Products renewal-

Article 43 of Regulation (EC) No 1107/2009

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Outline

1. **Article 43- General considerations**
2. **Renewal procedures**
3. **Mixed products (> 1 a.s)**
4. **Outlook**

Before

?

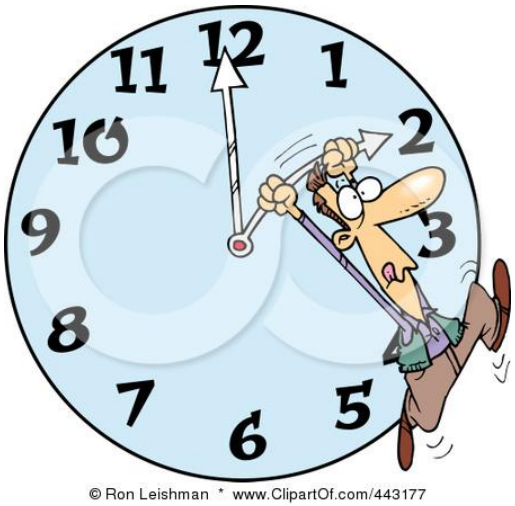
After renewal

1- Article 43- General considerations

Renewal of PPP Art. 43, GD SANCO/2010/13170 rev. 13

- **application for renewal of PPP** - **3 months** after Commission´s decision („date of application" DoA) of renewal of the a.s
- **evaluation** [compliance check + assessment] and **decision** on renewal of the PPP by **zRMS** - **6 months** (including Peer review: 3 w.)
- **decision** on renewal of authorisations by **cMS** - **3 months**

!!! Applications by ALL authorisation holders!!!
(notifying and non-notifying companies)
No application for renewal within 3 months or incomplete submissions : expiry of the authorisations or they will be revoked according to Art. 44 (3) and (4)



1- Article 43- General considerations

Preconditions for application according to Art. 43:

- **no new uses**!
- **GAPs remain unchanged** (what if the GAP has to be changed because of new end-points?)
- **no formulation change**! (except: non-significant change according to GD SANCO/12638/2011)
- **no new cMS** (for which the product is new)!

If preconditions are <u>not fulfilled</u>

-> considered as a new PPP according to Art. 33

-> new uses to be applied for after the renewal of the PPP, as an amendment according to Art. 33 or Art. 40

1- Article 43- General considerations

Challenges

- **short timelines** (for applicant as well as for MS)
- high number of PPP within a zone,
  high number of PPP with more than one a.s.
- new endpoints for the a.s. …

HOWEVER… Possibility to extend timelines:

- Art. 43 (6): *MS should extend the authorisation for the period necessary to complete the examination*
  In which case(s) does **extension** of authorisation apply? How long?

2- Renewal procedures

Application: Some (a lot of?) dossiers will **not be complete** due to lack of time to comply with **new data requirements, new endpoints, to complete long term or seasonal studies, or capacities of laboratories!**

Which data can be submitted later? (SANCO/2010/13170)

-> Cat. 4 studies

- studies related to new end points /time is insufficient to generate these studies (e.g. mesocosm studies, residue trials; efficacy trials if necessary because of changed end points -> lowering of amount active/ha)

MS may grant extension of the concerned authorisation until studies are made available

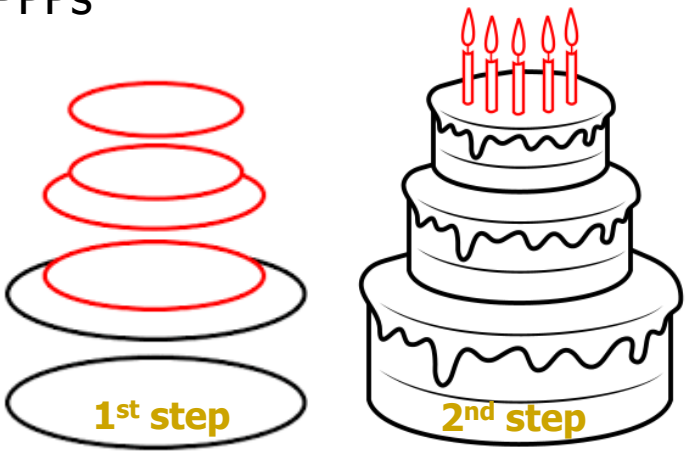
Cat. 1, 2, 3, 5 studies: eg: ”formal” studies which do not impact the safety of the PPP

2- Renewal procedures

Application (Cat. 4 studies ongoing missing) should contain:

- all necessary studies available at the time of application
- **list of studies to be generated**, i.e. Cat. 4 studies, including time table for study submission and justification – to be accepted by the zRMS
- **complete dRR**, only once all studies are available - **max. 2 years**
  - highlighting the changes to the risk assessment
  - old dRR acceptable for AIR 2 PPPs

-> 2 Steps application



2- Renewal procedures

- **compliance check** to be performed by each MS having authorisations, **compliance with the conditions and restrictions** of the active renewal
- where relevant´- applicant is non-notifier- : **data matching check** (PAI meeting, Sept 2015) to be performed by the zRMS (compensation studies, LoA or indications that studies will be provided)
- **equivalence check(s)** to be performed by the RMS for the active´s renewal

2- Renewal procedures

Assessment:

- assessment to be performed **by the zRMS**

-> begin of the evaluation only when dossier complete

-> only new information necessary to be considered

- based on the dRR provided by the applicant (quality…)
- „new" consideration of the risk envelope approach for some sections like residues, fate (worst case: GAP for one PPP? other PPPs covered?)

Presubmission meeting !!!!

Not to forget: comparative assessment (Art 50) as well as data protection issues to be dealt at MS level

2- Renewal procedures

Risk Assessment:

- **relevant chapters** only (for which new/changed endpoints are applicable), the others will **NOT** be considered **->** latest Guidance to be applied

Efficacy:

- **no assessment of efficacy** (=no updated BAD)
- exception for „**possible development of resistance or cross-resistance**" to be presented in a new dRR (Section 7) (OECD KIII6.2.8)

-> if GAP has to be changed because of risk assessment issues resulting from changed endpoints (i.e. necessary to lower the application rate/ha):

-> new efficacy trials (reflecting the new GAP) might be necessary („Cat. 4 studies")

3- Mixed products(>1 a.s.)

PPPs for which the period between the renewals of two a.s. is:

less than 1 year:

- **-> evaluation** only after the last a.s. has been renewed
- **->** BUT **application** after each a.s.´ renewal
- **-> dRR** to be provided once the 2nd a.s. renewed

more than 1 year:

- **-> no need for an assessment of the additional actives in the PPP since no agreed endpoints are applicable, o**nce the 2nd substance is renewed, there is no need to look at the 1st substance again

4- Outlook

Member States:

- Art 43 vs Art 33; Internal priority setting by authorities?
- strategy: comparative assessment (to be looked at asap)
- worksharing of MS (interzonal, within the zone)
- when evaluation of PPP ongoing before renewal of the a.s. and new EP are used, no article 43 necessary

Companies:

- reconsideration of the PPP portfolio, apply Art.40 in advance in some MS
- notification sheets to be sent: some PPP in the central zone are still without zRMS (no preference given by the applicant)
- quality of the dRR (old dRR acceptable for AIR2 PPPs/ completeness of information at the application)

4- Outlook

Implication for Data protection

- 30 months data protection from the renewal of the PPP (for a.s. and PPP data) - Art. 59
- if delayed submission of the complete dossier=> begin of the 30 months data protection with date of PPP renewal => max. 2y+1y evaluation

Situation for non-notifying companies

- application to be made 3 months after EI of a.s. renewal
- include a list of studies, justification why couldn t be made
- extension of the expiry date of the PPP in parallel to the reference PPP (if applied for)
- authorisation revoked at the renewal of the reference PPP
- new application Art 33 (based on Art. 34) as soon as data protection ok

4- Outlook

Implication for minor uses :

only for existing (authorised) minor uses

- when possible, e.g. authorisation holder is the data owner (residue data), evaluation to be performed by zRMS
- some cases, data owner (group of interest…) is not the authorisation holder and cannot prepare the dRR – solution has to be found at national level

Thank you for your attention