# Working Group 2

## What are the benefits of a monograph system?

### What substances

<u>Scope:</u>

Here only VMPs, only chemicals, how do we define further the substance?

**VICH Phase I as starting point, because also global issue –and some consideration of exposure necessary, but however clause maintained**

Lower priority highly potent active substances which would stop in Phase I -> more scientific discussion necessary

Do VMPs pose a risk to the environment and is data generation for those substances necessary, especially as effects are not seen?

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**Aim of the monograph**

- Who uses it? -> **product authorization mainly**
- Other stakeholders, such as environment agency?
- PBT assessment would be picked up by data submitted
- Some substances would not need all data – e.g. terrestrial vs aquatic use
- Generally follow VICH Phase II requirements for list of endpoints
- Additionnal available data optionnal.

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**Organisation**

- Studies would have to be evaluated by competent authorities (CA) and collectively agreed upon values for endpoints for the substance
- European procedure, no strictly national procedure for an AS
- Reduced burden for CA and shared data generation, but concern about costs and administrative burden of consortia and fees for assessment
- Would the bad experiences of the other systems be repeated/kept mind or is there now another mindset which helps cooperation between companies ?

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**Data assessment**

- Discussion on how much old data are available and how difficult the assessment would be
- Take into account information from good quality literature, if available
- Is there a weight of evidence approach?
- Discuss all available data -> agree on endpoints before single product assessments
- Single product ERA assessments easy, because only calculations and no study assessments, except for higher tier studies specific to product

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### Impact assessment

- Who would pay the cost of the assessment for the monograph? -> companies/consortia, but concern about costs and administrative burden of consortia
- Would old products be lost because there is no interest to keep them on the market?
- for ERA a reference to the endpoint enough to reduce administrative burden if Letter of Access allows to do so (data protection)?
- How is data protection guaranteed?
- A monograph might only be necessary for old substances. But then the publicity of end-points is lost or publication in PuAR or EPAR for new AS.
- cost of access for companies outside of consortia . Has to be framed by EU legislation, rules of later participation in the consortia or request for letter of access have to be transparent and accessible.
- A priori establishment of rules of functionning of consortia helpfull.

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**Current proposal of legislation**

Potential alternative to monograph:

- Scientific assessment during SPC harmonisation
- Class referrals taking into account all existing experience
- But not designed perhaps to ask for new studies in case of important data gaps?
- Issue of old but harmonised products without ERA.