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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products

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DRAFT

eHEALTH NETWORK 7TH NOVEMBER 2012

Subject: **Point 5 of the agenda: interoperability of databases of medicinal products in the EU**

For discussion and decision on follow up steps: background paper suggested by the Secretariat.

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1. INVOLVEMENT OF THE EHEALTH NETWORK

The Secretariat considers that the eHealth network (EHN) should clarify the expected level of its involvement in the work to make medicinal products databases interoperable.

The specifics of this suggestion are as follows: since a process towards semantic and technical interoperability is included in the pharmacovigilance provisions, with strong involvement of national and EU regulators, the eHealth network could:

- give political impetus for the adoption of standards on identification of medicinal products and resulting terminology, as agreed in the Commission Implementing Regulation 520/2012
- give a mandate to the eHGI, the Secretariat and the regulators to look into the opportunities to access the pharmacovigilance databases, according to article 57(2) of Regulation 1235/2010 (amending Regulation 726/2004), and also for other purposes such as ePrescriptions and pricing/reimbursement.
- give mandate to the eHGI, the Secretariat and the regulators to analyse in detail the needs unmet by the regulatory framework, in the short (before 2016) and longer terms.

Organisation of the discussion

- Introduction by the Chair
- Belgium perspectives on opportunities and challenges of interoperable databases: 15’
- EMA's report on current and possible future activities on interoperability of cross-border databases for medicinal products, presented by Guido Rasi, Director of EMA: 15’
- Discussion and conclusion: 30'

2. BACKGROUND INFORMATION

2.1. Introduction

The eHealth Network was set up under Article 14 of Directive 2011/24/EU on patients' rights in cross-border healthcare.

"Interoperability between the European and national databases for medicinal products" is on the agenda of the Network meeting of 7 November.

This topic was suggested by Belgium at the first eHealth Network meeting on 8 May 2012 and was supported by other Member States. The eHealth Governance initiative (eHGI) suggested in September 2012 to extend the scope to medical devices but this is not covered in this paper, due to lack of preparation time as well as timing considerations for the agenda of 7 November.

Why is it important?

ePrescription is defined as the electronic prescribing of medicine with the use of software by a legally authorized health professional, followed by the electronic transmission of this prescription data to a pharmacy where the medicine is dispensed. ePrescription conveys information related to the patient, the health professional and the medicinal product. Only the last point is covered in this note.

ePrescription can facilitate dispensation of medicinal products in a cross border context and improve patient safety and continuity of care.

Access to a patient's records allows the prescribing doctor, as well as the dispensing pharmacist to access and take account of the medical history/product history of the patient. In a cross-border context, this would require access to records held in another Member State.

Access to medicinal product databases of EU regulators would allow validation processes to be built in that would ensure that the prescribed product is correctly identified. In a cross-border context this access could help to identify the product in view of semantic differences or differences as regards the name of the medicinal product, dosage or authorisation status.

Interoperability means the **semantic**, **technical and connective interoperability** between existing (and future) databases, which is needed to ensure automatic export and import of data and information from one database into another. This would improve efficiency and also facilitate the access to these data (including on-line interrogation) by various actors and interested parties.

What are the issues at stake?

Experience from the EPSOS large scale project demonstrates that cross border ePrescription will require a common approach and a unique and unambiguous vocabulary i.e. reference terminology, to communicate electronically about medicinal products, medical devices, diseases, patient data etc.

Various databases exist at national and EU levels. As they have been built to meet different needs, they include different elements, different data and information. They also require major resources for their maintenance.

EU Member States use different database architectures and data models and apply non-harmonised coding, classifications and terminology to describe a medicinal product in national databases.

The added-value and the cost-effectiveness of any investment must be evaluated to avoid scarce resources being directed into projects that would duplicate efforts and not meet the required objectives.

2.2. Regulatory Framework

EU legislation on medicinal products lays down the requirements for databases covering information on medicinal products. This applies equally to centrally authorised products and nationally authorised products. The legislation requires EMA and/or national competent authorities to make available:

– EMA Eudrapharm database (searchable public database)

– EMA Eudravigilance database (pharmacovigilance database)

– EMA's upcoming EU medicinal portal and national portals

– National databases for nationally authorised products, which feed information into EMA databases

– Pharmaceutical Industry databases by which marketing authorisation holders submit information on medicines to EMA

In a briefing note dated 3 May 2012, EMA pointed out the difficulties to implement the legislative framework, notably for financial reasons, and the shortcomings of Eudrapharm. It should be noted that since then EMA is streamlining its IT projects.

An improved interoperability between the above databases would avoid duplication at EU level and national level, reduce costs and allow better access of the content of those databases for secondary purposes (e.g. eHealth applications).

It needs to be noted that:

1. With the upcoming adoption of the CEN/ISO standards for identification of medicinal products (five ISO IDMP standards) an important tool has been developed that will support the alignment of IT records and has the potential to establish unique identifiers. Commission implementing regulation 520/2012 on the performance of pharmacovigilance activities provides for the optional use of the new ISO/CEN IDMP as of 2016. This date is linked to the expected full availability of the upgraded Eudravigilance database and is intended to avoid investments at national level in functionalities which may in 2016 be replaced by the Eudravigilance database.

2. On the other hand, the issue of the technical interoperability of the EU and national databases will not be resolved until all Member States are correctly implementing the above mentioned regulation. A roadmap towards an integrated IT

architecture and the implementation of the international standards is being elaborated by the EMA in collaboration with the EU Regulatory Network.

3. Member States will soon vote on a draft Commission implementing act under Directive 2011/24/EU on recognition of prescriptions. The Act will stipulate the minimum information required, including the INN and the brand name for biological products.

2.3. Synergy between work on medicinal products databases and prices

The Commission is currently supporting an initiative called Euripid, which aims at collecting and standardising information on official prices of pharmaceuticals in the EU. 18 Member States are involved (plus Iceland and Norway).

The sustainability of this initiative is being discussed amongst the actors. Financial support can potentially come from the European Commission, Member States, or fees from additional, agreed users (access is currently restricted to national competent authorities contributing their data, and the European Commission).

Euripid faces similar challenges as EPSOS large scale project's work on cross border ePrescription as regard the unambiguous identification of individual medical products. The question of whether the work conducted under the regulatory framework for pharmacovigilance could help solve this issue could be explored.