Pandemic (H1N1) 2009 influenza vaccination in the EU

Dr Antoon Gijsens

Unit C3 - Health Threats
Directorate C - Public Health and Risk Assessment
Directorate-General for Health & Consumers
The need for EU coordination

- Vaccine – the most effective public health measure
  - individual protection & prevent onward transmission

- Vaccination = a Member States’ responsibility

- However
  - vaccine available in limited quantities
  - necessity to ensure adequate coverage of priority groups
  - not same level of preparedness in all Member States

Need for coordination at EU level
Main EU actors

EU task force

EC
- Coordination of the strategies
- Centralised Vacc. Market. Authorisation
- Procurement

EMA
- Review of effectiveness and Safety of vacc proposed for
- Centralised approval
- Opinion on Centralised Market Authorisation
- Pharmacovigilance

ECDC
- Scient. Recommendations on priority groups and target
- I-Move / Review of effectiveness
- Monitoring of side-effects
EU coordination - overview

- Information sharing, scientific guidance, policy coordination
  - Information sharing between Member States
  - Recommendations for pandemic (H1N1) 2009 influenza vaccination strategy
  - Evaluation and review of the vaccine capacity
- Regulatory authorisation of vaccines at EU Level
  - Evaluation of the vaccines proposed for centralised authorisation
  - Granting the market authorisation
- Monitoring of vaccination campaigns
  - Vaccine safety and effectiveness
  - Vaccine uptake
- Evaluation of vaccination campaigns and strategies
Information sharing and scientific guidance

Vaccine development and approval

Vaccine Procurement

Vaccination Campaigns

Pharmacovigilance/Vaccine effectiveness

Evaluation/Lessons learnt
Limited supply of vaccines = necessity to prioritise

August 2009: the Member States agree on priority groups:
- > 6 months with underlying chronic conditions increasing the risk for severe disease (16%)
- Pregnant women (1.5%)
- Healthcare workers (2%)

September 2009 – Commission Staff Work. Doc. Vaccination strategies against Pandemic (H1N1) 2009
- Commission’s views on priority and target groups
- Objectives of the vaccination strategy
  - Maintain essential services
  - Protect the vulnerable
  - Limit the spread of the infection
EU coordination – policy coordination

- Maintaining essential services
  - healthcare workers (2%)
  - workers in other essential services (4%)
- Protecting the vulnerable
  - all persons aged from 6 – 24 months (1.5%)
  - all persons from 2 – 64 yrs with underlying health issues (8%)
  - pregnant women (1.5%)
  - all persons aged 65 yrs and more (17%)
- [Limiting the spread of infection]
  - all persons aged from 25 mths to young adults (17% if up to secondary education; 25% if up to tertiary education)]
  - => 34 – 60.5% population; ~>54% coverage needed to reach herd immunity (R0~1.6; VE~70%)

MS are free to develop different strategies!
EU coordination – vaccine evaluation

- Procedures
  - National
    - Vaccine safety and efficacy evaluated by 1 national authority
    - Vaccine only licensed in one country
  - Decentralised – EU wide
    - Vaccine safety and efficacy evaluated by 1 national authority
    - Other countries mutually recognise the evaluation and license the vaccine
  - Centralised – EU wide
    - Vaccine safety and efficacy evaluated by European Medicines Agency
    - EU-wide vaccine license granted by European Commission
EU coordination – vaccine evaluation

- Centralised procedure – the mock-up procedure
EU coordination – vaccine approval

EU-wide approved vaccines

- 29 September 2009
  - Focetria (surface antigen, inactivated, adjuvanted MF59C.1) – Novartis
  - Pandemrix (split virion, inactivated, adjuvanted AS03) – GSK
- 06 October 2009
  - Celvapan (whole virion, Vero cell derived, inactivated, non-adjuvanted) – Baxter
- 23 March 2010
  - Arepanrix (split virion, inactivated, adjuvanted AS03) – GSK
  - Pending
  - Humenza (split virion, inactivated, adjuvanted AF03) – Sanofi Pasteur
EU coordination – access to vaccines

- Joint procurement mechanism
  - Objective: facilitating procurement for those Member States that had no procurement contracts in place by the end of summer 2009
  - Using other Commission's services expertise and MS' experience, DG SANCO worked with the interested MS on a procurement contract template

- EU countermeasures virtual stockpile (vaccines and antivirals)
  - EC acting as a broker between the Member States having surplus and the Member States in need
EU coordination – monitoring

- All Member States, except Poland, organised a vaccination campaign
- Total number of doses distributed: around 190 million doses
- Total number of vaccinated individuals: 46 million (~9% EU pop.); 31 M Pandemrix, 6.5 M Focetria, 0.56 M Celvapan, 8 M nationally licensed vaccines
- Groups that were vaccinated:
  - Priority groups: based on the August 2009 agreement between Member States
  - Beyond the priority groups: varied between the Member States, based on the public health objectives and national/regional situation
- Vaccine safety: excellent safety record, the vast majority of reported adverse reactions were non-serious
- Vaccine effectiveness: I-MOVE project (coordinated by ECDC), preliminary results point at 70% effectiveness
EU coordination – lessons learnt (1)

- Mock-up procedures worked well
- Strategy Coordination
  - Information sharing procedures worked well
  - EU policy coordination
    - Consensus over priority groups for vaccination
- Pharmacovigilance worked well
EU coordination – lessons learnt (2)

- **Access to vaccines**
  - Necessity to reconsider possibility for EU-wide initiatives
    - Joint procurement
    - Virtual stockpile

- **Communication**
  - Need for clear, straightforward public info
  - Need for strengthened risk and crisis communication strategies
  - Take into account the new social communication technologies
**Ongoing activities + next steps**

- Evaluation of pandemic vaccination strategies
  - Development of tool for MS to evaluate their pandemic vaccination strategy (provided to MS mid April 2010)
  - Questions on aspects of pandemic vaccination strategies linked to EU coordination
    - Answers from MS received 14 May 2010
    - Analysis to be finalised by end of June 2010
- BE Presidency Conference
  - 1-2 July 2010 – MS and the Commission
    - Discuss lessons learnt
- Revision of the EU Pandemic Preparedness Plan
Thank you for your attention!

DG SANCO web page on pandemic (H1N1 2009) influenza:
http://ec.europa.eu/health/communicable_diseases/diseases/influenza/h1n1/index_en.htm

ECDC web page on pandemic (H1N1 2009) influenza:

EMA web page on pandemic (H1N1 2009) influenza: