Data requirements for generic products (according to Article 34 of Regulation 1107/2009/EC) experiences and plans

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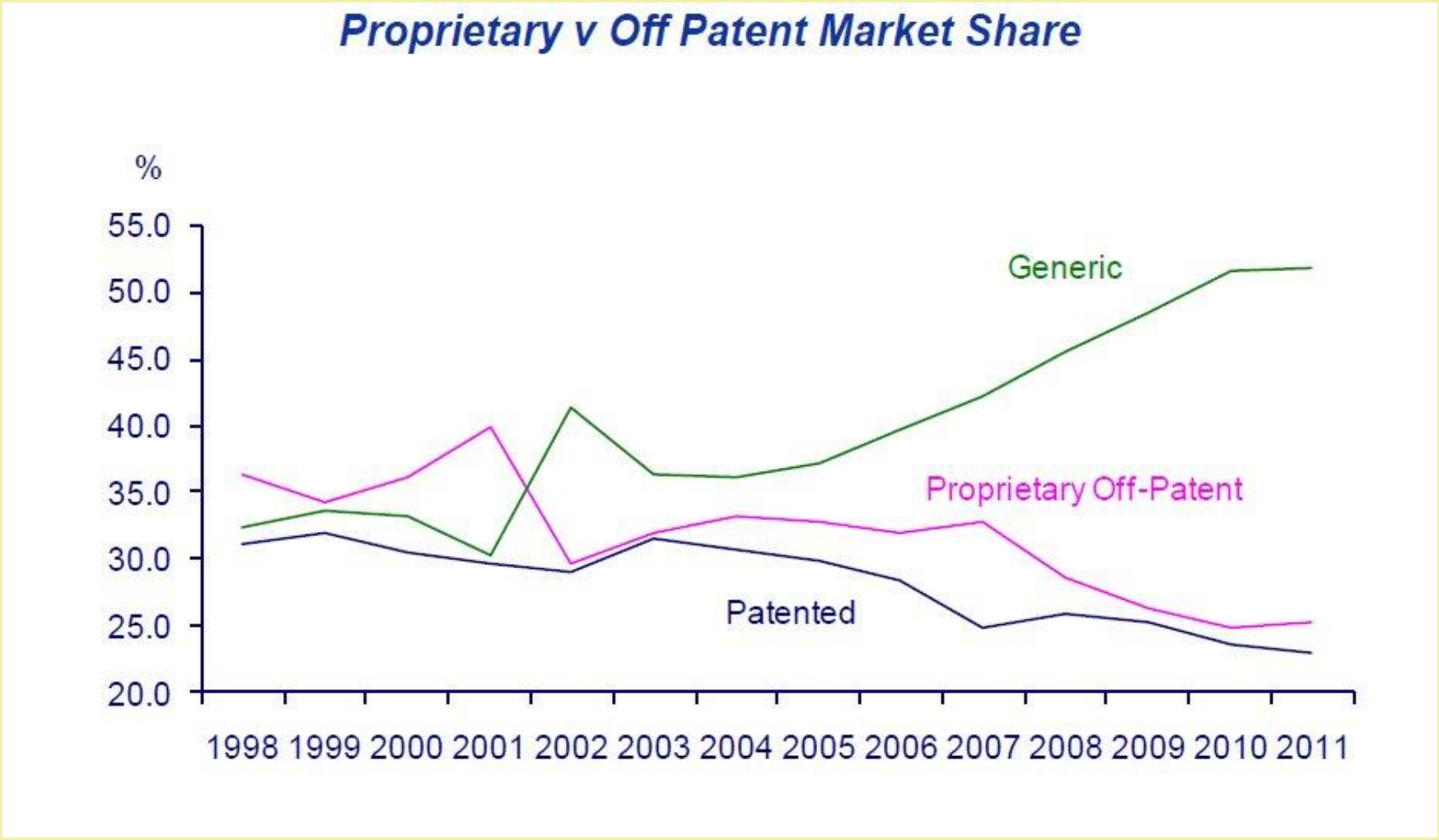
Improtance of the authorisation of the generic products

Data requirements and procedure according to Article 34 of Regulation 1107/2009/EC

Consequences of „Art. 34 PPP” authorisations

Hungarian Cases

Importance of generic PPPs



Phillips McDougall Ltd., Informa Conference, 2013

Importance of „Art. 34. PPPs”

„Art. 34. PPPs” - pros and contras:

- Data protection of several significant actives expired – e.g. glyphosate, 2,4-D, captan, azoxystrobin
- Several equivalent sources are available (glyphosate/84)
- Legal framework: Art. 34

- Data owner companies try to defend „off-protected” products (development of mixtures, new formulations, de-registrations)
- Uncertainties in registration procedure – lack of harmonised procedure

Importance of „Art. 34 PPPs” - Hungarian experiences

HU experiences:

- 3 new applications/MR / year with references to unprotected data /Art. 34
- Several inquiries about the possibility
- Big generic producers obtain LoA
- Small, local producers can not obtain LoA, they refer to expired data protection

Application according to Art. 33 for which Art. 34 applies

No special procedure for the „Art. 34 PPPs”

Legal framework is the same, applications have to be made according to Art. 33-39 of Regulation (EC) no 1107/2009.

Zonal application (zRMS, cMSs)

Timeframe for the assessment:

- 12 (+6) months / zRMS
- 6 weeks / commenting period
- 120 days / cMS

Reporting (application, registration report, decision, label)

The only difference: exemption from supplying the test and study reports according to Art. 34

„Art. 34 PPP” - Legal framework for the exemption

Art. 34 enables the „*exemption from supplying the test and study reports referred to Art. 33 (3)”.*

Prerequisites:

- test and study reports are available for the MS (reference product) +
- letter of access has been granted, or **data protection period has expired**

Question: New data requirements come into force but the authorisation of the reference product based on to the old requirements. Could Art. 34 be applied? (No, the new requirements have to be fulfilled)

Reference product

- No more than one authorised reference product allowed (no picking from different dossiers)

- Valid Uniform Principle authorisation - issued in accordance with Directive 91/414/EEC or Regulation (EC) No 1107/09

- Same reference product should exist in the zRMS and in all other cMSs

- Availability of the RR of the reference product possibly

Letter of access

Valid Letter of Access to the protected data

LoA that can refer to:

- active substance,
- equivalence report for the alternative sources,
- certain studies,
- PPP dossier

The source of the a.s. not always the same as the source of the LoA supplier.

Data protection period has been expired

Data protection situation could be different per cMSs for the same PPP.

Zonal assessment of „Art. 34 PPP” applications

GD is under preparation: *„GD on the assessment of applications for which Art. 34 of Reg. 1107/2009 applies”*

- prepared by Kostas Markakis (Greece)
- commented by MSs
- discussed by PAI working group

3 MSs can not accept Art. 34 as a type of application – no legal basis

Data requirements 1

Identification of the reference product
LoA, data protection status - overview table on cMSs

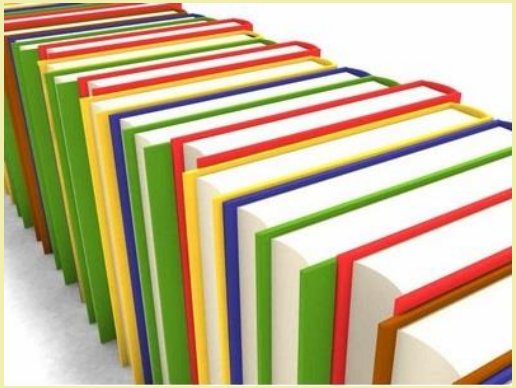
- **Identity of PPP** (points 1.1-1.6 of part A of Annex of
- Reg. 284/2013)
- **Information needed to identify the active substance (equivalence report)**
  - Statement of purity
  - Detailed information on impurities **(five batch analysis)**
- **Detailed quantitative and qualitative information on the composition of PPP**
- Declaration – no unacceptable formulants

Presented form: Part C of dRR

Hungarian requirement:

Section 2 phys-chem properties of the PPP (part of authorisation certificate)

Data requirements 2



Summary information of the PPP
(Presented form: Part A of dRR)

- Classification & labelling
- **Proposed uses** - same as reference product (fewer uses are acceptable)
- Product label
- Reference list

Questions:

- How can the applicant prepare a proper reference list?
- Is it possible to compile the whole Part A or only some points of it? (proposed uses, classification and labelling, reference list, but how to prepare risk management?)

HU requirement:

Efficacy studies in the South-Eastern EPPO zone (comparable effect proved)

Assessment procedure 1

The applicant has to prove that the **a.s. is equivalent** and the **PPP is comparable** with the reference product.

Assessment of equivalence of the a.s.:

1. Positive equivalence report is available on CIRCA
   1. Applicant is the same or
   2. Different – LoA

2. If the assessment of equivalence has not been conducted → new assessment of equivalencie according to the procedure Art 38 (GD SANCO/10597/2003)

Equivalence:
If the new source has the same or less harmful effects within the meaning of Article 4(2) and (3) due to its impurities compared to the reference source, then the new source can be considered (eco)toxicologically
equivalent to the reference source.

Assessment procedure 2

Comparability of PPPs – assessed by the zRMS, according to the GD on Significant and Non-significant changes, SANCO/12638/2011

Non-significant changes:

The changes are non-significant if the formulation consists of chemically equivalent co-formulants at the same amount

Examples for non-significant changes:

- Alternative source of co-formulants
- Cation exchange for anionic surfactants
- Adding a marker substance for authentication (<0,1%)
- New (equivalent) source of active substance e.g. lower minimum purity - this has an impact on the other co-formulants

Other changes – considering in each section

Examples:

Phys-chem: dye, anti-foaming agent < 5%

Toxicology: changes > 10 % - new studies,

Reporting, decision-making

- RR preparing (8 months, 6 weeks Σ 12 months) and authorisation in the ZRMS
- Final RR is uploaded to CIRCABC and notificaton is sent to other MSs of the zone. (dRR/RR is to be sent to the MSs and to the applicant except for the confidential information (detailed composition of the reference product!)

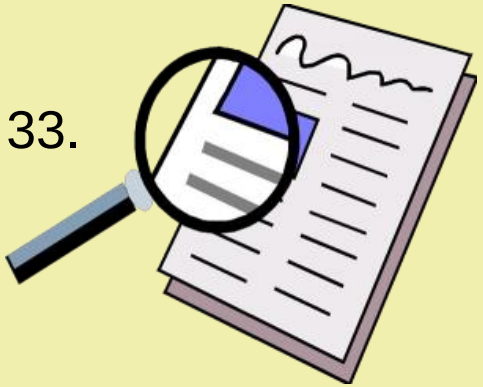
Content of the RR: Part A, Part C – assessment of the equivalence of the a.s. and comparability of the 2 PPPs

Outcome of RR:

assessment (comparability) positive
negative

cMSs agree or not (disagreement should be solved bilaterally)

In case of the product not comparable ⇒
new applicfation with a complete submission under Art. 33.



Decision-making in the cMSs

After receipt of the RR and the copy of authorisation – decision on the authorisation in the cMS.

The cMSs „*shall grant or refuse authorisations"* of the zRMS.

- reference product in the cMS is the same as in the zRMS
- data protection period of the reference product has expired

The uses in the authorisation should be the same as the authorisation of the reference product (in cMS or in zRMS?). (different crops)

Questions:
Is it possible that the authorisation in the cMS is different from the authorisation in the zRMS?
What to do if the composition of the reference product in the cMS is not the same as in the zRMS - similar assessment has to be conducted (within 120 days) or

- refusal?

Consequences of „Art. 34 PPP” authorisation

MR

Renewal

Amendment

Withdrawal

MR of „Art. 34 PPP”

Mutual recognition according to Art. 40-42.

Requirements:

- copy of authorisation granted by zRMS
- statement that the product is identical to that authorised in the zRMS
- RR (+ complete dossier) = equivalence+comparability

Decision-making is the same as in case of cMS.

Question is the same: Is it possible that the authorisation in the cMS is different from the authorisation in the zRMS?

Renewal of the authorisation

AIR 2 or 3: New period of data protection starts for the a.s. and the product (Art. 59 (1).

- 30 months from date of first renewal of authorisation of the product
- only to new data used to support the renewal of the a.s./re-authorisation of the product
- expires at different times in each MSs (athough renewal timescales harmonised)

Consequences to „Art. 34 PPP”:

data submission for the new data or

withdrawal of the authorisation

After 30 months – new application possible referring to Art. 34. (But new requirements!)

Amendment of the authorisation of reference product / „Art. 34 PPP”

No extra data protection in case of label extension (10 years from the date of first authorisation) → the owner of „Art . 34 PPP” can apply for label extension referring to the expired data protection

Authorisation holder withdraws reference authorisation:

- Authorisation survives until renewal

Hungarian experiences as „zRMS”

1. Herbicide application before the Reg. 1107/2009 - suspended, reasons:
   - reference product has an „old” authorisation (not according to UP)
   - data gaps (empty documentation) - suspended

2. After step 2 procedure of the reference product and additional data submission (Part C of dRR, efficacy, Sec 2. were required)

assessment: equivalence confirmed
comparison confirmed
efficacy trials have proved the comparable effects

3. Decision making: authorisation document issued and „confirmatory data” ordered: Sec. 2 of Annex III (phys-chem data) have to be submitted

Hungarian experiences – MR of Art. 34 PPP authorisation

1. A zMS issued an authorisation for the PPP„G”. The RR contained references on data of product „O”.
2. Generic company applied for MR in CZ, SK and HU referring to Art. 40 & 34.
3. The reference product „O” was registered in HU and the data protection was expired
4. Checking the composition of product „O” of the zMS and product „O” authorized in HU we realised that the composition of the two reference products were not the same. REFUSAL

Problems and open questions - summary

- Harmonised GD or detailed „manual” for „Art. 34 PPP” applications needed
- Not every MS can accept applications according to Art. 34
- Status of reference product is important (Authorisation according UP and RR available)
- How can the generic applicant prepare:

  Part A and Reference list
- Content of authorisation can be different in the zRMS and cMS
- New data requirements, new endpoints – new protected data

But we are optimistic!


Thank you for your attention!