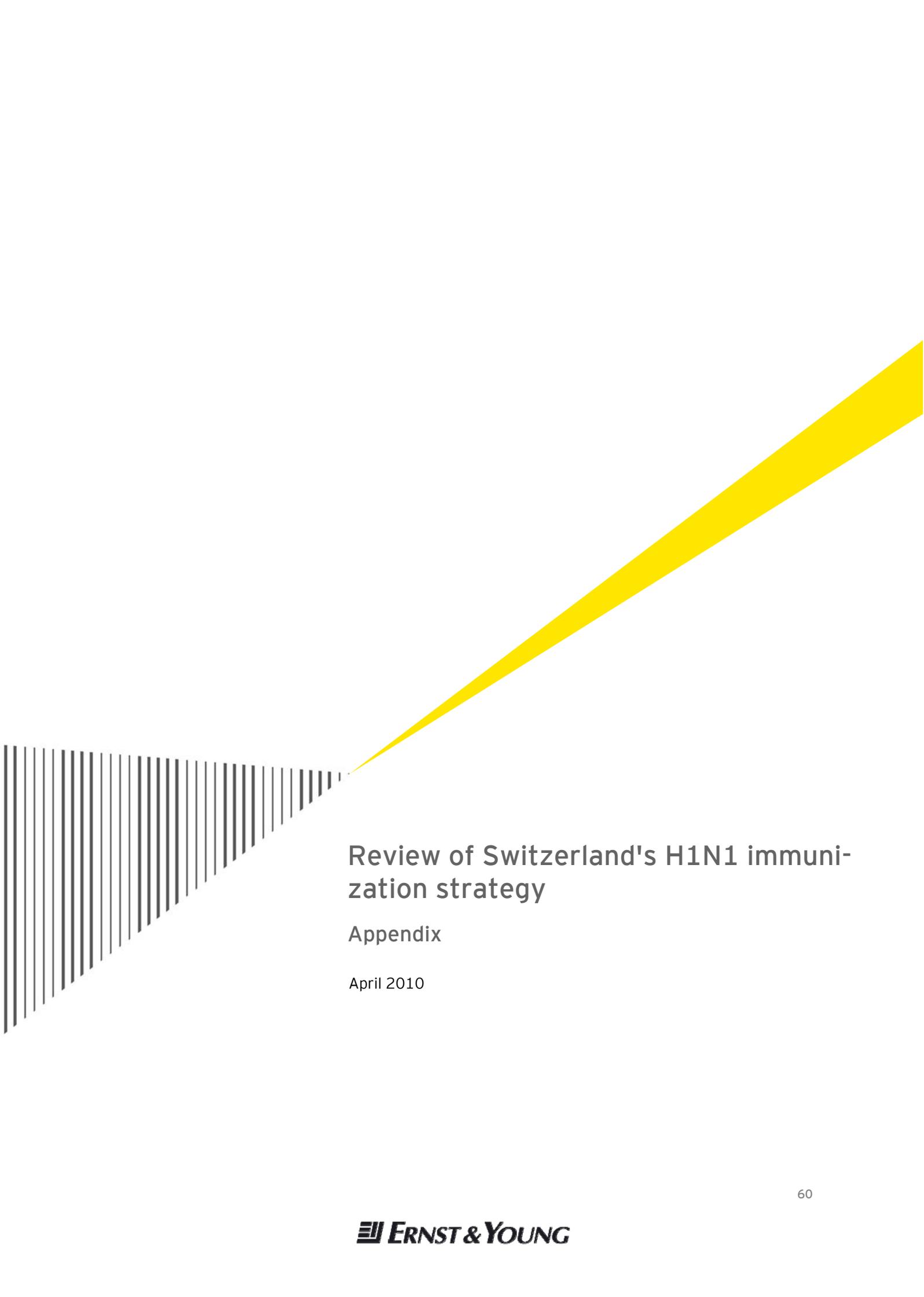
Crisis committee

The crisis committee (cf. Art. 55 paragraph 2, draft legislation) should be composed in a way that allows the committee to act effectively, a representative composition is not required. At maximum, the committee should consist of 7 members. The committee as proposed in Art. 55 draft legislation would be too big and therefore not effective enough.

Autorisation

In the context of vaccine approval during H1N1 pandemic, differing recommendations of Swissmedic, EKIF and FOPH caused confusion both amongst GPs and the public. Confederation should therefore be given the authority to clarify things in such a situation.

- **Proposed addition: In “ordinary” and “extraordinary” situations, the Confederation is authorized to give recommendations about the use of vaccines (after consultation of Swissmedic and EKIF) which are superior to recommendations of Swissmedic and EKIF.**



Review of Switzerland's H1N1 immunization strategy

Appendix

April 2010

Appendix 1: Chronology in Switzerland, Germany, France and the United Kingdom

	International	Switzerland			Germany	France	United Kingdom
Time (Week / date)	Information about development of pandemic on international level	Information about development of pandemic in Switzerland	Actions of federal and cantonal authorities	Communication	General chronology	General chronology	General chronology
Main Sources	WHO	"Lageberichte" and "Newsletters"	"Lageberichte" and "Newsletters"	Press releases and press briefings (aired via www.tv.admin.ch) Press releases	Robert Koch-Institut and press releases	Press releases and media conferences of the Department of Health	Press releases and media conferences of the Department of Health
2005 / 2006		Occurrence of H5N1 in Switzerland.	16 / 18 October 2006: Federal Council decides to buy 8 million vials of pre-pandemic vaccine → Supply agreement with GlaxoSmith-Kline.		Occurrence of H5N1 in Germany The Robert Koch-Institut (RKI) publishes the German pandemic influenza plan (Nationaler Influenzapan-demie-plan).	Launch of the site "L'Info pandémie grippale" http://www.pandemie-grippale.gouv.fr/ 26 February 2006: Occurrence of H5N1 in France (in a wild duck) 4 September 2006: The French government announces the verification of the national plan against the bird flu as well as the G-1 paper in terms of the continuation of the economic life during a pandemic event. The French government has evaluated the risk of a possible contamination to be negligible. However, the surveillance on future occurrences was maintained. 15 November 2006: Situation update on the bird flu	Occurrence of H5N1 in the UK June 2006: The National Health Service (NHS) holds a workshop on pandemic.

2007 / 2008					An updated version of the pandemic influenza plan is released. It includes an overview of measures, tasks and guidelines as well as some checklists.	9 February 2007: The government announces the 3rd edition of its pandemic preparedness plan. 11 April 2008: France down rates the risk of bird flu to "low".	5 March 2007: The Department of Health hosts a workshop on pandemic. 22 October 2008: The Department of Health establishes the UK international preparedness strategy. The strategy demonstrates the preparedness over the coming three to five years.
Jan 2009							29 January: The Department of Health agreed with Roche and GSK on the antiviral stockpiles. The contract contents the delivery of 7.6 million treatments of Tamiflu and 10.6 million treatments of Relenza.
Feb 2009			Publication of renewed Swiss Influenza Pandemic Plan on federal level.				
Mar 2009							
Apr 2009	25 April: WHO declares pandemic phase 4.	29 April: First H1N1 case in Switzerland.	29 April: As a response to first H1N1 case Federal Council convenes a Pandemic Task Force ("Sonderstab").	26 April: First Press Release "Switzerland increases Flu Surveillance" 29 April: Special Pandemic Committee is announced by Press Release		28 April: The French government publishes the National Plan for Prevention and Fight against H1N1. 30 April: France declares the risk class 5A on the pandemic scale. A daily situation report is launched.	27 April: The Secretary of State for Health confirms that the country is well prepared for any flu pandemic. 25 possible H1N1 cases are under investigation in the UK. The first 2 cases are confirmed. 30 April: The government announces that all households in the UK will receive a swine flu leaflet which includes information on how to recognize the symptoms and how individuals can protect themselves against the disease.

<p>May 2009</p>			<p>1 May: Press Conference FOHP</p> <p>3 May: Press Conference FOPH</p> <p>5 May: Press Conference FOPH</p> <p>6 May: Press Release related to WHA and focus on H1N1 together with second press release about counter-measures</p> <p>12 May: Press Conference FOPH</p> <p>22 May: Press release about second confirmed case in Switzerland</p>	<p>2 May: A free hotline is established in terms of questions with swine flu.</p> <p>4 May: Doctors are obliged to notify case of swine flu to RKI.</p> <p>12 May: Germany reports 12 confirmed cases of swine flu.</p> <p>13 May: Germany does not consider checking immigrating passenger for detecting possible cases of swine flu.</p> <p>29 May: Germany reports 19 confirmed cases of swine flu.</p>	<p>1 May: France sets up a pandemic task force (Cellule Interministérielle de Crise).</p>	<p>1 May: The first non-imported case of swine flu is detected.</p> <p>4 May: The number of confirmed cases reaches 27.</p> <p>5 May: Five schools shut after pupils fall ill.</p> <p>The government announces the appointment of a National Director for NHS Flu Resilience.</p> <p>15 May: The Department of Health announces the agreement with vaccine manufacturers for the supply of up to 90 million doses of pre-pandemic H1N1 vaccine.</p> <p>28 May: The swine flu is spreading faster in UK than anywhere else in the EU.</p>
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Jun 2009	11 June: WHO declares pandemic phase 6.		5 June: Purchase of emergency reserve of Tamiflu. Federal Council declares phase 6 also for Switzerland.	5 June: Press Release about purchase of emergency reserve of Tamiflu together with Press Conference FOPH 11 June: Press release about declaration of phase 6 with no additional measures for Switzerland together with Press Conference FOPH. 25 June: Press release about first H1N1 Lessons learned at Ministers' Meeting in Mexico 29 June: Press releases related to legal framework for transmittable diseases and to new obligation for practitioners to inform about H1N1 cases.	7 June: Germany reports 49 confirmed cases of swine flu. 11 June: Germany does not introduce new measures in terms of the new WHO phase 6. The country is supposed to be well prepared. 15 June: Germany reports 168 confirmed cases of swine flu. 22 June: Germany reports 251 confirmed cases of swine flu.	12. June: The Cellule Interministérielle de Crise (CIC) decided - following the WHO declaration - to maintain the national risk level on 5A. The decision was approved by the prime minister.	1 June: The number of confirmed cases is 244. 11 June: Following the WHO move to phase 6, the Dept. of Health says this does not trigger any material change to UK's response to the swine flu outbreak. 14 June: Biggest daily increase in cases. Total number of confirmed cases is at 1,121. The first swine flu-related death is registered. 25 June: The government says that swine flu is spreading so rapidly that it cannot be contained. 30 June: The number of confirmed cases is at 6,538.
Jul 2009			8 July: Subscription of contract between Federation and GSK (Pandemrix®) by GSK. <ul style="list-style-type: none">• 8 million vials of Pandemrix® (antigen only)⁹• 10-dose vials / package of 50 vials 16 July: Conclusion of contract between Federation and Novartis (Celtura®). <ul style="list-style-type: none">• 5 million doses of Celtura®• Multidose vials Estimated delivery dates: Oct, Nov and Dec 2009	9 July: Press release about the need to keep up the vigilance (over 100 cases reported in Switzerland) together with Press Conference FOPH. 27 July: Press Conference FOPH 27 July: Introduction of website www.pandemia.ch, serving as information channel for the public.	15 July: Germany reports 834 confirmed cases of swine flu. 16 July: Germany buys 50 millions doses of vaccine against swine flu. The doses should be sufficient for 30 percent of Germany's population (based on a 2 doses to provide protection). 22 July: Germany reports 1,818 confirmed cases of swine flu.	2 July: France reports 288 detected cases of H1N1. 7 July: Le ministère de la Santé communicates to the French public the measures taken and how to behave during the pandemic season. 15 July: The Health minister ordered 94 million vaccines from GSK, Sanofi and Novartis. 30 July: France reports the first death caused by H1N1 in a girl with the age of 14.	2 July: The Secretary of State for Health says that the UK has moved past stage of trying to contain the virus and into the "treatment phase". 9 July: The UK has reported 14 deaths since the outbreak. 23 July: A National Pandemic Flu Service, consisting of a dedicated web site and call centres is launched.

⁹ ConFederation had already bought 8 million of adjuvants from GSK in 2006 (cf. above) that could be combined with the newly developed antigen.

<p>Aug 2009</p>		<p>17 August: Subscription of contract between Federation and GSK (Pandemrix®) by the director of the FOPH.</p> <p>End of August: Additional financial means to purchase vaccines amounting to CHF 84 m approved by Finance delegation of Swiss parliament.</p>	<p>4 August Press Conference FOPH</p> <p>13 August Press Conference FOPH</p> <p>20 August Press Conference FOPH</p>	<p>3 August: Germany reports 7,177 confirmed cases of swine flu.</p> <p>5 August: The university hospital of Mainz starts clinical trials of vaccine against swine flu for children.</p> <p>14 August: Health insurances are obliged to reimburse swine flu vaccination costs for all patients.</p> <p>20 August: Germany reports 12,500 confirmed cases of swine flu.</p>	<p>France has reported 2 deaths since the outbreak of H1N1.</p> <p>18 August: The French government communicates the prevention measures in terms of the beginning of the new school year.</p>	<p>6 August: UK's Chief Medical Officer says that the first wave of the swine flu pandemic has passed its peak.</p> <p>The UK has reported 36 deaths since the outbreak.</p> <p>13 August: The government says that people with diabetes, asthma and heart disease will be the first to get the vaccine, followed by pregnant women.</p> <p>20 August: The UK has reported 59 deaths since the outbreak.</p> <p>25 August: A decline in demand leads the Dept. of Health to close down two of the emergency call centres.</p>
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<p>Sep 2009</p>	<p>21 September: Decreasing dissemination: Southern hemisphere.</p> <p>Increasing dissemination: USA, Japan, France, UK.</p> <p>28 September: Decreasing dissemination: Southern hemisphere.</p> <p>Increasing dissemination: North America, Caribbean countries, Northern Ireland, Israel, Norway, Netherlands, Sweden.</p> <p>Number of consultations be- low threshold for an epidemic in Ireland, Israel and Russia.</p>	<p>21 September: 1166 cases confirmed (25 hospitalizations).</p> <p>28 September: 1209 cases confirmed in Switzerland (25 hospitaliza- tions).</p>	<p>18 September: Agreement between Confed- eration, cantons and health insurance concerning the fi- nancing of the vaccine and of the execution of the vaccina- tion.</p> <p>25 September: EMA approves Focetria® (Novartis) and Pandemrix® (GSK) except for children under six months of age</p> <p>28 September: Meeting of Vaccination Task force (KDA, MVA, GKA, ADF) about questions around the vaccinations (e.g. number of vials per risk group, start of vaccinations etc.).</p> <p>30 September: European Commission ap- proves Pandemrix® and Focetria® for use in the H1N1 in- fluenza pandemic.</p>	<p>10 September: Press Conference FOPH</p> <p>18 September: Organization and costs of the vaccination is clarified (ap- proval by Federal Council):</p> <p>Vaccinations are organized by cantons. Vaccination costs are jointly carried by Federa- tion, cantons and health in- surers.</p> <p>Among other countries Swit- zerland supports the United States in their plan to help developing countries in their fight against the H1N1 pan- demic influenza. Obama thereby wants to ensure a rapid access to vaccines for developing countries.</p> <p>21 September: Gynaecologists recommend treatment of pregnant women with Tamiflu.</p>	<p>2 September: Germany reports 16,100 con- firmed cases of swine flu.</p> <p>26 September: Germany has reported the first death of swine flu since the outbreak.</p>	<p>24 September: The French prime minister communicates the priority order of people willing to be vaccinated.</p> <p>29 September: France has reported 6 deaths since the outbreak of H1N1.</p>	<p>10 September: The National Health Service (NHS) prepares to double its intensive care capacity to cope with predicted surge of swine flu cases in fall.</p> <p>13 September: The Dept. of Health reaches a deal with the General Practi- tioners (GP) in regard to swine flu vaccinations. GP surgeries are to receive £5.25 per dose of vaccine given.</p> <p>17 September: The number of reported cases of swine flu rises for the first time in several weeks indicat- ing that the second wave of the virus could have begun. The UK has reported 79 deaths since the outbreak.</p> <p>24 September: The swine flu vaccine to be used in the UK is given ap- proval by the European regu- lators.</p>
<p>1 - 11 Oct 2009</p>	<p>5 October: Decreasing dissemination: Argentina, Chile, New Zea- land, Australia, South Africa.</p> <p>Increasing dissemination: USA, Canada, Mexico.</p> <p>Number of consultations be- low threshold for an epidemic in Belgium, Spain, France, Ireland, Israel, UK and Japan.</p>	<p>5 October: 1259 cases confirmed in Switzerland (23 hospitaliza- tions).</p>		<p>5 October: www.pandemia.ch had ap- proximately 200000 visitors since introduction (see 27 July), 6 million pages visited and > 300'000 downloads.</p> <p>In addition, >100'000 paper brochures „Pandemic influ- enza - All you need to know“ were ordered. Also the Can- tons inform the public about H1N1. The Federal Office of Public Health mentions Can- ton Valais as a good example: FAQs, TV-Spots from local TV stations.</p>	<p>7 October: The German government pro- claims that people should take the opportunity for a vaccina- tion.</p> <p>8 October: Germany has reported 2 deaths since the outbreak. There are around 23,000 con- firmed cases of swine flu.</p>		<p>11 October: The Dept. of Health orders NHS managers to ensure that frontline health staff are vac- cinated against the virus.</p> <p>The UK has reported over 100 deaths since the outbreak.</p>

<p>12 - 18 Oct 2009</p> <p>13 October: Decreasing dissemination: Argentina, Chile, New Zealand, Australia and South Africa.</p> <p>Increasing dissemination: USA, Canada, Mexico, Japan, Belgium, Spain, France, Ireland, Israel and the UK.</p> <p>17 October: By the end of the week 46 member states of the USA report a considerably increased influenza dissemination.</p> <p>In Canada the number of influenza cases has increased for the 5th consecutive week.</p>	<p>13 October: 1291 cases confirmed in Switzerland (23 hospitalizations).</p>	<p>13 October: A new version of the H1N1 strategy paper is in progress. A first internal draft should exist by the end of the week.</p> <p>Based on data available EKIF and the FOPH recommend that the following risk groups are to be vaccinated first: People with an increased complication risk or others that can transfer the virus to such people. As soon as enough vaccines are available all groups willing to be vaccinated are advised to do so.</p> <p>For the distribution of 1000 vials of Relenza the cantons will be provided with the distribution of the vaccine.</p>	<p>12 October: Launch of promotional campaign "Still protected?" in pharmacies. Initiators: Pharmasuisse, FMH and FOPH. Medical background: Swiss vaccination plan 2009.</p> <p>The event is promoted in local radio spots, bills in pharmacies and two background spots in German and French spoken Swiss TV.</p>			
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<p>19 - 25 Oct 2009</p>	<p>19 October: Start of vaccination campaign in Japan.</p> <p>Increasing dissemination in the northern hemisphere. Number of consultations above threshold for an epidemic in the USA, Canada and Mexico. Increasing number of cases also in Western Europe and Northern Asia. In some countries epidemic threshold is exceeded, however, less severe dissemination than in North America.</p> <p>Very few cases in the southern hemisphere.</p> <p>20 October: Start of vaccination campaign in France.</p>	<p>19 October: 1328 cases confirmed in Switzerland (23 hospitalizations).</p>	<p>20 October: All important stakeholders in the area of vaccinations meet to discuss the approval process, recommendations and organizational questions. Details regarding the meeting and outcomes were not made available. The following statement is issued: "A meeting of all important partners took place on the 20 October. An agreement was achieved. On 30 October detailed information about the pandemic vaccination will be communicated in a joint media conference.</p> <p>21 October: Federal council decides to support Barack Obama to make 10 percent of its H1N1 vaccine supply available to other countries through the World Health Organization (WHO). The director of the FOPH is authorized to pass 10 to 20 percent of the purchased vials to the WHO as soon as Switzerland's needs are fulfilled.</p> <p>23 October: Swissmedic approves Pandemrix® (GSK) for all patients except pregnant women, children < 18 years and adults > 60 years. (vs. recommendations FOPH: Pandemrix® also for adults > 60 years).</p> <p>Amendment I of agreement between Novartis and Confederation:</p> <ul style="list-style-type: none"> • Delivery of a mutually agreed number of prefilled syringes in replacement of multidose vials (Celtura®). • Delivery of 240'000 doses of Focetria® in prefilled syringes or multidose vials by the end of October in replacement of the equal number of doses of Celtura®. 	<p>19 October: Demoscope survey revealed that the Swiss public is better informed about the existence of H1N1, however, there is little readiness to be vaccinated, mainly due to general concerns about vaccines, their reliability and possible adverse reactions.</p>		<p>20 October: Start of vaccination campaign in France with a press conference by the health minister.</p>	<p>21 October: The swine flu vaccinations begin at NHS hospitals.</p>
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<p>26 Oct - 1 Nov 2009</p>	<p>21/26 October: Start of vaccination campaign in the UK. First among nursing staff, then risk groups.</p> <p>24 October: Obama declares H1N1 a national emergency.</p> <p>26 October: Start of vaccination campaign in Germany.</p> <p>The European commission publishes an interactive overview of the EU countries' information campaigns with regard to the pandemic influenza (H1N1).</p>		<p>27 October: Swissmedic approves Focetria® (Novartis) but recommends that it should not be used for children under 6 months. For pregnant women, general practitioners have to judge according to the recommendations of the FOPH.</p>	<p>26 October: New communication tool: Pandemic-vaccination-check. This is a questionnaire which allows individuals to find out whether they belong to the risk group or not.</p> <p>30 October: Press conference. Together with Mr. Zeltner (Director FOPH) representatives of Swissmedic, cantonal health directors' conference, EKIF and FMG inform about vaccinations. Switzerland has stocked two types of vaccines that are approved by the national approval authority Swissmedic: Pandemrix® from GlaxoSmithKline for adults above 18 (excl. pregnant women) and Focetria® from Novartis for children above 6 months, adults (incl. pregnant women).</p> <p>Approval for Celtura® is still in process at Swissmedic.</p>	<p>26. October: The vaccination program against swine flu begins. It is the biggest vaccination program in Germany ever.</p>	<p>France has reported 22 deaths since the outbreak at the end of October.</p>	<p>26 October: GPs receive first deliveries of vaccine.</p> <p>29 October: Official figures reveal that 750 people - 103 of whom are children - are in hospital care (157 of these patients in critical care). The number of deaths has reached 137.</p>
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2 - 8 Nov 2009	<p>2 November: The pandemic continues to spread out in the northern hemisphere, particularly in the U.S. and in Canada. In Europe the intensity is very high in Ireland and Iceland and high in White Russia, Northern Ireland, Luxembourg, Malta and Sweden.</p> <p>The situation in the Ukraine evolves very rapidly but seems very similar to that observed in Chile and Argentina three months ago. Between the 13 and 30 October 2009 more than 2300 were hospitalized, of which 131 were severe cases. The latter and the death cases emerged within the population young adults from 20 to 50 years of age that have had no complications before. Difficulties arise from limited health resources.</p> <p>6 November: WHO team evaluates situation in the Ukraine. By 6 November 40'000 people were hospitalized and 109 of death confirmed.</p>	<p>2 November: 1700 cases confirmed in Switzerland (33 hospitalizations).</p>	<p>6 November: "National vaccination day". Individuals may obtain a vaccination for a lump-sum price at doctors who support the activity.</p> <p>7 November: Unofficial "start of vaccination" on Cantonal level (official "start" announced for 16 November), meaning Cantons that already received the vaccine started to vaccinate the public.</p>	<p>3 November: New fact sheets about pandemic influenza on www.pandemia.ch in 13 languages.</p> <p>5 November: Press Conference FOPH</p>	<p>5 November: The RKI communicates that there is only the H1N1 virus circulating within the country. There are around 55,000 confirmed cases of swine flu.</p>		
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<p>9 - 15 Nov 2009</p>	<p>9 November: Decreasing dissemination: In South East and tropical parts of Asia (with the exception of Cambodia, Nepal and Sri Lanka) and in Central and South America.</p> <p>Increasing dissemination in the northern hemisphere. Very high influenza activity in Ireland, Iceland and parts of Russia. High activity in White Russia, Bulgaria, Northern Ireland, Italy, Norway, Netherlands, parts of Russia and Sweden.</p> <p>Asia: In western- (Oman), central- (Afghanistan) and eastern parts (China, Japan, and Mongolia) increase of influenza activity.</p>	<p>9 November: 2403 cases confirmed in Switzerland (48 hospitalizations of which 11 severe cases).</p>	<p>13 November: Swissmedic approves Celtura® (Novartis) for children above 3 years of age and for adults of all ages.</p>	<p>9 November: Press Conference FOPH 12 November: Press Conference FOPH 13 November: Press Conference FOPH</p>	<p>10 November: Germany has reported 12 deaths since the outbreak. 13 November: Doctors are relieved from their obligation of notification in terms of confirmed cases.</p>	<p>9 November: The health minister announces the beginning of vaccination in France on November 12.</p>	
<p>16 - 22 Nov 2009</p>	<p>16 November: Considerable dissemination in some Scandinavian, Eastern and South Eastern European countries.</p> <p>Decreasing dissemination: In the USA, Ireland, Belgium and the UK.</p> <p>Increasing dissemination: Canada, Japan and Mongolia.</p>	<p>16 November: 3500 cases confirmed in Switzerland (75 hospitalizations of which 16 severe cases).</p> <p>18 November: First case of death in Switzerland due to H1N1: Baby in the canton of Basel-Land.</p>	<p>17 November: Amendment II of agreement between Novartis and Confederation:</p> <ul style="list-style-type: none"> • Delivery of 240'000 doses of Focetria® in prefilled syringes as soon as possible in replacement of twice the same number of doses of Celtura®. <p>19 November: Expanded approval: Swissmedic approves Pandemrix® also for use by adults above 60 years.</p> <p>20 November: Pandemrix® may now also be used for children above 6 months (approval by Swissmedic).</p>	<p>16 November: Since risk for infection no longer varies between countries, directions on travelling were removed from www.pandemia.ch</p> <p>18 November: Given first case of death in Switzerland (see left column) press conference is held where FOPH Director answers questions from the media.</p> <p>19 November: Communication about the latest pandemic figures and about the status of the vaccine distribution. In addition, two more cases of death were confirmed by the Federal Office of Public Health (both in Winterthur, canton of Zurich).</p>	<p>22 November: The Vaccination Committee wants to expand its recommendation. People from 6 months up to 24 years should obtain the vaccine.</p>		<p>19 November: The Dept. of Health announces that the vaccination program is to be extended to children aged between six months and five years.</p> <p>20 November: Health officials in Wales confirm that a strain of swine flu resistant to the anti-viral drug Tamiflu is spreading from person to person.</p>

<p>23 29 Nov 2009</p>	<p>24 / 30 November:</p> <p>Influenza activity continues to stay on an increased level in Europe, North America and Asia and overtakes seasonal influenza levels in numerous geographical regions.</p> <p>Increasing dissemination: Northern-, Eastern and South Eastern Europe, as well as, Central Asia.</p> <p>Decreasing dissemination: Belgium, Iceland, Ireland and the USA.</p>	<p>24 November:</p> <p>6500 cases confirmed in Switzerland (123 hospitalizations of which 28 severe cases). Rapid dissemination of H1N1 in Switzerland. Estimated number of people going to doctors in this week: 20'000 (compared to 12'000 in the previous week). 3 cases of death confirmed.</p>	<p>23 November:</p> <p>Successive start of vaccination in the Cantons.</p> <p>27 November:</p> <p>The Federal Council mandated Swissmedic to negotiate with EMEA - at the request of the Federal Department of Home Affairs, the Federal Department of Foreign Affairs and the Federal Department of Economic Affairs. Swissmedic shall be provided with the possibility to rely on EMEA's decisions more closely.</p>	<p>24 November:</p> <p>Since so far no cases of H1N1 has been reported for children and young adults, specific advice regarding the protection of children are now posted on website http://www.pandemia.ch/de-ch/risikogruppen/kinder.html</p> <p>26 November:</p> <p>Press conference FOPH.</p>	<p>23 November:</p> <p>The virus mainly attack young people; this population has a reported rate of infection five times higher when compared to other groups</p>	<p>26 November:</p> <p>The UK has reported 242 deaths since the outbreak. The number of people catching the virus appears to be falling.</p>
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<p>30 Nov - 6 Dec 2009</p>	<p>30 November: 8000 cases confirmed in Switzerland (143 hospitalizations of which 33 severe cases). 4 cases of death confirmed.</p> <p>First week of December: Based on the reported number of cases the transmission of H1N1 in Switzerland reached its peak.</p>		<p>3 December: FOPH press conference.</p>		<p>30 November: The demand for vaccination is very high. The French government augments the efforts for better vaccination opportunities.</p> <p>France has reported 92 deaths since the outbreak at the end of November. The virus is circulating with high intensity.</p> <p>L'Institut de veille sanitaire (InVS) conveys that a mutation of the virus type H1N1 was found in two persons who died. The virus mutation will be closely investigated. No new measures are taken.</p> <p>1 December: The French prime minister holds a press conference in order to stress the willingness of the French government to reinforce the vaccination deployment.</p> <p>4 December: 1.76 million people have been vaccinated since the beginning of vaccination. The vaccination has been provided in 896 centres throughout the country.</p>	<p>3 December: The number of reported cases of swine flu falls for the fourth successive week.</p>
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<p>7 - 13 Dec 2009</p>	<p>7 December: Increasing dissemination: Central Europe, Central-, Eastern- and South Asia.</p> <p>Decreasing dissemination: In the USA. Peak seems to be reached in Northern and Western Europe.</p> <p>In Africa: Co-circulation of pandemic virus H1N1 and seasonal virus H3N2 observed.</p>	<p>7 December: 10'000 cases confirmed in Switzerland (213 hospitalizations of which 52 severe cases). 8 cases of death confirmed.</p>	<p>7 December: Evaluation of the preparation and execution of the Swiss vaccination strategy H1N1 in view of the revision of the epidemic law assigned to Ernst & Young and to the expert team constituted by the review's commissioner.</p>	<p>7 December: Follow-up survey on the knowledge status and measures of protection of the Swiss population shows that the population is well-prepared to the ongoing H1N1 pandemic:</p> <p>75% of the interviewees rely on personal hygiene measures, and a little more than every second respondent is careful about his/her physical health. Compared to the previous survey the application of these two measures has increased clearly. But the willingness to vaccinate has decreased, especially due to a lack of knowledge about the vaccine safety and the moderate course of the pandemic. The influenza campaign is increasingly known, is well received and accepted that it is the FOPH that informs about the pandemic influenza. Since July the amount of information and number of people stating they have been informed doubled from 18% to 32%.</p> <p>These are the results from a follow-up survey conducted by Demoscope on behalf of the FOPH in mid November.</p> <p>10 December: Press conference FOPH</p>		<p>7 December: Start daily situation report with reference to the vaccination update (Point de presse sur la campagne de vaccination)</p>	<p>10 December: The swine flu pandemic has been less lethal than feared with a death rate in England of 26 per 100,000 cases.</p>
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<p>14 - 20 Dec 2009</p>	<p>14 December: Increasing dissemination: Central and South Eastern Europe, as well as, South and East Asia.</p> <p>Decreasing dissemination: In the USA, Canada, most Northern European countries, Eastern and Western Europe with the exception of France.</p>	<p>14 December: 10'900 cases confirmed in Switzerland (300 hospitalizations of which 64 severe cases). 8 cases of death confirmed.</p>	<p>14 December: Expanded approval: Swiss-medic approves Pandemrix® also for use by babies / children from 6 months of age.</p> <p>Mid December: Reutilization strategy: Federal Council decides to</p> <ul style="list-style-type: none"> • keep adequate reserve for Swiss population • sell 4.5 million to the WHO and to other countries. <p>16 December: In the context of excess vaccine doses the Federal Council decided to renounce 3 million doses of antigen from GSK with a payment reduction.</p> <p>19 December: The Federal Council's forward planning foresaw a sale of 1.5 million of doses of Pandemrix® to interested countries. Iran showed interest and negotiations were started.</p>	<p>14 December: Up to this date 180'000 people had checked online for asses whether or not they should get vaccinated.</p> <p>16 / 17 December: Members of the communicators' network of the Health Security Committee HSC met in Luxembourg on 16 and 17 December. On the agenda were e.g. survey results of Eurbarometer, an exchange about the association of vaccination opponents, key messages for the future and evaluation of the crisis communication through an external German agency. Head of the FOPH's communications section, Sabina Müller, represented Switzerland.</p> <p>17 December: Press conference FOPH.</p> <p>Press Release about the next steps in the H1N1 Strategy (mention of donation to WHO and sales to other countries.</p> <p>19 December: The Federal Council confirms that GSK will deliver 1 to 1.5 million doses to the World Health Organization in the name of Switzerland following the Obama initiative.</p>	<p>16 December: Pregnant women are allowed to receive the vaccine without adjuvant</p> <p>Germany has reported 119 deaths since the outbreak. The activity of the virus is decreasing.</p>		
<p>21 - 27 Dec 2009</p>				<p>22 December Press Release about two Tamiflu resistant cases</p>			

28 Dec 2009 - 3 Jan 2010	<p>30 December:</p> <p>EU: The pandemic wave declines in almost every country within the EU. A French study assumes that a lot of people were infected by H1N1 but showed no symptoms (app. 5 times the figure that was reported) according to the RSR1 report on 30 December. MAV confirmed that this number was also likely to be true for Switzerland.</p> <p>WHO: M. Chan informs media, giving the following four main messages:</p> <ul style="list-style-type: none"> • The world is now better prepared to cope with future pandemic situations. • The world has been fortunate that this pandemic has so far been moderate. • Challenges with public communications during this pandemic. • It is too early to consider the pandemic over. 					<p>By the end of December, nearly 5 million people have received the vaccine.</p> <p>By the end of December France had reported 224 deaths (132 only in December) since the outbreak. The peak of dissemination was reached at the beginning of December and was decreasing thereafter. France mainly registered the virus type H1N1 within the country.</p>	<p>30 December:</p> <p>The pandemic virus is decreasing in major EU states.</p> <p>31 December:</p> <p>Indicators show that swine flu activity is continuing to decrease across the UK.</p>
4 - 10 Jan 2010	<p>4 January:</p> <p>Transmission of the H1N1 virus still occurs in mild zones of the northern hemisphere, however, the peak seems to be left behind in most countries of that geographical region.</p> <p>Increased levels of influenza activity are reported from some Eastern and South Eastern European-, as well as, Western-, Central- and South Asian countries.</p>	<p>4 January:</p> <p>More than 13'000 cases confirmed in Switzerland (441 hospitalizations of which 79 severe cases). 12 cases of death confirmed.</p>	<p>4 January:</p> <p>Negotiations about reutilization of excess vaccine in process.</p> <p>The closing down of crisis operations and the organization established to manage the crisis is currently in the planning phase and will presumably be presented to FOPH management for decision. From February there will be a transition phase with a crisis "wrap-up" and an evaluation of the FOPH's management of the crisis.</p>	<p>7 January:</p> <p>Press conference FOPH</p>	<p>7 January:</p> <p>Germany wants to cancel half of the ordered 50 million dosages of vaccine. The people's willingness for vaccination is much smaller than expected.</p> <p>Germany has reported 159 deaths since the outbreak.</p>	<p>5 January:</p> <p>The French Health minister announces the cancellation of vaccine orders. From the ordered 94 million vaccines, only 50 million shall be assumed. The vaccine manufacturers GSK, Sanofi-Pasteur and Novartis are concerned.</p> <p>The vaccines manufacturers are quoted to be open for re-negotiations in terms of the cancelled orders.</p>	<p>8 January:</p> <p>The number of cases falls to such a low level that the government is considering selling or giving away excess supplies of vaccine.</p>

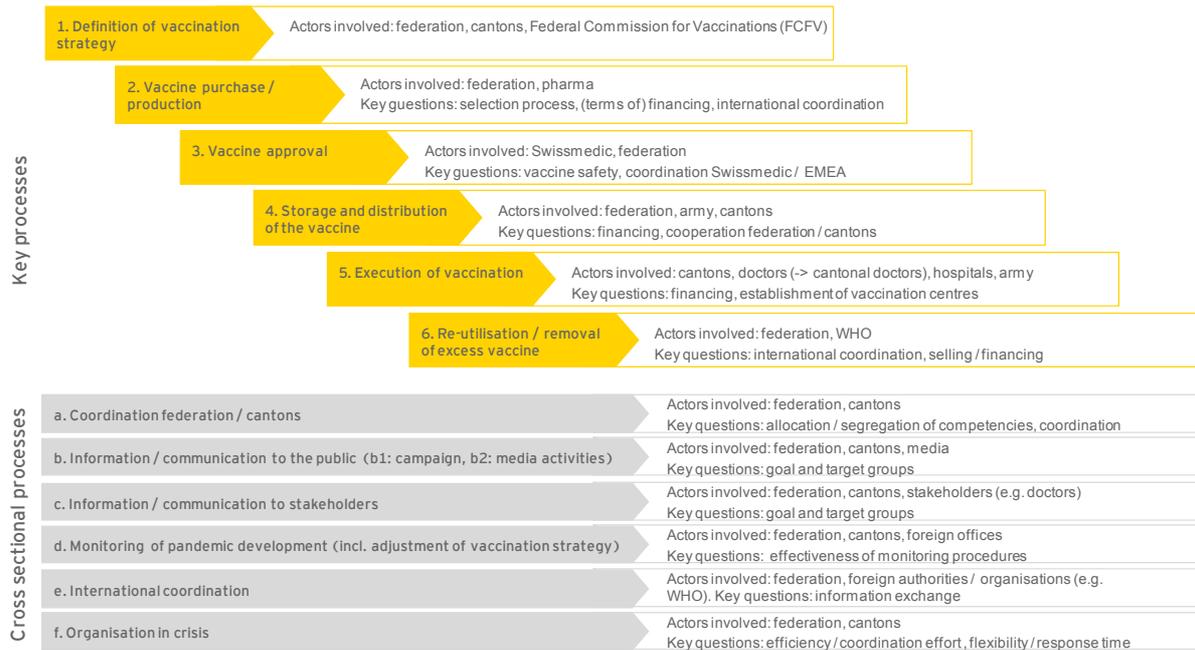
11 - 17 Jan 2010			14 January: Press release regarding the current situation and the need for evaluation	12 January: The German government agreed with GSK to only take on 34 million doses.	
18 - 24 Jan 2010				20 January: Germany has reported 189 deaths since the outbreak.	22 January: France will close their local vaccination centres by the end of January. Vaccination will be maintained at doctors' clinical practice.
25 Jan - 31 Jan		26 January: Iran signed a contract to take over 900'000 doses of Celvira® from Swiss stocks.	28 January: Press release about the sales contract to Iran		28 January: In total 5,741,553 people have been vaccinated. France has reported 285 deaths since the outbreak. The virus activity is very moderate. France declares the pandemic wave to be finished.
Feb and on- wards			5 February: Press Conference FOPH	5 February: Vaccination will be continued at the pharmacies.	3 February: Cases of swine flu have been dropping consistently since Christmas with fewer than 5,000 new cases each week. The government announces that the National Pandemic Flu Service is to be stood down. 11 February: The National Pandemic Flu Service shut off the phone line and web site.

Appendix 2: Guide used in interviews

Remark:

The guide was developed as a grid pattern and is derived from the process landscape, as illustrated below. The first two questions of each subject area examine the interviewee's involvement in the respective process stage. Responses to these initial questions for each subject area subsequently guided the sequence and selection of the remaining questions.

Process landscape regarding plan and implementation of vaccination strategy



Opening questions

What role do you have in the context of planning and implementing the vaccination strategy (according to the process landscape)?

Questions regarding core processes¹⁰

Formulation of vaccination strategy

What are your responsibilities within the formulation of the vaccination strategy or how are you involved in this process, respectively?

What challenges have been encountered in the formulation of the vaccination strategy in your view? (e.g., segregation of duties between federations and cantons)?

What are the objectives of the vaccination strategy and on what basis were they defined?

How are the federal and cantonal vaccination strategies coordinated (pandemic plans) and unclarities and contradictions between federation and cantons avoided?

Are the Swiss vaccination strategy and its implementation in line with the recommendations of the WHO? How was the vaccination strategy changed and optimised since the last assessment of the pandemic plan by the WHO in 2007?

Were experiences and „lessons learned“ in countries where the H1N1 pandemic influenza reached its peak level earlier included into the vaccination strategy?

Should different scenarios have better been anticipated and prepared? (e.g. insufficient amount of capsules at the beginning of the vaccination campaign)?

Does the pandemic precaution plan regarding „moderate“ pandemic influenzas needs adjustments?

Purchase / production of vaccine

What are your responsibilities in the context of the production or purchase of the vaccine, respectively? How are you involved in this process?

What challenges were encountered in the production and purchase of the vaccine in your view? (e.g., segregation of rights and duties between federation and cantons)?

Why was there no advertised bidding in the vaccine purchase process? What criterias were used to determine the two suppliers?

The conditions that have been negotiated with the suppliers were criticized especially in terms of liabilities. How do you assess these conditions?

Who is responsible for financing the vaccine production? Were difficulties encountered in that context? Were financial means in the vaccine purchase process approved correctly?

Was sufficient / insufficient / too much vaccine purchased?

Why did Switzerland only purchase adjuvanted vaccine? How did other countries (F, D, NL) act in this regard? Why?

Approval of vaccine

What are your responsibilities within the production and purchase process or how are you involved in this process?

What difficulties were encountered during the vaccine approval process in your view (e.g. segregation of rights and duties between federation and cantons)?

How would you assess the efficiency of the approval process (especially in terms of time aspect, also see accelerated approval process for Celtura® vs. Pandemrix®)?

What challenges were encountered at the interface Swissmedic / EMEA (see late approval and different approval conditions of Swissmedic vs. EMEA (e.g. recommendations related to age), differences in approval procedure)?

What challenges were encountered at the interface Federation / FOPH, EKIF and Swissmedic, respectively (vaccination recommendations vs. approval conditions) (see differing

¹⁰ As for the general willingness to take a H1N1 vaccine respectively as for the effectiveness of the vaccination strategy: cf. DEMOSCOPE survey.

vaccination recommendations of BAG vs. Swissmedic (e.g. indications on age for Pandemrix®)?)

As reason for the low willingness to be vaccinated doubts concerning the safety of the vaccine is stated among others. How do you assess this? Was the communication in connection with the approval of the vaccine (information about safety of the vaccine) sufficiently accommodated? How do you assess the handling with adverse reactions caused by the vaccination?

Distribution / storage of vaccine

What are your responsibilities in connection with the distribution / storage of the vaccine or how are you involved in this process?

What challenges were encountered in the area of vaccine distribution and storage (e.g.. segregation of rights and duties between federation and cantons)

In the implementation of the vaccination strategy there was criticism about the differing accessibility to vaccine within different cantons and public groups (with regard to time, location and practical aspects). Why? How do you assess the coordination between the cantons in this context?

In addition, it was criticised that the vaccine Pandemrix® was only available in a capsule of 10 and that once the capsule was opened it had to be used within 24 hours. What is your opinion on this?

Execution of vaccination

What is your responsibility regarding the execution of the vaccination strategy and how is your involvement in the process?

In your opinion which challenges were encountered during the execution of the vaccination (e.g.. segregation of rights and duties between federation and cantons)?

Did the organisation (execution through family doctors, vaccination centres and sometimes employers) prove value regarding the execution of the vaccinations, as well as, regarding the willingness of the people for being vaccinated? In particular, how did vaccination centres perform? And how do you judge the interaction between the different cantons?

Which are the implications of a delayed vaccination start in comparison to the European Union (in connection with people's willingness for being vaccinated)?

How is the financing of the execution of the vaccination arranged? And which challenges were encountered (reimbursements through health insurance)?

Re-utilisation / removal of vaccine

What is your responsibility regarding the re-utilisation and removal of the vaccine, respectively, and how is your involvement in the process?

Which challenges were encountered due to the re-utilisation / removal of vaccines (e.g.. segregations of rights and duties between federation and cantons) in your opinion?

What will happen with unused vaccines?

How is the international coordination ensured in this context? What questions arise with regard to the transmission of the vaccine to the WHO / developing countries?

Questions to cross sectional processes

Coordination of federation and cantons

How are rights and duties of federation and cantons segregated with respect to the planning and implementation of the vaccination strategy?

What challenges were encountered within the allocation and segregation of rights and duties between federation and cantons? Is there a need for adaption?

Information / communication of the public (incl. recommendations)

What are your responsibilities within the information / communication to the public (incl. recommendations) or how are you involved in this process, respectively?

What challenges were encountered within the area of information / communication to the public in your view (e.g.. segregation of rights and duties between federation and cantons)?

b1: Campaign

Which were the objectives and target groups of the campaign and why? Were they adapted to the vaccination strategy?

Are there differences to other countries?

Were the campaign's objectives and target groups reached?

How is the FOPH campaign incl. its planning and execution assessed by different actors (communication instruments: check, tv spots, bills, sticks in public transport, brochures, hotline (Medgate))?

b2: Media activities

What were the goals and the target groups of media activities and how were they selected? Were they aligned with the vaccination strategy?

Are there differences to other countries?

Were the objectives and target groups targeted by the media activities reached?

What challenges have been encountered during the communication with and by the media?

Stakeholder information / communication

What are your responsibilities within the stakeholder information/communication, or how are you involved in this process, respectively?

From your point of view, what challenges have been encountered during the process of stakeholder information/communication, especially with the medical fraternity (e.g.. segregation of rights and duties between federation and cantons)?

What were the goals and the target group of stakeholder information / communication and how have they been selected?

What challenges have been encountered during stakeholder information / communication, especially with the medical fraternity (after altering the change of strategy)?

Monitoring pandemic development

What are your responsibilities within the process of monitoring of the pandemic development, respectively how are you involved in this process?

What challenges have been encountered during the process of monitoring of the pandemic development (e.g.. segregation of rights and duties between federation and cantons, e.g..)?

How is assured that the vaccination strategy is adapted to the actual developments of the pandemic influenza and the necessary measures are implemented in a efficient and effective way?

International coordination

What are your responsibilities within the international coordination, and how are you involved in this process, respectively?

From your point of view, what challenges have been encountered in the international coordination?

Organisation in crisis

How is the crisis organisation H1N1 constituted on federal and cantonal level?

Did the crisis organisation stand the test, in particular regarding the coordination effort / efficiency and flexibility / response time?

Appendix 3: List of documents reviewed for this analysis

- Contract GlaxoSmithKline - Swiss Confederation
- Contract Novartis - Swiss Confederation (including letters from both sides)
- Website Swissmedic (approval decisions)
- Website EMEA (approval decisions)
- Federal Office of Public Health: Newsletters and status reports
- Results of Public surveys conducted by Demoscope (Private Swiss Survey Firm)
- Pandemic plan (Federal and Cantonal) including updates
- www.pandemia.ch
- Data about delivery provided by distributors
- Epidemic law SR 818.101 and Pandemic act SR 818.101.23
- Fact sheet about revision of epidemic law
- Minutes of all Pandemic Task Force meetings

Appendix 4: An Overview of the Swiss Federal System and the Health Sector

Switzerland is a multi-ethnic, multilingual and multi-confessional nation shaped by the will of its people. It has been a federal state since 1848. Its political system is characterised by a federal structure (federalism) with three different political levels: *the Confederation, the cantons (26) and the communes*. The Confederation has varying degrees of responsibilities in areas such as foreign policy, national security, monetary policy, environment, transportation and *health*. The Federal Constitution makes explicit the *tasks/responsibilities of the Confederation; the cantons are responsible for all others*. Federal responsibilities are administered by the Federal Chancellery and seven departments which in turn are responsible for some 90 federal agencies.

Each canton has its own constitution, parliament, government and courts. Each canton has a number of political communes. The cantons determine the degree of autonomy of their *communes* and their responsibilities can therefore vary quite considerably. In addition to the tasks allocated to them by both by their canton and the Confederation, the communes also have their own powers in various areas.

The Federal Constitution, adopted in 1848, provides the Federal State with *very limited responsibility in the field of health*. As such, the cantons have a high degree of autonomy that has continually shaped the development of the Swiss health system. This means that, for example, in the case of the preparation and execution of a pandemic plan, the cantons have autonomy in the development and exercising of their own pandemic plan, as well as for its execution. Each canton is obliged to name a medical officer who has specific responsibilities in the case of a pandemic crisis, particularly regarding the supervision and enforcement of the epidemic law and fighting infectious diseases.

The exception here is when a pandemic has reached a critical state and is declared a threat to national health safety, the federal authorities can step in and take over the leadership and implementation of a national pandemic plan.

There has been ongoing debate for several decades over the respective roles and responsibilities of the cantons and the Confederation.

Further information on the Swiss Federal Administration is available on the website: www.admin.ch

The Swiss Federal Office of Public Health

The Federal Office of Public Health (FOPH) is part of the Federal Department of Home Affairs. It is the national authority on health matters and represents Switzerland in international organisations and in dealings with other countries. The FOPH shares responsibility with the cantons for public health and the development of a national health policy. It is responsible for the healthcare, accident, and military insurances system. It specifies which services are paid for by the compulsory health insurance and supervises the insurance funds.

The principal aim of the FOPH is to promote and maintain the good health of all people living in Switzerland. Towards this end, it draws upon a range of measures to raise people's awareness about their health. In turn, this helps them take greater responsibility for their own well being and health improvement. It seeks a general and consistent improvement of everyone's health through campaigns aimed at health promotion, disease prevention and health protection as well as measures for the curing of illnesses and alleviation of suffering caused by disease and accidents.

The FOPH's work covers a wide range of areas including epidemiology and infectious diseases; substance abuse, harm reduction and addiction prevention; food safety; noise and radiation protection; risk assessment and control of chemical and toxic products; stem cell research and bioterrorism and health, accident and military insurance.

Its tasks and responsibilities include:

Consumer protection (particularly in relation to food, chemicals, therapeutic products, cosmetics and utility goods).

Monitoring communicable diseases, food safety, chemical and radiological protection.

National programs designed to reduce substance dependence (tobacco, alcohol, illegal drugs) and promote healthy lifestyles (nutrition and exercise, healthy environment) and for the national HIV/AIDS prevention program.

Regulating the basic and postgraduate education of doctors, dentists, pharmacists and veterinary surgeons and awarding the relevant Swiss degrees.

Legislation on biological safety, research on humans (including stem cell research) and transplantation medicine, and for supervising activities in these areas.

The FOPH employs around 600 people, with a budget of CHF 200 million (2010).