Workshop Conclusions

Overall agreement on benefits of monograph system – but also issues.

Possibility is there: it's all about the (**big devil in the**) details!! A number of "ifs" that are not minor.

Clear rules, penalties.

Negative example: MRL implementation, to some extent REACH. Lessons-learned!!!

Benefits of transparency and increased data availability:

- Potential improvements for RA, for other legislations and impact assessments.
- Main benefit: collection and availability of validated data.

Workshop Conclusions

VICH Phase I as starting point – highly potent active substances less of a priority.

Evaluation would have to be by CA – collectively agreed upon values.

Discussion on how much old data is available.

Agree on endpoints.

Who pays for cost of assessment of monograph??

Concerns re. **costs and burden**.

How is data protection guaranteed?

Potential alternative to monograph: scientific assessment during SPC harmonisation.

Workshop Conclusions

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.

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??

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

Workshop Conclusions

Prioritisation – possible cut-off process?

How to organise / who pays costs?

How to reduce burden?

Learn from experience for MRL, REACH & Co.!!!

Avoid loss of existing products!!!

Question of data protection