New Pharmaceutical Legislation – initial assessemnt of the impact on off- patent medicines

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Medicines for Europe

Pharmaceutical legislation

- Medicines for Europe's general support for the Pharma Review objectives:
  - Ensure access to affordable medicines for patients, and address unmet medical needs;
  - Enable innovation for the development of high quality, safe, effective medicines, harnessing the benefits of digital and emerging science and technology while reducing the environmental footprint;
  - Enhance the security of supply of medicines and address shortages;
  - Reduce regulatory burden and provide a flexible regulatory framework.
  - Address antimicrobial resistance (AMR)

EC key measures to improve access to off patent medicinal products

The intention of the EC was to improve access to affordable off patent medicines by following measures:

- Market entry of generic and biosimilar medicines shall occur earlier than under the current rules on day one of loss of the patent/SPC protection. For orphan medicines, to ensure that generics and biosimilars can enter the market as soon as the market exclusivity period ends.
- Procedures to authorise generics and biosimilars shall be simplified and accelerated,
- Bolar provision to be broaden and to make the development more predictable for the generics and biosimilars industry by harmonising their implementation EU wide.

Main expectations and focus areas for Medicines for Europe

- To foster competition and market entry on day one of loss of any protection.
- To enhance security of supply of medicines and to address shortages
  - To tackle the multifactorial root causes of shortages
  - To report shortages in an efficient way
  - To propose measures for supply chain resilience and to reduce regulatory complexity associated with supply chain management
- To establish a proper balance between the promotion of innovation and access to affordable medicines after exclusivity expiry- no delays, not evergreenings, no misuses.
- To stimulate innovation in known molecules
- To increase efficiency in regulatory processes and to avoid duplication, to simplify regulatory procedures and foster digitisation, to reduce the administrative burden for industry and authorities

Incentives

- General support for more targeted incentives for innovation with a focus on patient access and unmet medical needs
- Shortening of the initial standard period of regulatory protection from 8 to 6 years welcome
  - Maximum period of regulatory protection (RP) that can be granted will be even higher than today
  - RP can add up to a max of 12 years for innovative medicines, while today the max is 11 years.
  - For orphans addressing a high unmet medical need, RP can add up to max of 13 years, while today the max 10 years
- Predictability and transparency of criteria/ decision on granting protection are crucial for all parties
- Incentives for innovation in known molecules (repurposing) a 4 year data protection period welcome

Regulatory efficiency
Some Regulatory/ Procedural Changes

- Shortening of the assessment time from 210 days today to 180 days welcome
  - Incomplete applications will be invalidated during the evaluation, if applicants fail to provide the missing data within set deadlines
  - Shortening of time for the Commission to authorise the medicine from 67 to 46 days.
- DCP/ RUP- some improvements to address barriers and inefficiency not allowing a fast reaction to patients' needs (update of AR on request, not by default), but simplification can go further
- Active Substance Master File (ASMF) certification
  - To address inefficient system of assessing the same documentation for an active substance multiple times.
- Digitalisation of the regulatory network and regulatory operation
  - good reinforcement of digitalisation of variations (submission via database for some variations) but details to be defined;
- Removal of MA renewal process after 5 years
- Definition of generics in art 9 - broader definition to address new possible sources of evidence and modern evidence generation tools (i.e. modelling, RWE/RWD)
- Risk Management Plan (RMP) and risk minimisation measures- reliance of originators data, unless bridging needed
- Labelling
  - States may allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language package is marketed.

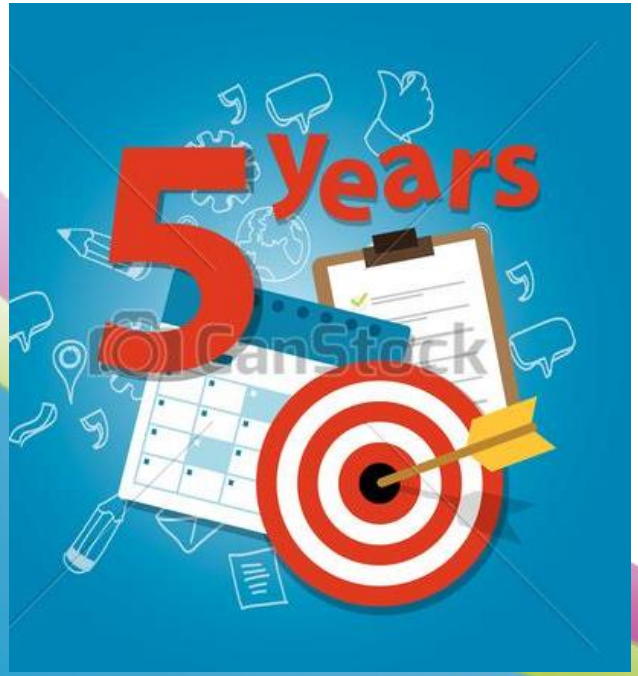
Some Regulatory changes where clarification needed

- Changes in the legal basis
  - Removal of 10b fixed dose combination as a legal basis
  - Bibliographic application allowed when the ref product is not available on the market anymore
- ePI – good that this option is included but phasing-in to ePI only is too long
- MSs opting in the DCP/ MRP
  - The competent authority of a Member State may request for justified public health reasons to opt-in enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the decentralised procedure of its request within 30 days of from the date of submission. of the application. The applicant shall provide the competent authorities of those Member States opting-in- entering the procedure with the application based on an identical dossier without undue delay.

Environmental measures (ERA)

- Strengthening the environmental risk assessment under the marketing authorisation
  - Enhancing ERA by introducing a refusal ground for the marketing authorisation where companies do not provide adequate evidence for the evaluation of the environmental risks or if the proposed risk mitigation measures are not sufficient to address the identified risks.
- For generic and biosimilar medicines – no duplication of studies, reference to existing knowledge (ERA of the reference product if exists)
  - Extending ERA to all products already in the market and potentially harmful to the environment.
- Concept of environmental monographs for active substances

medicines for europe
better access. better health.



Watch this space
in next 5 years!

Thank you
for your attention