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Agence nationale de sécurité du médicament et des produits de santé

Comité d'interface – GT Amélioration des processus

Harmonisation des informations de sécurité – sujet européen

Mathilde GEYNET KOVACS – Janvier 2022

Retour d’information suite aux discussions européennes – « RSI project »

Proposition de Medicines for Europe

- Baseline safety information not harmonised to allow further updates (products approved via different procedures, with different/not harmonized reference products…)
- Core safety text (RSI), referring to sections 4.3 - 4.9 of the SmPC and corresponding sections in the leaflet, should be agreed
- **Proposal for worksharing** (RSI WS) with CMDh, as one of the authority, and industry initiatives – to be started as a **pilot project**
- WS → without a need for subsequent individual variations and justification. The change should be implemented by MAH preferably with the next printing of the leaflet or within the designated timeline of 6 months

Retour du CMDh en novembre 2020

- Existing tools at the EU network always need to be considered first (Article 30 referrals, work-sharing procedures for safety variations)

- **Open to start a dialogue on the proposal "IF":**

  - all trade associations commit to participate in the project
  - The preparatory work should be performed by all MAHs with the same product/same active substance (e.g. consortium)
  - Data/clinical overview (scientific discussion) should always be provided to support the RSI proposal
  - For the implementation of agreed reference safety information a variation would always be needed

  Commitment from all trade association would also be needed that agreed reference safety information will be implemented without further discussion.

Retour du CMDh en novembre 2020 => si les conditions sont remplies

- Clear advantages (theoretically consistent safety information per active substance to HCP and patients + safety updates much easier for industry) but so many challenges
- Dedicated group with **representatives from all Trade associations** could be established to discuss all aspects (pros/cons, methodology, keeping the RSI up-to-date)
- Very few, carefully selected substances could be considered for the **limited pilot project**
- Project would be built on voluntary basis and the outcome would not be legally binding, i.e. **procedure would be informal** (inspiration from PSUFU TT and principles?)

Evolution de la règlementation à suivre

- Veterinary legislation and harmonisation of PI: see what would be their progresses in the field (→ art. 70 NVR – harmonization procedure)

- EU Commission strategy and draft roadmap for legislation revision: would human legislation go on the same direction?

- should **core SmPC be made available in the future**?

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