Hva er konsensus i EU?

Inger Heggebø, Seksjon for koordinering av utredningsoppdrag

Statens legemiddelverk

Hva er konsensus i EU?

«Andre land har godtatt det»

«Får ulike tilbakemeldinger fra ulike land»

«Norge er så strenge»

«Vi sendte en tilsvarende endring i forrige uke – hvor Norge var CMS – den ble godkjent»

Fakta

- Alle landene er blitt enige om prinsippene for hvordan endringer skal kategoriseres og telles
- Det reflekteres i Q&A som er publisert

Prinsipp

- Som CMS skal du kunne stole på den valideringen som gjøres av RMS

Utfordring

- RMS vurderer allikevel ulikt

→ Blir konfrontert med ulik praksis i ulike prosedyrer

Question 3.11

- **Which type of variation should be submitted for the implementation of changes in the SmPC, not already covered by the Classification Guideline, for which no new quality, pre-clinical, clinical or pharmacovigilance data are provided by the applicant?**

An update of the SmPC to implement change(s) in the Summary of Product Characteristics not already covered by the Classification Guideline and for which no new data are provided by the applicant should be submitted as a **C.I.z, type IB variation**.

(….)

Furthermore, an adaption of a **generic/hybrid** application to a product information **text NOT being the reference product** to which the original application for marketing authorisation refers, may **NOT be submitted according to category C.I.2** of the Variation Classification Guideline but **has to be submitted as a type II variation C.I.4**

IH2

Question 3.19

- **How should the outcome of a PRAC signal recommendation be implemented?**
- In accordance with the "CMDh Recommendation for classification of unforeseen variations according to Article 5 of Commission Regulation (EC) No 1234/2008" the implementation of product information updates after a PRAC signal recommendation may be submitted as **type IAIN notification under C.I.z** when harmonised national translations are available in all member states. If **minor assessment is needed a type IB** variation under C.I.z would be applicable. However, if the implementation of the product information update needs to be substantiated by **new additional data** submitted by the MAH then a **type II** variation under category C.I.z must be submitted.

Lysbilde 5

IH2 Sette inn bide av signal - kanskje trafikkskiltet i canary wharf?

Inger Heggebø; 10.11.2016

Question 3.20

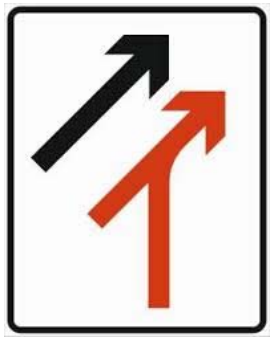
How should the outcome of a Union safety referral procedure be implemented?

- Answer:
- Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a Union safety referral procedure (submitted in accordance with **art 31** and **art 107i** of directive 2001/83/EU) should normally be submitted as **a type IAIN C.I.1.a variation**. This is provided that the medicinal product **is covered by the defined scope** of the procedure (i.e. included in Annex I) and the following condition is fulfilled in accordance with the classification guideline:
- "The variation implements the wording requested by the authority and it does not require the submission of additional information and/or further assessment."
- Often further assessment is needed. For example, proposed new text can not be implemented without adapting or deleting previously approved text. In some referral outcomes there are optional texts to be implemented depending on the pharmaceutical form.
- Therefore, applicants are always encouraged to consider if **further assessment** would be needed by the authorities when implementing the outcome of a Union referral procedure and in this case submit the application as a **type IB** C.I.1.a instead.

Question 3.23:

Can a MRP variation be submitted under C.I.2.a (Change in the product information following assessment of the same change for the reference product) as a type IB if the product information of the reference product is not harmonised in all member states concerned?

- Answer:
- The reference product that is adapted to has to be the reference product from the original application which has to be confirmed in the application form. **It has to be identical for all products** in the application and **approved via MRP/DCP** (including products harmonised via an article 30 referral) or **via the Centralised procedure**. The European procedure number of the reference product should also be stated in the application form. If the reference product is approved via **the National procedure** in several **member states, i.e. the product information is not harmonised, the variation should be submitted as a type II variation under C.I.2.b**.
- However, **these type II variations would be accepted with a limited data package**. An **update of the overview** and a **sound justification** for all proposed changes (e.g. explaining why a certain reference text has been selected for a specific change) would be regarded as sufficient documentation in these cases. As a general rule the **highest level of safety information** as included in the reference product's product information should be chosen



Question 4.14

How can MAs be adapted to the most current version of the SmPC, if the results of several procedures, e.g. PRAC/ PhVWP recommendations and PSUR worksharing, have to be considered?

- Answer:
- The applicant has to submit **one variation** application according to **C.I.3.a, b or z** for **each single change** applied for. **The single change is defined by one data package triggering the variation**. All these single changes may be **combined in one grouped** application, see also examples for acceptable and not acceptable groupings for MRP/DCP products, http://www.hma.eu/96.html.
- **It is not acceptable for generics to wait for the originator to have implemented all these changes and subsequently submit a single variation C.I.2.a** in order to adapt to the originator. **Nor is it possible for any MA to include all the changes in a Company Core Data Sheet (CCDS) and to submit a single variation of type II under category C.I.4.**

Question 4.17

How can I submit variations when several changes are falling under the same category in the classification guideline?

- Generally, **each trigger in a variation application results in a single variation** which may be submitted in a **grouped** application. In case of several variations under the same classification the **type of change, number and title of each of these variations should be mentioned.** E.g. a grouped type II variation application of 3 type II variations C.I.4, this category should be repeated 3 times and the changes of each type II variation should be explained under the precise scope and background for change.

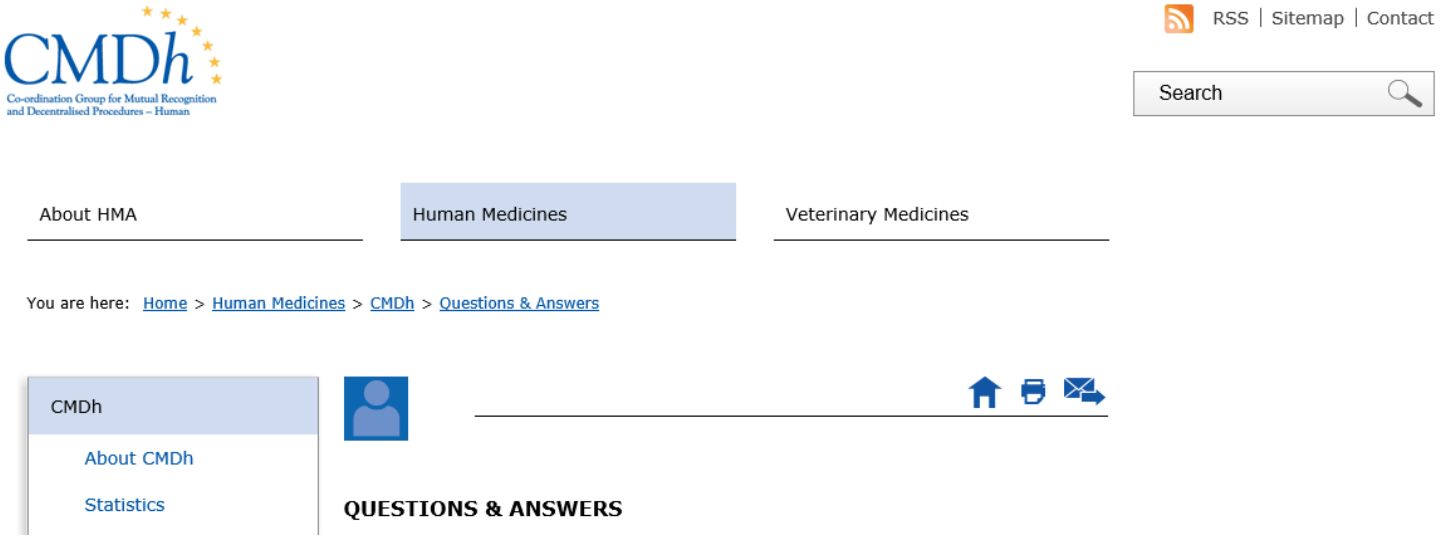
Question 4.19

How can <u>generic</u> MAs be adapted to the most current version of the SmPC of the reference medicinal product, if the results of several procedures, e.g. type II variations have to be considered?

- The applicant has to submit **<u>one</u>** variation application according to **C.I.2 a, b or z** for **<u>each single change</u>** applied for. The single change is defined by **one data package triggering the variation.**
- All these single changes **may be** combined in one **grouped** application, see also examples for acceptable and not acceptable groupings for MRP/DCP products,
- http://www.hma.eu/96.html. (For implementing PRAC recommendation or PSUR worksharing see Question 4.14, which is applicable for all MAs)
- It is **not** acceptable for generics to wait for the originator to have implemented all these changes and subsequently submit **a single variation C.I.2.a** in order to adapt to the originator. **Nor** is it possible for any MA to include all the changes in a Company Core Data Sheet (CCDS) and to submit a **single variation of type II under category C.I.4**.

Referanser

- Lenke til CMDh Q&A:



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