Drug Safety Monitoring in a Prepandemic and Pandemic Avian Flu Mass Vaccination Scenario

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Background (1)

- The Swiss government has decided to offer prepandemic and pandemic avian flu vaccination to all inhabitants
  - 8 million doses of prepandemic vaccine are stored
  - Distribution during late prepandemic phase, within 4 weeks
  - Swissmedic has to carry out drug safety surveillance even in case of a prepandemic and pandemic scenario

- Vaccination programmes are organized by the Cantonal Health Authorities
Background (2)

• **Prepandemic Phases I-V:**
  – Daily business is running as usual, no restrictions
  – Prepandemic vaccination programme causes workload peak at pharmacovigilance unit

• **Pandemic Phase VI:**
  – Resources are reduced by at least 25%
  – Working from home may be possible
  – Second workload peak due to pandemic vaccination

• **Resources at Swissmedic:**
  – Allow the processing of 4’000 Adverse Drug Reaction reports per year
The Swiss Pharmacovigilance Network

PHARMACEUTICAL INDUSTRY

FOPH EKIF

WHO PROGRAMME FOR INTERNATIONAL DRUG MONITORING

FOPH: Federal Office for Public Health
EKIF: Eidgenössische Kommission für Impffragen
Challenges

• Avian flu vaccine contains a new adjuvans and influenza drugs may be used over a longer time period
  -> detection of new risks may require fast action

• Assumption: 1 ADR per 1000 vaccine doses:
  -> 8‘000 ADR reports to be expected within a few weeks

• Observation by other countries:
  -> no failure can be accepted

• Need for intensive and fast exchange of information:
  -> communication network must be installed beforehand
Swiss Concept

- Maintain the well accepted procedures for ADR reporting
  - Points of contact and workflows are not changed

- Simplify and speed up the reporting
  - Electronic reporting only by means of a self explaining webbased tool

- Reinforce the resources for data management and signals
  - Regional pharmacovigilance centres: More manpower
  - Contract with a CRO as call centre and for timely report handling
  - Swissmedic to focus on signal detection and analysis
  - Safety Board for signal evaluation

- Exchange of information on a daily basis
  - FOPH / Safety Board: on the need for risk reducing measures
  - Statistics about the vaccinated population (ADR incidences)
Status and Activities (1)

• **Pandemic ADR database is ready**
  – Developed in collaboration with the WHO Uppsala Monitoring Centre
  – Simplified online reporting form for primary reporters
  – Signal detection and evaluation tool for Swissmedic
  – Electronic data exchange with marketing authorization holders according to ICH Guideline E2B

• **Collaboration with FOPH and other experts is established**
  – Section Pandemic Affairs
  – Federal Commission for Vaccines

• **Epidemiological studies with the prepanademic vaccine**
  – Small pilot study in 2008 (200-400)
  – Large cohort study in 2009 (>3’000)
Status and Activities (2)

- **Database Refinements**
  - Language versions German, French, Italian
  - Secure access
  - Tool to gather demographic data about the vaccinated population
  - Implementation of experiences from studies

- **Development of the Info Concept**
  - Daily business
  - Pandemic scenarios

- **Staffing and Outsourcing**
  - Negotiation with CRO’s and call centres
### List of reports

You can filter reports by date, header, report IDs, and other criteria.

#### Reports that you have previously entered

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<th>Header</th>
<th>Date created</th>
<th>Date last saved</th>
<th>Reporter name</th>
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<td>12.12.2007</td>
<td>Schneider</td>
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Proposals for Collaboration

• Between Countries
  – Forum to exchange experiences from previous pandemics
  – Update information about pandemic preparedness
  – Database on safety and efficacy of pandemic medicines

• WHO / UMC
  – Provide PaniFlow for ADR collection to all WHO member states (translation into local languages?)
  – Provide common pandemic ADR database and signal detection tool
  – Provide epidemiological data about rare diseases which may also be triggered by pandemic vaccination and other medicines