EU Legislative and Policy Developments in the Public Health area: focus on Medicinal Products

Updates: January – March 2014

EMA Management Board

19-20 March 2014

Presented by: Mr Andrzej Rys,

Director

Directorate General for Health and Consumers

Health and Consumers

Pharmacovigilance deliverables

- ✓ Post-authorisation efficacy studies (PAES): preparation of delegated act
  - Public consultation (Nov. 2012 – Feb. 2013) ✓
  - Expert group meeting/consultation (March – Oct 2013) ✓
  - Adoption of delegated act by the Commission (Feb. 2014) ✓
  - Submission to EP and Council – right to object (Feb- April '14)✓
  - Publication and entering into force

Pharmacovigilance deliverables

- ✓ Joint action: exchange of experience and knowledge on pharmacovigilance systems.
  - 3.3 million euro grant awarded to the Pharmacovigilance Joint Action SCOPE – Strengthening Collaboration for Operating Pharmacovigilance in Europe
  - Expected to support the implementation of the pharmacovigilance legislation across the EU
  - Leader is the UK, 24 Member States are participating
  - EMA is participating as a collaborating partner
  - Project started November 2013 and will run until October 2016
  - 10 March 2014 was the first General Advisory Board meeting
  - Nearly all work packages are on schedule

Fees for pharmacovigilance – procedural aspects

- EP and Council reached an agreement at the Trilogue on 12 February 2014
- COREPER endorsed the agreement unanimously on 19 February 2014
- EP Plenary vote scheduled on 16 April 2014
- After EP vote, text to be formally adopted by Council
- Next step: text to be signed by President of EP and Council and, subsequently, to be published in the OJ (June 2014?)
- Applicability:
  - **Procedure-based fees: probably as of August/September 2014 (~ 60 days following publication in the OJ)**
  - **Annual fee: as of 1 July 2015**

Report on the functioning of the Advanced Therapies Regulation

- ✓ Report mandated by Regulation 1394/2007
- ✓ Public consultation showed significant interest in the topic (63 contributions)
- ✓ Summary of the public consultation published on 22 May 2013:
  - **Overwhelming majority of contributors requested changes but the type and extent of changes requested are very diverse (often in contradiction).**
  - **Lack of harmonisation in the application of the hospital exemption perceived as a problem.**
- ✓ Report to adopted by end of March 2014.
- ✓ Publication will follow shortly thereafter.

Falsified Medicines 1 / 3

➢ ***EU Directive adopted in June 2011 - Transposition by January 2013***

Implementing measures (I):

- Delegated act on the detailed rules for a **unique identifier (UI)** for medicinal products, and its verification
  - → Impact assessment finalised. Most cost-effective options:
    - Fully harmonised UI carried by a 2D barcode
    - UI verification at point of dispense + risk-based checks by wholesalers
    - UI repository set up and managed by stakeholders under NCA supervision.
  - → MS consultation on content of Act and lists of exceptions ongoing
  - → Adoption of Delegated act by end 2014.

Falsified Medicines 2 / 3

Implementing measures (II):

- Delegated act on principles and guidelines of **GMP for active substances** in the EU:
  - → Consultation of MS experts concluded.
  - → Adoption planned for Q2 2014.
- Establishment of a common **EU logo for online pharmacies**.
  - → Adoption aimed before the summer.
- Guidelines on (i) **GDP for API** and (ii) risk assessment for **GMP for excipients**:
  - → GMP for excipients with COM for internal process, but awaits from EMA/IWG GDP for API. Parallel COM process for the guidelines.

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Importation of active substances

- No significant shortages to date
- Most API sites are either covered with written confirmation or exempted because of "listing" of the non-EU country.
- CH, US, JPN and AUS have been listed. Brazil and New Zealand assessments are on-going. No new requests.
- The Commission is following-up on GMP non-compliance of API sites covered by W-Cs.
- The API Q&A now clarifies that EU statements of GMP non-compliance supersede the corresponding written confirmations.

Clinical Trials

- ✓ The Regulation proposal was adopted by the Commission in July 2012.
- ✓ The Council and EP reached political agreement in December 2013.
- ✓ The EP plenary vote will take place on the 3rd of April 2014. The formal vote in the Council will follow.
- ✓ Once formally adopted, the Regulation will be published in May/June.
- ✓ It will become applicable no earlier than two years after its publication in the OJ.
- ✓ The entry into application of the Regulation is linked to the full functionality of the Clinical Trials Portal and Database, developed by EMA.

Revision of Veterinary Medicines legislation

Update on timelines:

- ✓ Positive opinion of Impact Assessment Board on revised version of Impact Assessment
- ✓ Consultation of Commission services on-going
- ✓ Draft legislative proposal: *adoption planned for 2014* (package of medicated feed and veterinary medicines)

Antimicrobial Resistance

- ✓ Commission's conference on antimicrobial resistance : state of play of action plan, human and veterinary sector (11.12.2013);*more than 180 participants, presentations by EC, WHO, OIE and FAO*
- ✓ Staff working document, expected 2nd quarter of 2014
- ✓ Decision 2013/652/EC monitoring AMR in food/animals (into force 2014)
- ✓ Three agencies (ECDC/EFSA/EMA) preparing joint report on the analysis of the relationship between consumption of antimicrobial agents and the occurrence of AMR

Revision of Medical Devices (MD) and in vitro diagnostics medical devices (IVD)

European Parliament

3rd April 2014 : 1St reading plenary vote on the basis of the test voted on 22 October 2013 mandating the Rapporteurs to engage in Trilogues with the Council on the basis of the voted amendments.

Council

22 meetings of the Council Working Party (CWP) on Pharmaceuticals and Medical devices under CY, IE, LT and EL PRES. First reading through both proposals achieved except for the final provisions and the Annexes. Examination of compromise texts ongoing.

Next meetings:
10 April, 16 April CWP
20 June: EPSCO council

Health Technology Assessment Network

- First meeting October 2013, all MS + Norway; EMA regularly invited; stakeholders are observers
- Next meeting on 7 April to discuss 1st draft strategy paper "Long term provisions for EU cooperation in HTA" (adoption in Oct 2014)
  - "Life cycle approach" to HT and importance of synergies with regulators (dedicated strategy paper planned October 2015)
  - Possibility to rely on existing EU Agencies to ensure financial sustainability for EU cooperation on HTA → EMA to play a role in a possible Joint Action 3 on HTA
- EMA-EUNetHTA ongoing cooperation at scientific level (next meeting May 2014)
- EMA involved in the "SEED consortium" on early dialogues with HT Developers

eHealth Network

- First **guidelines on sharing of patient summary data** adopted unanimously (Nov 2013)
- The guidelines contain the minimum (clinical) dataset to be shared across borders
- Next: **guidelines on ePrescription**
- Mutual recognition of prescriptions is also possible by electronic means
- Guidelines likely to refer to work of EMA on IDMP (International Standards on Identification of Medicinal Products)
- Question: will IDMP and SNOMED CT be interoperable?

Mutual recognition of prescriptions

- Implementing Directive 2012/52/EU on measures to facilitate the recognition of medical prescriptions issued in another Member State: on-going assessment of transposition measures

European References Networks (ERN)

- Adoption of two Commission Decisions on 10 March 2014*:

  (1) criteria for ERNs and providers wishing to join a Network

  (2) establishment and evaluation of ERN and exchange of information and expertise in relation to the establishment of ERN and their evaluation

  *(delegated act currently under scrutiny of EP and Council)

Thank you!

European Commission

Public Health information:

http://ec.europa.eu/health/index_en.htm

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