EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Cooperative Models Between Regulators and Regulated Stakeholders

EMA International Experience

VIII Conference of the Pan American Network on Drug Regulatory Harmonization (CPANDRH), Mexico City

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Content

The EU Regulatory System for Medicines

Based on a network of decentralised National Competent Authorities (NCAs) in the Member States, supported and coordinated by a centralised agency, the European Medicines Agency (EMA)

- 28 Member States, ~ 50 NCAs, ~ 500 million people

The European Commission is a centralised EU institution, whose role includes:

- Proposing new or amending legislation for the pharmaceutical sector
- Adopting implementing measures, ensuring and monitoring the correct application of EU law
- Overseeing the activities of the EMA

Routes to Medicines Approval in the EU System (1)

Centralised Procedure

- Assessment via EMA, resulting in a single marketing authorisation throughout the EU

Decentralised Procedure

- Assessment of a new (not previously authorised) medicine by a Reference Member State on behalf of a group of other Member States

Mutual Recognition Procedure

- Assessment of a medicine authorised in at least one Member State by a Reference Member State on behalf of a group of other Member States

National Procedures

- Assessment by a Member State of a medicine for approval in its own jurisdiction

Routes to Medicines Approval in the EU System (2)

- ✓ The various routes to medicines approval in the EU system are based on a single assessment system so that any assessment report (AR) from any of the agencies in the EU network can be used as a basis for reliance by other regulators

The EU Medicines Agencies Network Strategy to 2020

Published in December 2015

Highlights collaboration in the global regulatory environment as a strategic priority area

Aims at further developing a strong international role for the network by, among other things:

- Capacity building
- Promoting reliance and work-sharing with other regulators

Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000292.jsp&mid=WC0b01ac05800293a4

The International Generic Drugs Regulatory Programme (IGDRP) Information Sharing Pilots (1)

Launched in July 2014

Using the EU Decentralised Procedure as a model for sharing of information (Assessment Reports) during the scientific assessment phase of the procedure

ARs are shared by the EU Agencies in real time with the participating non-EU authorities

- During decentralised procedures for generics participating in the pilot
- Upon request from the company applying for marketing authorisation
- The receiving authorities benefit from the information in the EU ARs but maintain their own regulatory responsibilities for decision-making

The International Generic Drugs Regulatory Programme (IGDRP) Information Sharing Pilots (2)

Currently the pilot involves EU authorities and:

- Health Canada
- Swissmedic
- Taiwan FDA
- Therapeutic Goods Administration (TGA) of Australia

From January 2015 on, the information sharing pilot has been extended to include some applications for generic medicinal products through the Centralised Procedure

The WHO Collaborative Registration Program (1)

Started in 2014 by WHO

Aimed at facilitating and accelerating the national registration of products already assessed and pre-qualified by the WHO

Extended to medicines authorised by Stringent Regulatory Authorities (SRA), as defined by WHO

Objective:

- Accelerate the national approval process in countries where resources may be limited, based on the assessment work already carried out by the SRA, while
- Allowing competent authorities that might have limited regulatory resources to retain their regulatory responsibilities and make their own decisions

The WHO Collaborative Registration Program (2)

EMA has participated to the pilot since November 2014 (4 products so far)

EMA ARs are shared by companies holding marketing authorisations for EU centralised products (art, 58 scientific opinions) with regulators in African countries

EMA:

- Confirms, upon request from the company, that it has no objections to the sharing of its ARs
- Confirms that the Quality Information Summary provided by the company complies with the information in the dossier assessed by EMA (according to WHO procedures)

Use of EU ARs by Regulators Outside the EU

In addition to established cooperation programs, regulators outside the EU often request/allow applicants to provide EU ARs, which are used or considered while assessing products in the receiving country

The use of the EU ARs may be foreseen in the legislation or guidelines of the receiving countries, e.g.:

- Canada
- Mexico
- Singapore
- Switzerland

Modalities for Sharing EU Assessment Reports with Regulators Outside the EU (1)

EU ARs can be shared with non-EU regulators:

- Directly or
- Through the marketing authorisation holder/applicant

Direct exchange

- If a Confidentiality Arrangement (CA) is in place, unredacted EU ARs can be exchanged by EU agencies without further bureaucracy
- CAs are in place between the EU and: US FDA, Health Canada, Japanese MHLW and PMDA, Swissmedic, Australian TGA, WHO
- If no CA, the EU agencies still exchange their ARs unredacted , but the consent of the MAH/applicant is requested
- A template to facilitate MAHs/applicants to consent has been published on the EMA website

Modalities for Sharing EU Assessment Reports with Regulators Outside the EU (2)

Exchange of through the marketing authorisation holder/applicant

- EU ARs can be exchanged by the marketing authorisation holder/applicant provided that it assumes any and all liabilities for any disclosure, particularly with regard to redaction of e.g. personal data and commercial information

✓ The EU system however is exceptionally transparent, most of the information is on the web (e.g. EMA European Public Assessment Reports)

See Q/A n.68 in the EMA pre-submission guidance

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000028.jsp&mid=WC0b01ac0580022716

Conclusions

The challenges faced by regulators in an increasingly complex regulatory environment and the need for cooperation are shared and recognised by the EU Agencies network, and emphasised in the recently published EU network strategy

A joint effort between regulators and the pharmaceutical industry to increase international cooperation is needed

EMA and the other agencies in the European network are trying to facilitate the sharing of assessment and inspection work among regulators

This will be beneficial to both regulators and regulated stakeholders, as well as to the patients, as it has a big potential to avoid duplication of work and to facilitate an easier and faster access to important medicines

Thank you for your attention

Further information

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