



Pandemic (H1N1) 2009 influenza vaccination in the EU

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The need for EU coordination

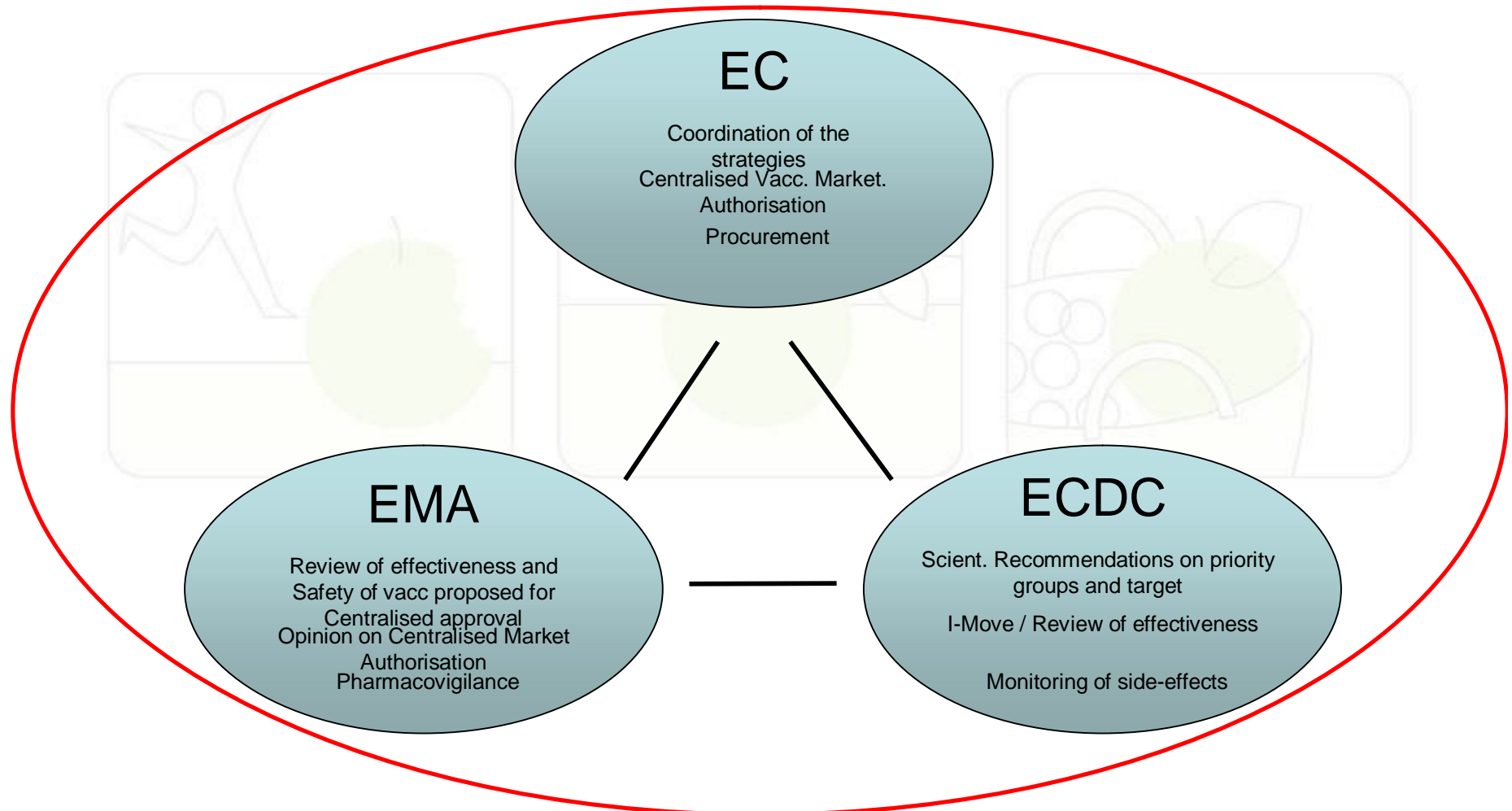
- Vaccine – the most effective public health measure
 - individual protection & prevent onward transmission
- Vaccination = a Member States' responsibility
- However
 - vaccine available in limited quantities
 - necessity to ensure adequate coverage of priority groups
 - not same level of preparedness in all Member States



Need for coordination at EU level

Main EU actors

EU task force



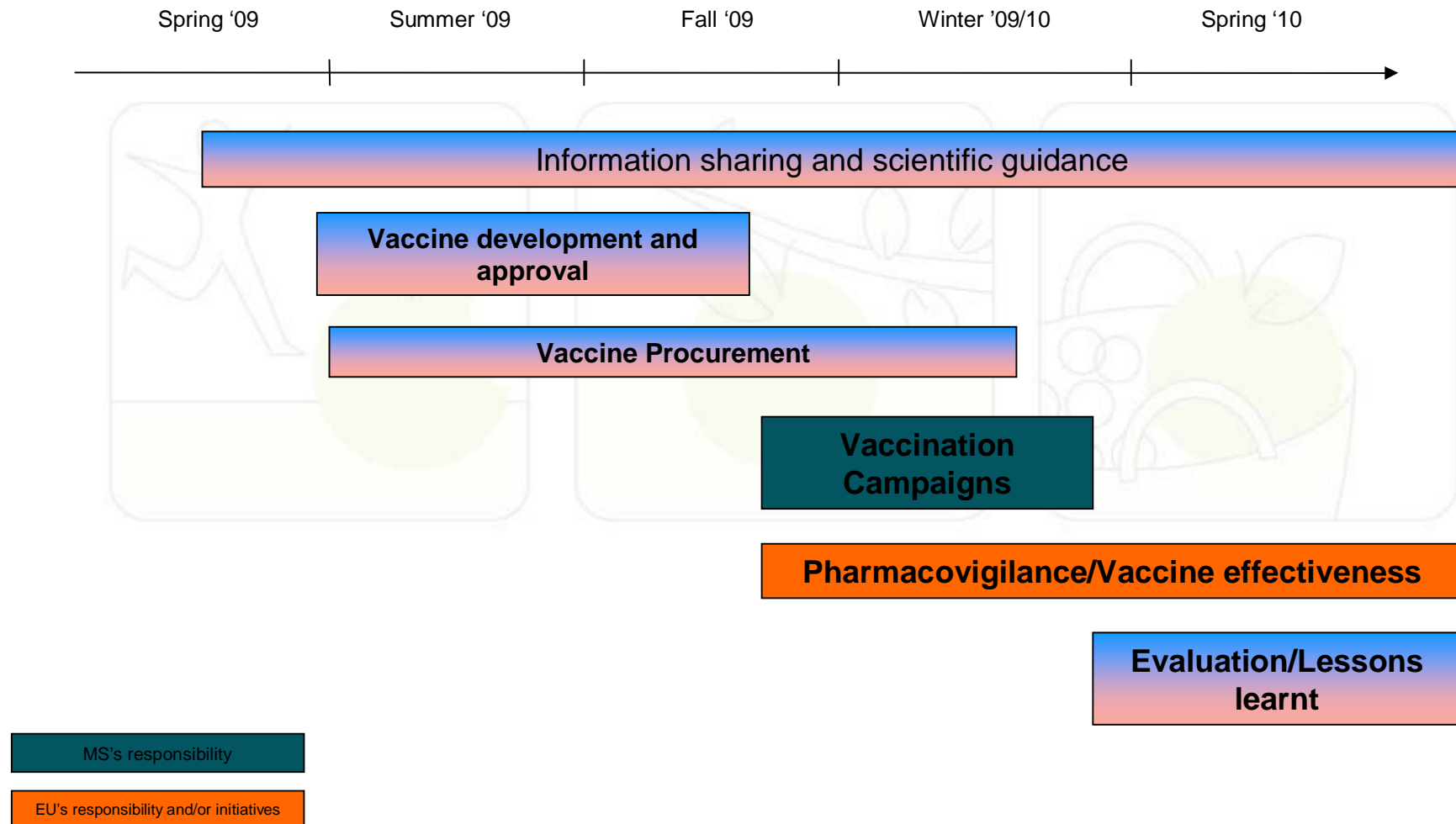


EU coordination - overview

- 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



EU coordination - time line





EU coordination – policy coordination

- 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 – 64yrs 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

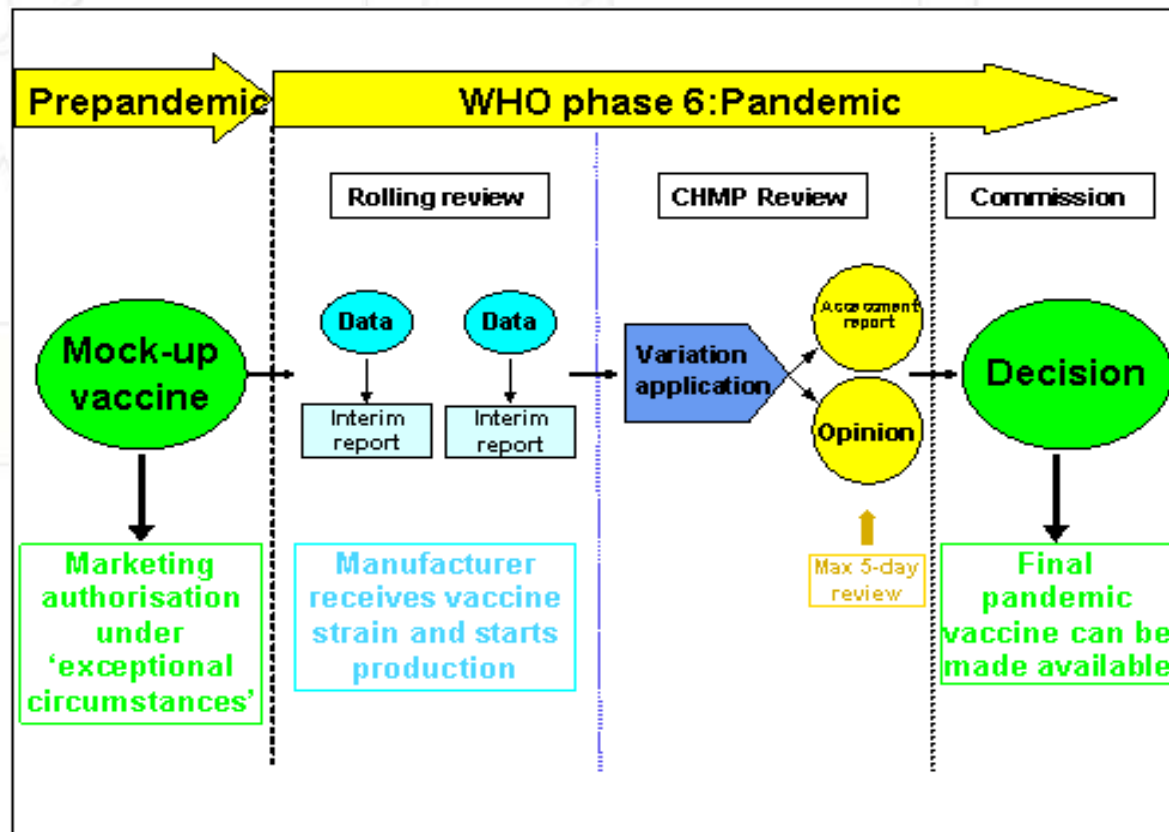
- vaccine safety and efficacy evaluated by 1 national authority
- other countries mutually recognise the evaluation and license the vaccine

■ 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:

<http://www.ecdc.europa.eu/en/healthtopics/H1N1/Pages/home.aspx>

EMA web page on pandemic (H1N1 2009) influenza:

<http://www.ema.europa.eu/influenza/home.htm>