EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ZonMw-congres: Goed Gebruik Geneesmiddelen 2018

De EMA en haar rol in goed gebruik geneesmiddelen
EMA's role in the rational use of medicines

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(potentiële) Belangenverstrengeling	Geen
Voor bijeenkomst mogelijk relevante relaties met bedrijven	Niet van toepassing

Problem statement

- WHO definition: Rational use of medicines requires that "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community"
- Non-rational use of medicines is a major worldwide problem
- WHO:
  - >50% of all medicines are prescribed, dispensed or sold inappropriately
  - Half of all patients fail to take their medicines correctly

⇨ Widespread health hazards (such as AMR)

⇨ Wastage of scarce resources (including high healthcare costs)

- Several actors are involved in the rational use of medicines (authorities, policy makers, legislators, healthcare professionals, patients, pharmaceutical industry, …), hence a holistic approach and problem resolution is needed

EMA’s role in the rational use of medicines

- Is to a large extent limited as EMA cannot directly influence the prescription of medicines itself
- However, EMA can contribute to a more rational use of medicines through initiatives that fall within its remit

Examples of EMA initiatives in achieving a more rational use of medicines (1/2)

- Facilitating access to medicines:
  - Introduction of the PRIME scheme for innovative medicines
  - Biosimilar development, EU being at the forefront
- Improving the availability of up-to-date, high-quality and independent information on medicines:
  - Better labelling of indications
  - EMA/HMA/EC Action Plan to improve Product Information, with initial focus on improving access to electronic product information
  - "Modernisation" of SPCs for "old" antibiotics in the context of the fight against AMR

Examples of EMA initiatives in achieving a more rational use of medicines (2/2)

- Generating more robust evidence to facilitate the B/R assessment of medicines:
  - Big data and real world data initiatives
- Fostering a more collaborative approach with the various parties in the healthcare system:
  - EMA moving towards a role as an "enabling regulator"
- Working globally:
  - EMA contribution to WHO initiative on essential medicines
- Repurposing of "old" medicines:
  - EMA involvement in STAMP (Safe and Timely Access to Medicines for Patients) initiative

Focussing on EMA as an “enabling regulator”

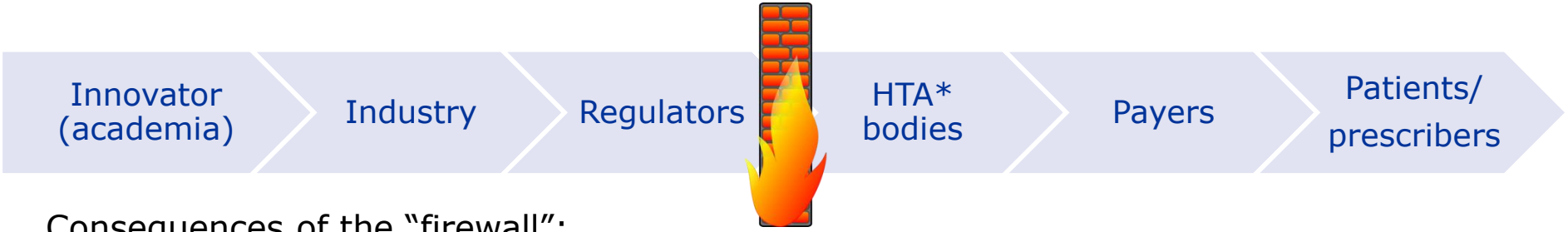
- Examples:
  - More efficient drug development/evidence generation plans
  - Better tools and methods for drug monitoring
  - Giving weight to the patients voice

More efficient drug development/evidence generation plans (1/2)

- How it was: the historical, linear, non-interaction model

*HTA – Health Technology Assessment

More efficient drug development/evidence generation plans (2/2)



Consequences of the "firewall":

- Different evidence-standards → need for extra studies (to satisfy information needs of different decision makers) → inefficient development plans
- Delays in patient access
- (Avoidable?) disagreements on treatment population
- Fragmented approach to post-licensing knowledge generation

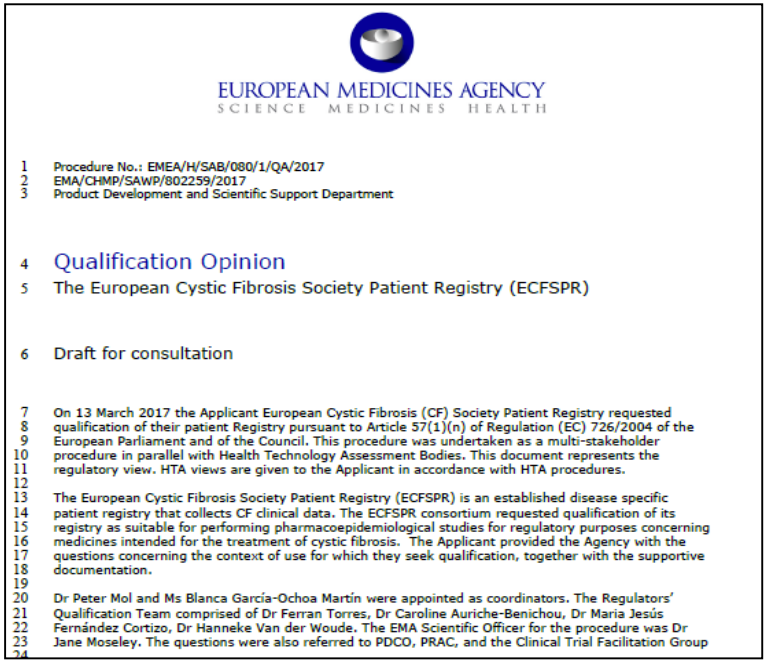
Tearing down the firewall: How to achieve? (1/3)

- First step: parallel advice (Regulators and HTA bodies) to drug developers in a pilot phase
- Second step: learnings from pilot phase resulted in July 2017 in the launch of a single platform (EMA and EUnetHTA as equal partners) for multi-stakeholder advice through parallel consultation

Tearing down the firewall: How to achieve? (2/3)

- Third step: post-licensing evidence generation as the next domain of collaboration on evidence planning
- Qualification of novel methodologies for medicine development in parallel with HTA bodies:
  - First parallel review completed for the European Cystic Fibrosis Society Patient Registry (ECFSPR).
  - Under public consultation until 9 April 2018

[Qualification opinion - The European Cystic Fibrosis Society Patient Registry (ECFSPR)]



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Procedure No.: EMEA/H/SAB/080/1/QA/2017
EMA/CHMP/SAWP/802259/2017
Product Development and Scientific Support Department

Qualification Opinion

The European Cystic Fibrosis Society Patient Registry (ECFSPR)

Draft for consultation

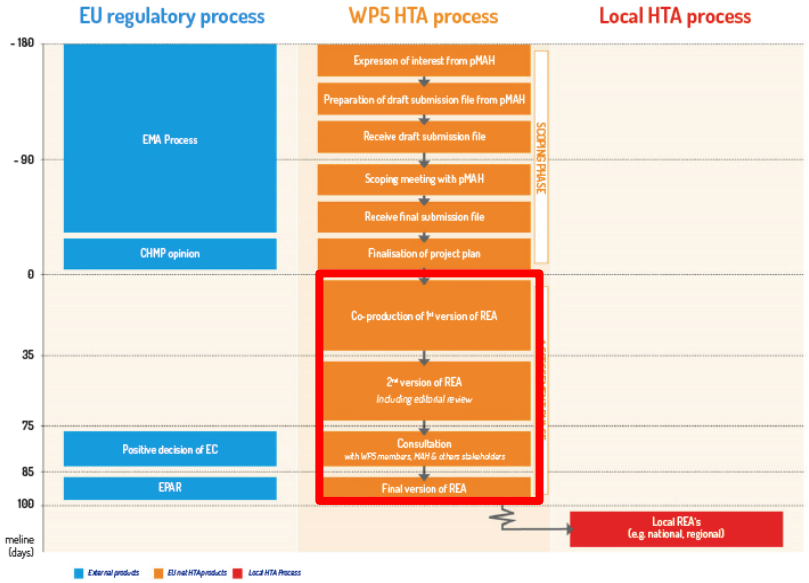
On 13 March 2017 the Applicant European Cystic Fibrosis (CF) Society Patient Registry requested qualification of their patient Registry pursuant to Article 57(1)(n) of Regulation (EC) 726/2004 of the European Parliament and of the Council. This procedure was undertaken as a multi-stakeholder procedure in parallel with Health Technology Assessment Bodies. This document represents the regulatory view. HTA views are given to the Applicant in accordance with HTA procedures.

The European Cystic Fibrosis Society Patient Registry (ECFSPR) is an established disease specific patient registry that collects CF clinical data. The ECFSPR consortium requested qualification of its registry as suitable for performing pharmacoepidemiological studies for regulatory purposes concerning medicines intended for the treatment of cystic fibrosis. The Applicant provided the Agency with the questions concerning the context of use for which they seek qualification, together with the supportive documentation.

Dr Peter Mol and Ms Blanca García-Ochoa Martín were appointed as coordinators. The Regulators' Qualification Team comprised of Dr Ferran Torres, Dr Caroline Auriche-Benichou, Dr Maria Jesús Fernández Cortizo, Dr Hanneke Van der Woude. The EMA Scientific Officer for the procedure was Dr Jane Moseley. The questions were also referred to PDCO, PRAC, and the Clinical Trial Facilitation Group

Tearing down the firewall: How to achieve? (3/3)

- Fourth step: bridge from regulatory opinion to relative effectiveness assessment
- Collaboration between Regulatory and HTA assessors in the context of joint production of relative effectiveness assessment:
  - Make available to HTA reviewers the outcome of the regulatory assessment based on the **final** CHMP opinion
  - Facilitate mutual understanding of the outcomes of each decision making
  - Respect the respective **remits** and under **confidentiality** arrangements



Conclusions

- Rational use of medicines is a multidimensional concept where many parties have a stake
- Collaborative approach between all stakeholders is an important pre-requisite in order to promote rational use of medicines
- EMA has taken, and will continue to take, its responsibility to strive for a more rational use of medicines through targeted initiatives

Any questions?

Further information

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