Working Group 1

What are the benefits of a monograph system?

- How does a monograph system contribute to the harmonization of ERAs and SPCs?
- How could a monograph system improve the transparency and thus reliance to the pre-approval system?
- Does a monograph system on APIs enhance the environmental safety of VMPs?
- How could a monograph system contribute to transparency to the public?
- Are there financial benefits?

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What are the benefits of a monograph system?

Overview

- Competition
- Sensitive Information
- Resources and Impacts
- Financial Implications
- Public Transparency
- Update of information

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What are the benefits of a monograph system?

- Competition and sharing of sensitive Information
  - Examples from Reach
  - No history or culture of sharing in VMP – Consortia will be difficult and costly to put together
  - Problematic of Originators versus Generics companies
  - Diverse companies (eg. Companies exporting to non-EU with only one MA)
  - Access to data must be regulated (Obligation with conditions set)
  - Needs careful vetting respective competition law

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What are the benefits of a monograph system?

- Sensitive Information
  - Studies difficult to share
  - Endpoints less sensitive - Cannot be used by competitors in the risk assessment
  - Data protection for clinical and safety data – different system to suggested Monograph data sharing
  - Challenges of consortium building – ownership and mainitenance of data

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- Resources and impacts
  - Novel approach that needs careful vetting regarding resource requirements
  - Example of MRL establishment as a warning sign
  - Other changes to legislation are on the way
    - SPC (Standard Product Characteristics) Harmonisation
    - Exemption for Generic products from full ERA
  - Potential conflict with aim of the commission to boost number of drugs
  - Prioritization process necessary – Burden could be one criteria

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- Financial Implications
  - Save some duplication of work in Market authorisation
  - Savings for companies only possible when sharing is possible and not to costly

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What are the benefits of a monograph system?

- Public Transparency
  - Potentially useful for further assessment of risk assessment strategies
  - For other legislations and impact assessments - Best if endpoints are harmonized
  - The collection and availability of validated data is the main benefit

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- Update of information
  - Evidence will build up if pharmacovigilance evidence is included – all in one place
  - Linking of other data sets (eg Water surveillance and market data on Pharmaceuticals) might be a more efficient way
  - Source attribution is the big challenge