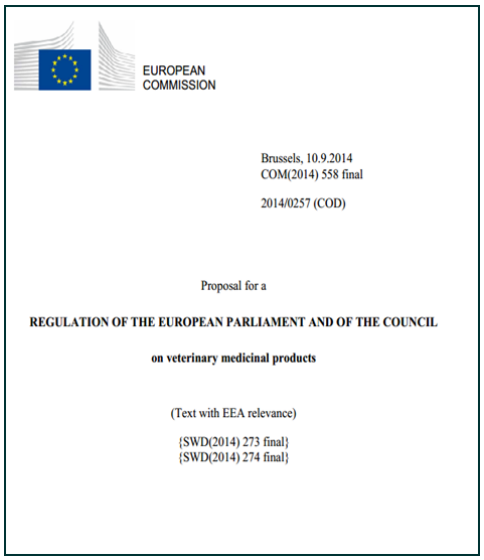
How to find the path to SmPC harmonisation?

Caroline Edlund Toulemonde

Infoday 17th of March 2017

Draft VMP regulation



EUROPEAN COMMISSION

Brussels, 10.9.2014
COM(2014) 558 final

2014/0257 (COD)

Proposal for a

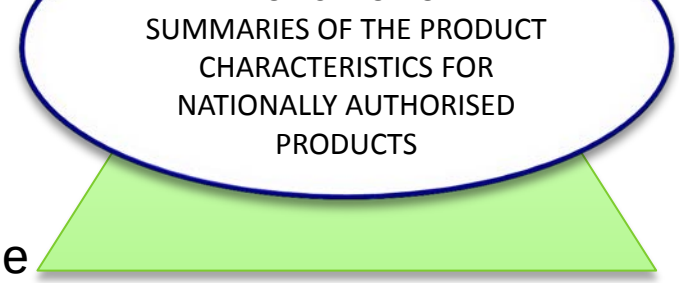
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on veterinary medicinal products

(Text with EEA relevance)

{SWD(2014) 273 final}
{SWD(2014) 274 final}

European Commission



Council of the European Union

European Parliament

Why do we need harmonisation?

Many SmPCs of nationally authorised products differ in some respects between MSs.
As a result, dosage, uses and warnings may also differ.
This applies to both products from one MAH and to products from different MAHs.

The **same product** belonging to the same MAH and approved in two or more EU MS

...with different SmPCs

... and manufactured in **one** or more sites according to **several** specifications

Group of **essentially similar products** (i.e. originator products and associated generics)

...with different SmPCs

...and **different** manufacturing processes and sites

Group of **similar products** belonging to different MAHs and approved in the same or different EU member states

...with different SmPCs

...and **different** manufacturing processes and sites

Scope of draft COM proposal

What are our objectives ? (1)

Commission's objectives (impact assessment & draft Regulation)

Commission's objectives (impact assessment & draft Regulation)

- Increase availability in the Union, and free circulation of veterinary medicines
  - Low risk products – administrative to correct discrepancies
  - Riskier products –Scientific reassessment of SmPC to choose the SmPC with minimum risk
  - Re-assessment
  - Re-assessment for environmental reasons shall fall under the scope of the Union referral procedure

According to the Commission, in the short term, harmonisation will be burdensome for agencies and MAH, but the long term benefits are:

- Reduced administrative burden for harmonised products
- Free circulation of approved veterinary medicines across the Union

European Commission

What are our objectives ? (2)

European Parliament's (EP) objectives (EP amendments)

- Supports harmonisation of low risk bioequivalent products
- Introduces the possibility for MAHs to request harmonisation
- Introduces possibility to scientifically re-assess groups of products if Public Health or Animal Health interest at Union level
- Introduces harmonisation of special precautions regarding impact on the environment
- Introduces possibility to harmonise quality data set if relevant
- Requires all antibiotics to be re-assessed within 5 years
- Once harmonised, National products to be **eligible for MRP**

Some members of the EP see SmPC harmonisation as an occasion to address Public Health or Animal Health issues

What are our objectives ? (3)

Council and MSs objectives

- Different from one MS to another – little information is available on this
- National agencies' objectives influences the MS
- What role does EMA play?

More transparency and dialogue on MSs objectives and needs with regards to SmPC harmonisation would help find the path forward.

What are our objectives ? (4)

Industry's objectives

- Focusing the harmonisation exercise on the cases allowing to achieve the Commissions' objectives i.e. focus efforts where it is justified
- Making the harmonisation procedure easy for all, **predictable** with an impactful outcome
- No resubmission of existing data, and protection of data where new data has to be generated
- Ensuring harmonisation is maintained after the procedure, to be able to benefit from reduced administrative burdens
- Clear distinction of SmPC harmonisation procedure from Union Referral procedures

Seen as both an opportunity and a constraint. Pragmatic SmPC harmonisation will make it easier to manage/update the dossiers of products registered in several different MSs.

The burden of harmonisation

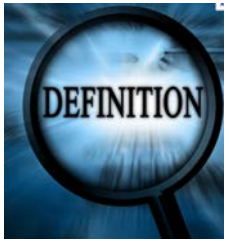
It will take a lot of work…

The burden and costs will be high for agencies and MAHs

- Can we make the process fit for purpose (streamlined) ?
- Ensuring the objectives of all stakeholders are met ?
- Minimising the risk of niche products being removed from the market ?
- Managing the work with current resource/funding in agencies and companies?

Efficient SmPC Harmonisation

Preparatory work 1



Terminology

- Definitions are key – are we using the same language?
  - Same products / Essentially similar products / Similar products

Harmonisation needs

- What type of products?
- Which elements for the different types of products?
  - Conditions of use for essentially **similar** products
  - Complete SmPC and quality part of dossier for **same** products

Efficient SmPC Harmonisation

Preparatory work 2

Triggers for harmonisation

- Which products should be harmonised?
  - Order of priority
    - *Essentially similar products with unacceptable differences of SmPC*
    - *Same products from one MAH*
  - Voluntary as the preferred option for same product
  - Mandatory only when justified for groups of essentially similar products

Evaluation procedure

- Simplified procedure
- Detailed approach and guidance adapted to type of products undergoing SmPC harmonisation

Efficient SmPC Harmonisation

Industry suggestions

- **Simplified procedure for "Same (identical) products",** leading to one SmPC for the same (identical) product in all Member States where product is approved
- **Harmonised "same" products to be turned into MRP** otherwise new difference will arise and the products will be disharmonised again
- **Simplified for "Essentially Similar Products",** when justified, to remove SmPC discrepancies between originators and generics (i.e. no scientific reassessment
- Updating for PH or AH reason of "groups of similar products", should be managed through a Union referral procedure - already today

Overview

Group Type	Procedure	Characteristics
Same Product belonging to the same MAH, approved in 2 or more MSs , with different SmPCs	Voluntary harmonisation	Administrative. Company proposes harmonised SPC. + chance to harmonise quality & convert to MRP.
Group of Essentially similar products (i.e. originators and generics, different MAHs) with different SmPCs	Mandatory harmonisation	Targeting groups where there will be highest impact/benefits. Administrative, no re-assessment. MAH and authorities propose harmonised SmPC, individual MAH to convert Nationally approved products into MRP.
Serious Risk identified	Use Referral Procedure	
All other products	NOT NEEDED	NO ACTION

In conclusion

Europe IFAH
Representing the European Animal Health Industry

The Commission's draft text does not meet its objectives and would result in huge increase of administrative burden

But there are many common objectives between all stakeholders and good concepts on the table allowing us to work towards a :

- Pragmatic
- Fit for purpose

Regulation

Elaborating a satisfactory way forward requires dialogue and exchange

Europe IFAH
Representing the European Animal Health Industry

THANK YOU