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EGGVP views on Generics and Ecotoxicology

Brussels, 7 June 2015

Who we are?

- **E**uropean **G**roup for **G**eneric **V**eterinary **P**roducts **– EGGVP**
- Association representing the pharmaceutical industry of **generic VMPs in Europe**
- Founded in **2002**, not-for-profit organization, based in Brussels
- **22 members, MAHs of generic VMPs** (19 are "vet only" companies)
- > 5000 employees, turnover > €1,3 billion/ year
- Majority of **SMEs**

In this presentation…

- **The generic principle and ecotox**
- **Are all the efforts in environmental risk assessment (ERA) taking us any further forward?**
- **The new VMPs regulation, generics and ecotox**
- **EGGVP views on monographs: principles for workable system**

The generic principle and ecotox

- Current Directive 2001/82 (as amended) Article 13: "…the applicant shall not be required to provide the results of the safety and residue tests of the pre-clinical and clinical trials…"
- However Art. 12 has an additional bullet point on ecotox (not taken over in Art 13)
- This is why also for generics, an environmental safety package is required

Why this exemption?
This is a violation of the generic principle
Copy-paste error?

Are all the efforts in ERA taking us any further forward?

What the current situation bring us so far

- **Duplication of data, redundant assessments** of the same molecules based on different studies, whose results may differ, **unnecessary testing repetitions**
- **Risk of dis-harmonization** between generic and reference product
- **Divergent decisions** in the MA of similar VMP
- **Inefficient use of resources** for both applicants and authorities; preparing an ERA file is time and money consuming
- **Market launch often delayed** by additional ecotox requirements

Monograph system could partially solve these problems

New regulation, generics and ecotox: EC and EP proposals

- The **inconsistent situation** in present Directive was one of the reasons for asking for a new legislation
- However: Request to **submit ecotox data for generics is supported by both EC and EP** – Art. 16.6
  - ✓ EC: if reference product authorised before 20.07.2000 or if phase II ERA was required for reference product
  - ✓ EP: if evidence of increased risk posed by generic
- EP recommends exploring **possibility for monographs**

New regulation, generics and ecotox: EGGVP proposals

- **Deletion of Article 16.6**
  (and amendment of recital 27)

In **exceptional cases**, for products authorised before 20 July 2000 and where there is **evidence** that a constituent is a hazard for the environment, ERA may be required to all the marketing authorisation holders concerned (**innovator + generic**).

Support possibility for a **monograph system to be explored**

EGGVP views on monographs: principles for workable system

General principles

- Strong **cooperation between industry and CAs** is essential
- Functioning should be **ruled and supervised by CAs** by means of **official guidelines**

3 scenarios

I. NEW APIs - no data available
(NO consortium needed)

II. EXISTING APIs - data available / partially available
(Consortium needed)

III. EXISTING APIs – no data available
(Consortium needed)

I - NEW APIs
→no data available

Originator MAH prepares an ERA MF for the new API

ERA MF: submitted by originator MAH to EMA for assessment procedure

Costs for assessing ERA MF: Fee to be paid by originator MAH to EMA

Who should need the data		
YES	**MAYBE**	
NEW VMP	**HYBRID VMP**	
Letter of access (no consortium)	***Letter of access (no consortium)***	

II- EXISTING APIs
→ data (partially) available

Critical: Stringent prioritisation. Criteria???

EC prepares the list of APIs

CAs (NCAs, EMA) identify products and compile data available from dossiers

EMA contacts all concerned MAHs (generics and innovators)

Consortium is created; ERA MF is being developed

ERA MF is submitted to EMA by Consortium

EMA to assess the ERA MF

Costs for assessing ERA MF: Fee to be paid by Consortium to EMA

plete –
RA MF adopted

Info not complete –
Request further data to consortium

III- EXISTING APIs
→ no data available

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Rules set under official Guidelines

EGGVP proposal: **guidelines to be prepared by CAs**, their **leading role** essential

Basic set of rules for operation under **transparency and predictability**

1. **Letter of access**: applicant(s) to single data owner (originator)
2. **Consortium:** from applicant(s) to multiple data owners (members of consortium)

Supervisory role from CAs shall avoid discriminatory practices and competition issues

1. Timings – delays access market competitors?
2. Obligation to provide data – right from data owner(s) to refuse access and avoid competition?
3. Cost for access - may prevent competitors accessing data?

Guidelines' content

1. Define **criteria consortium set-up** and management; cost sharing, property rights of MAHs involved…
2. Fix appropriate **timings**
3. Describe **flowchart** procedure (as in previous slides)
4. Set up **financial arrangements** for accessing data
   - Cost estimation (initial cost, inflation, administrative costs)
   - Likewise "royalties" (progressively decreasing depending on factors: time, number of data holders, number of applicants…)

Once information is available at EMA, anyone can request it under principles and rules set in guidelines

Limitations, concerns, open questions…

- MFs will **not resolve** problems of **disharmonisation** and divergent decisions since these are not based upon finished product but on active ingredient.

- **Property rights:** benefits for “data donors”? Data protection?

- **Financial arrangements** for accessing data: difficult to calculate the right and proportionate fee from the total cost. **Many variables** and difficult to predict,

- Setting and management the system: **costs and burden.**

Final remarks

- **EGGVP proposal** would be **compliant with COM** proposal for new regulation for VMPs, and also in line with **EP report**
- Practical details on operability of the system will make the difference (feasibility); **guidelines are key**
- Still **many open questions**; looking forward to listening and discuss ideas with all concerned parties!

Thank you for your attention

Any questions please?

Discussion welcome!