EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA and International Engagement for Generics Development

Expanding Generic Drug Access Through International Engagements

CDER SBIA Webinar

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Disclaimer

The views expressed in this presentation are those of the speaker and are not necessarily those of EMA.

EU Regulatory Network and Cooperation

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- Number of approval routes for generics in the EU i.e. national (1 Member State (MS) only); Decentralised (DCP) or Mutual Recognition (MRP) procedure (1 MS takes the lead); or centralised (EMA). Majority by far via DCP and MRP.
- EMA Scientific Advice for generics is not just for centralised applications
- Similarly, for generics developers who may be targeting the DCP or MRP, also options for national Scientific Advice (SA) or simultaneous national SA (SNSA) through the EU MSs, i.e., there are multiple avenues to get SA in the EU.
- CMDh coordinates DCP and MRP and can seek scientific input from CHMP
- EU Regulatory Network based on cooperation between Members States

PSA for generics: key points

- Focus is on sharing information and perspectives with harmonisation and increased convergence as potential benefits. If advice divergent, the Applicant will have a clear understanding of the reasons.
- Number of key points from experience:
  - The pilot aspect relates to the processes in place to implement the parallel advice. The end result is a 'full' EMA Scientific Advice and usual fees and waivers apply Fees payable to the European Medicines Agency | European Medicines Agency (europa.eu).
  - The use of an EU reference medicinal product in bioequivalence (BE) studies is a legal requirement (Q and A 1.2 Generic and hybrid applications | European Medicines Agency (europa.eu)) that cannot be circumvented. The PSA for generics is not, therefore, a forum to discuss the use of a non-EU reference product.
  - This is in line with EMA Scientific Advice more generally where matters of a purely regulatory nature are outside of scope Scientific advice and protocol assistance | European Medicines Agency (europa.eu)

Key points continued

- While different regulatory definitions, the PSA program will be available to those products where EMA and FDA's definitions overlap.
- From the General Principles of the PILOT PROGRAM: EMA-FDA PARALLEL SCIENTIFIC ADVICE (europa.eu) for EMA, complex generics are hybrid applications under Article 10(3) of Directive 2001/83/EC as amended: : *"In cases where the medicinal product does not fall within the definition of a generic medicinal product as provided in paragraph 2(b) or where the bioequivalence cannot be demonstrated through bioavailability studies or in case of changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration, vis-à-vis the reference medicinal product, the results of the appropriate pre-clinical tests or clinical trials shall be provided"*
- It should be clarified, however, that for EMA 'conventional' generics (under Article 10(1) are also eligible to participate and the use of the term 'complex generics' is increasing in the EU based on the nature of products themselves.

Hybrid applications

- EMA considers the hybrid route may allow innovation in development of medicinal products e.g., new indications, new pharmaceutical forms, but acknowledges Applicants can see potential for additional studies as off-putting.
- However, it can also allow a degree of flexibility ('bridge' v's formal bioequivalence between test and reference and consideration of clinical relevance).
- For these reasons, PSA particularly appropriate for programs that may benefit from harmonised non-clinical and clinical studies involving e.g., innovative PK/comparative bioavailability study designs or the use of e.g., modelling and simulation.
- Example: Cuprior EPAR H-4005-AR-en (europa.eu): *Since TRIUMPH-2 was conducted versus the US FDA approved trientine product, the data are only supportive, but informative for the characterisation of the PK behaviour of Cuprior (linear PK)*.

Conclusions

- International engagement on generics development is happening
- The PSA pilot on generics presents opportunities
- If any queries on eligibility contact scientificadvice@ema.europa.eu
- PSA meetings formally requested by sending a single justification letter to both EMA emainternational@ema.europa.eu and FDA preANDAHelp@fda.hhs.gov

Any questions?

Further information

[Send a question to the European Medicines Agency | European Medicines Agency (europa.eu)]

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