EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

A/H1N1 vaccines benefit-risk monitoring: EU added value

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Background

ENCePP Meeting on vaccine vigilance, 17 September 2009

Objectives

- To provide an overview of the EU Strategy for Influenza A/H1N1 vaccines benefit-risk monitoring, in particular as regards research needs
- To learn about planned or existing projects on the safety and effectiveness of A/H1N1 vaccines that may contribute to the strategy, especially those to be carried-out at the EU level
- To agree on principles of communication and collaboration between research groups and regulatory/public health authorities
- To brainstorm about needs for research

➔ Need for research

- Monitoring of vaccine safety in vulnerable populations (children, pregnant women, immuno-compromised subjects)
- Surveillance of rare adverse events, eg. GBS
- Investigation of emerging safety issues
- Benefit-risk assessment/modelling

Where are we now ?

European Medicines Agency

ecdc EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

HMA Heads of Medicines Agencies

European Strategy for Influenza A/H1N1
Vaccine Benefit-Risk Monitoring

European Strategy published on 5 November 2009

http://www.emea.europa.eu/pdfs/human/pandemicinfluenza/european_strategy.pdf

or: EMEA website → Pandemic influenza website → Latest news

EMEA and National Competent Authorities

- Establishment of a EU Pandemic Pharmacovigilance Rapid Response Expert Group (PREG) – weekly TCs, more if needed
  - analysis of emerging safety issues and recommendations
- Procedures for rapid assessment and decision-making
  - e.g. variation of product information for high fever after 2nd dose
- Collection of EU-wide information on
  - vaccination policies
  - exposure data
  - background rates on adverse events of special interest
- Communication
  - National competent authorities' website and publications
  - EMEA Weekly Pandemic Pharmacovigilance Update

Marketing Authorisation Holders

- Monthly simplified Periodic Safety Update Reports
  - summary of important information from spontaneous reports and analysis of safety issues in populations at risk
- PASS of 9,000 subjects for each vaccine stratified by age
  - on-going – first interim data have been filed and are being analysed
- Pregnancy registries
  - on-going with operational difficulties
- Rare disorders (eg. Guillain-Barré syndrome) and populations at risks
  - limited research activities from MAHs (eg. GSK & rare autoimmune disorders)
- Effectiveness studies
  - sharing of information between ECDC consortium, EMEA and MAHs

Research groups

- Inventory of ENCePP centres with research activities/database relevant for A/H1N1 vaccine B/R monitoring:
  - 43 projects, 8 multicountry, 35 national (14 countries)
- Multicountry projects
  - ENTIS: prospective follow-up data on exposed pregnancy registries
  - EUROCAT: statistical monitoring of congenital anomaly prevalence
  - EuroSIDA: prospective cohort of HIV-infected patients
  - FLUSECURE: effectiveness and safety cohort study
  - I-MOVE: 8 case-control studies and 4 cohort studies on effectiveness
  - INSIGHT network: two flu studies in H1N1 infected patients
  - RegiSCAR: severe skin reactions in relation to H1N1 vaccines
  - VAESCO
    - calculation of background rates of specific AESIs
    - EU-wide hypothesis testing studies of GBS and other AESIs

Research groups (cont'd)

- WHO International case series study on Guillain-Barré syndrome
  - Several ENCePP centres participating or pending, eg. academic hospitals in Spain, Greece and Portugal; VAESCO centres
- Collaborations between academic centres and regulatory authorities

  e.g.
  - case-control and cohort studies sponsored by Ministries of Health
  - use of public registers – extension to vaccine safety monitoring

What remains to be done ?

- Foster the collaboration between investigators working on the same topic at national and multicountry levels
  - e.g. agreeing on pregnancy outcomes – agreeing on definitions
- Establish collaboration for analysis and interpretation of results across studies
- Design study on benefits and risks of vaccination in large populations
- Take the opportunity to identify and address hurdles for vaccine safety monitoring in Europe
- Take the opportunity to develop new methodological approaches or adapt existing ones in the field of vaccine safety.

Examples of methodological approaches

- Pregnancy registry with post-natal follow-up (UKTIS)
- Distributed network approach for calulating background rates of events (VAESCO)
- Study in immunocompromised subjects (EuroSIDA)

Thank you !