SAFER EUROPE WITHOUT FALSIFIED MEDICINES

EU2017.EE Estonian Presidency of the Council of the European Union

V Session – availability of medicinal products after February 2019

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Preamble

- The causes of existing medicine shortages in EU are widely acknowledged to be multifactorial – is it likely that EMVS implementation will add to these factors?
- Reasons can range from lack of availability of the API, compliance issues in manufacturing, global consolidation, unintended impact of pricing and tendering policies, as well as problems within the supply chain
- There is still no universally accepted definition of what a medicine shortage consists of
- It is against this pre-existing background that we

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To what extent would the setting up of EMVS impact availability? – 1

- Delegated Regulation 2016/161, preamble para. (2), states that *'diverging authentication mechanisms for medicinal products based on different national or regional traceability requirements may limit the circulation of medicinal products across the Union'*
- An harmonised approach has been fundamental to EMVS thinking from the outset, and forms one of the guiding principles of the 'Blueprint' model
- In principle, therefore, EMVS should not have any widespread impact on medicines availability
- Some elements of the harmonisation project, notably with a view to multi-country packs, remain incomplete

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To what extent would the setting up of EMVS impact availability? – 2

- However, in a purely speculative assessment, the following issues might have an impact on product availability:
  - 'teething troubles' at EMVS implementation
  - possible late national implementation, including end user connection
  - system and re-tooling costs might cause small manufacturers to withdraw (some of) their products from (some) market(s)
  - manufacturing consolidation for the same reasons, leading to higher risk of supply failure in the event of any compliance issue
  - in the parallel distribution context, would products from countries with the six-year exemption be regarded as in some way deficient compared to serialized products?

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How might these issues be mitigated?

- NCA role in facilitating reach out to end users/MAH
- Learning from existing repository systems (such as DE), e.g. information exchange via EFPIA/MfE workshops
- Maximize time allocated for pilot systems
- Intensive training for operational and pharmacy staff (SOPs)
- Let's try to make the system work first, and worry about secondary uses later

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Access to data in the repositories

- Ongoing dialogue between COM/MS & EMVO
- EMVS designed primarily as a verification system (limited capacity for anything other than basic volumetric measurement)
- Difference between ‘aspirational’ and ‘pragmatic’ access
- This process of dialogue should be allowed to complete its course

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Conclusion

- For the vast majority of manufacturers, system compliance is already well advanced
- Consequently, continuity of supply for most of the range post-Feb 2019 should not be adversely effected by EMVS implementation
- Some risk of impact at the fringes
- Planning for the known risks and cooperative action should mitigate this effect

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Thank you!

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GIRP the vital link in healthcare

PGEU GPUE Pharmaceutical Group of European Union Groupement Pharmaceutique de l'Union Européenne

medicines for europe better access. better health.

efpia European Federation of Pharmaceutical Industries and Associations

E A E P C European Association of Euro-Pharmaceutical Companies

Association of Pharmaceutical Manufacturers in Estonia

emvo European Medicines Verification Organisation

Republic of Estonia Agency of Medicines

Republic of Estonia Ministry of Social Affairs