Transparency and Dissemination of Information

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European Medicines Agency

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Scope

- Addressing transparency and dissemination of information (…released by EMEA…)
- Not addressing the EMEA transparency policy as adopted by Management Board in October 2002
- Not addressing Transparency Directive *89/105/EC*

Transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems

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More transparency in order to, among others:

- Receive information on availability of medicines in the EU
- Receive validated and useful information for treatment decisions by patients (potential benefits, safety and risks, optimum use etc.)
- Collaborate with the EMEA communication strategy (i.e. in case of product alerts, explanation on opinions etc.)

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Transmission/dissemination of information on medicines

- EMEA + PO should encourage alternative sources of information voluntary and statutory
- Structure of EMEA web site to be reorganised
  - Search by disease name, medication class, therapeutic indication, INN
- E-mail lists of patients organisations (safety updates, SMOPS, EPARs, guidance documents…)

Implementable as such by EMEA

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European Public Assessment Report (EPAR) and Q&A

- Patient friendly version to be developed with comparison with other therapeutic options considered during evaluation
- Post-authorisation commitments, deadlines and completion available for patients and general public
- EMEA should produce Q&A documents to address specific situations affecting the use of medicines (case-by-case)

Implementable as such by EMEA

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Timing of information dissemination before CHMP opinion

- Confirmation of submission of applications, procedural timetables for specific products
  - Currently PO not informed on when CHMP is evaluating a given product. How to sent spontaneous opinions?
- Provision of additional information prior to CHMP opinion to be decided between EMEA and industry (e.g. clock stop, questions raised)

Implementable as such by EMEA

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Transparency and awareness of EMEA

- Freedom of access to information vis à vis patients' needs: starting point for EMEA
  - Necessity of limitations to this freedom has to be demonstrated on a case by case basis
- The EMEA, after discussion with industry, needs to clearly define the concept of "commercially confidential information" in order to allow for transparent communication
  - Else, how could PO participate to readability testing?
- EMEA and its role/activities should be publicised and better known by the public

Implementable as such by EMEA

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Screening and identification of information on med

- Based on collaborative approach between regulatory bodies (e.g. NCA), health education officers, patient groups, consumer org. and industry
- Information on all medicines authorised in the EU should be made available
- Data sources: EudraVigilance, EuroPharm, databases of NCA
  - PO: to express expectations o what information should be publicly available from these databases

Harmonised approach required

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Validation of information on medicines

- Level of validation of information should be reflected, including reliability of data source
- PO to develop a template guidance against which information provided by them and external sources could be validated
- PO could consider self-regulation mechanism concerning the information to be presented

Harmonised approach required

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Transmission/dissemination of information

- MS should make a listing of national patients associations
  - publicly available
  - In line with criteria defined in the Policy on Patients and Consumers organisations involved in EMEA activities

Harmonised approach required

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Information regarding withdrawal of products under development

- Information on withdrawal or premature cessation of a product under development which is not validated by a scientific assessment highlights an area which requires review.
- It is suggested that this issue will be referred to be considered by the European Commission

Amendment to current legislation required

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Some comments received

- Increased workload for EMEA
  - Medical information sector
- Potential to affect the Agencies timelines (additional procedures, e.g. readability testing)
- FDA procedures as a reference
  - EU can develop its own model
- Specific Information on the disease: out of the scope of the Agency
  - For patients it is crucial to put the drug in the context of the disease, e.g. when treatment guidelines exist. Validation under EMEA responsibility. Links with Patients' Organisation web sites (code of conduct accreditation)
- Not all products evaluated by CP.
  - To focus on products for which CP is mandatory
- Public hearings during scientific evaluation
- E-mail lists of patients organisations (safety updates, SMOPS, EPARs, guidance documents…)
  - Not to patients directly as it could interfere with Dr to patient relationship
- Patient version of EPAR reviewed by MAH to protect commercially confidential information
  - To revisit the concept of "commercially confidential information"