Working Group 3

How could a monograph system on APIs be implemented in the legislative framework?

- Who has to be involved in the process?
- What is the most effective way to push a monograph system forward?
- Which legislative frameworks are affected/ have to be adapted?
- Do recitals have to be defined; are these supportive for the process? If yes, which?
- Which chapters and articles of the defined legislations have to be changed/extended/included?
- Which players (actors) have to be named in the legislation?
- How complex has a monograph system to be described in the legislation?
- Potential pre-work to be done for Implementation (consultation, time frame, cost-benefit analysis)?
- How can consortia of applicants be formed and who represents those consortia during the assessment procedure?

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Q1: Who has to be involved in the process?

This question is actually 2 questions:

Q1.a: Who is concerned by the system:

- Every MAH
- Regulatory networks
- Assessment boddies
- Other data holders (can be addressed using channels of other substance groups, e.g. ECHA)
- Other regulatory networks

Q1.b: Who is involved in (political) process of establishing the monograph system?

- Many overlaps with Q1.a. Additional actors:
- MEPs, Eur Council, EU Comm

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Q2: How to implement such a system? Legislation – no legislation?

Agreement on benefits of such an approach – if:

1. care is taken to avoid loss of existing products.
2. safeguard measures for data protection, but…
3. system needs to avoid unnecessary burden.

Main pro argument: Legislation leads to higher Q of data in particular for old substances, agreed-on and harmonised data, harmonised assessment.

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Q3: How should a monograph system be implemented?

Every MAH should contribute – no contribution => penalty/no access to data => **Implies need for European legislation!!**

Benefits of implemented legislative acts (vs. changes to regulation).

Issues with substances for minor species that rely on major species data => possibly out of market because of decision to not invest??? Ditto major species.

Restricted access to monograph data

Important to have clear definitions in basic act: terms, guidance. **Learn from REACH & Co.!!!!**

Risk-based prioritisation, step-by-step approach => progressive impl., cut-off process??

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Q4: Recitals? Articles changed/extended/included?

Basic act should incorporate process , objectives, key criteria & timeframe (e.g. definitions, accessibility)

Most of scheme should be dealt with in delegated acts, implementation!!

Which legislation would need to be addressed?

1. VMP,
2. possibly EMA,
3. Fees,
4. HMP,
5. PPP

How to organise / how to finance assessment????

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Q5: Pre-work for implementation?

- Dossier-sharing among MS should be investigated beforehand (maybe not possible)
- Cost-benefit
- Impact Assessment
- Stakeholder processes

How to get HMP-producers on board?

=> Use strategic approach to get data for monograph process!!