Přehled EU závěrů bezpečnostních přehodnocení

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Vedoucí oddělení farmakovigilančního hodnocení

Jak to celé vzniklo

- podzim 2022 - Strategic review and learning meeting – joint PRAC-CMDh
- pořadatel SÚKL v rámci CZ předsednictví v Radě EU
- sdílení praxe zveřejňování závěrů bezpečnostních přehodnocení (referaly, signály, PSUSA, ale i bezpečnostní změny II. typu, atd.) na úrovni jednotlivých členských států a EMA
- závěry bezpečnostních přehodnocení jsou různě rozesety v rámci EU regulační sítě – webové stránky EMA, CMDh, jednotlivé národní agentury
- iniciativu převzala pracovní skupina při CMDh (SOS WS)

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- Podzim 2023 - k usnadnění základní povinnosti držitelů udržovat aktuální informace o přípravku v souladu se současnými vědeckými poznatky vytvořila pracovní skupina při SOS WG **přehled všech odkazů**, na kterých jsou **závěry evropských přehodnocení** vztahujících se zejména k **bezpečnosti** zveřejňovány a které musí držitelé pravidelně sledovat
- Stránky CMDh – v navigačním menu pod kategorii „Product information“

- https://www.hma.eu/human-medicines/cmdh/product-information.html

SÚKL

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  - Press Releases
  - COVID-19
  - BREXIT
  - Nitrosamine impurities
  - Procedural Guidance
  - CMDh-Referrals
  - **Product Information**
    - Pharmacovigilance procedures outcome
    - Referral Art. 30 and 31 (non-pharmacovigilance)
    - CMDh Recommendations

PRODUCT INFORMATION

The marketing authorisation holder (MAH) is responsible to keep its product information updated in line with current scientific knowledge or recommendations.

The MAH is responsible for regularly monitoring relevant sources of new information and recommendations

On this website you will find links where to find recommendations and outcome resulting in amendment of the product information.

Pharmacovigilance procedures outcome

Referral Art. 30 and 31 (non-pharmacovigilance)

CMDh Recommendations

Core SmPC/PL

Paediatric work sharing procedures

MRI Product Index

SÚKL

PHARMACOVIGILANCE PROCEDURES OUTCOME

- **Referral procedures Art. 31 and 107i** +
- **Periodic safety update reports (PSURs)** +
- **Safety signals** +
- **Post-authorisation safety studies (PASS)** +
- **Outcome of PRAC advice** +
- **PhVWP recommendations** +

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Referral procedures Art. 31 and 107i +

Periodic safety update reports (PSURs) -

More information on PSURs can be found at EMA website

PSUSA procedures (PSUR single assessment) +

PSUR Follow up procedures (PSUFU + variations) +

Outcome of informal PSUR work-sharing procedures +

Safety signals +

Post-authorisation safety studies (PASS) +

Outcome of PRAC advice +

PhVWP recommendations +

- **Product Information**
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- Templates
- CMD Working Parties / Working Groups
- Paediatric Regulation
- Pharmacovigilance
- Falsified Medicines
- Questions & Answers
- Contact Points
- Recently Published history

Changes to product information following the outcome of PSUSA procedures (PSUR single assessment) can be found on:

- for **centrally authorised products (CAPs)** - a Decision will be published per product for the CAPs and the Decisions are identified by the word PSUSA in the procedure number. **The European Commission's website**.
- for **mix of centrally authorised products and nationally authorised products** (NAPs, including MRP/DCP products) - PSUSAs are listed under both "**Procedures for centrally authorised medicinal products**" and "**Procedures for nationally authorised medicinal products**". A Decision will be published per product for the CAPs; a single Commission Decision will be published per active substance for the NAPs. The Decisions are identified by the word PSUSA in the procedure number.
- for **NAPs only (including MRP/DCP products) for which there is no CMDh consensus** - PSUSA are listed under "**Procedures for nationally authorised medicinal products**".
- for **NAPs only (including MRP/DCP products) for which there is consensus within the CMDh** - **EMA website**. Published results from PSUSA NAP (MRP + NP) can be searched by substance name and category or procedure number on the EMA's website as follows: Categories – Human Medicine – Periodic safety update report single assessments. EMA publishes the lists of nationally authorised medicines involved in PSUR single assessments for active substances contained **only in nationally authorised medicines**, together with the outcomes of assessments that lead to a variation of marketing authorisations **EMA Website.**

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