ATMP-HE:
Pharmacovigilance activities to be performed by the Holder

Federal Agency for Medicines and Health Products

BRUSSELS

24.04.2017

famhp
federal agency for medicines and health products

Pharmacovigilance activities

-> reference in CHAPTER VIII of the Royal Decree

-> THE HOLDER OF AN ATMP-HE SHOULD PERFORM PHARMACOVIGILANCE ACTIVITIES TO MONITOR THE SAFETY/EFFICACY, TO EXAMINE HOW TO AVOID OR MINIMIZE THE RISKS AND IF NECESSARY TO TAKE APPROPRIATE CORRECTIVE MEASURES, AND TO DETECT ANY CHANGE IN THE B/R BALANCE.

The Holder of an ATMP-HE should:

Application dossier

- **Dispose of a Qualified Person** responsible for pharmacovigilance (QPPV) which is **available 24/7**
- **Implement a Pharmacovigilance System**, and **make the PSMF available** for the FAMHP upon request**, submit the Summary of the PSMF**
- Prepare the **RMP** and update it if necessary

- **Monitor the efficacy/safety information**, and the **outcome of risk minimisation measures** if implemented
- **Assess the undesirable effects** reported for an ATMP-HE

→ **Patients follow-up**

- **Provide an annual report** on the ATMP-HE
- **Ensure** the required **traceability**

Follow-up of the patients

-> references in CHAPTERS VIII and XI of the Royal Decree

The treating physician or the hospital pharmacist ensures the follow-up of the patients treated with an ATMP-HE for a period and with a periodicity that will be agreed on during the ATMP-HE application.

The **following data** should be **recorded in the patient's file** to ensure an appropriate diagnostic and therapeutic follow-up:

- ***Personal information***: identity, personal & physical characteristics (age, gender, size, weight, ethnicity (if justified), medical history (co-morbidities, co-medications including dependencies if necessary), indication of the treatment, other useful information
- ***Reference number of the medical prescription***
- ***Date(s) of ATMP-HE administration(s)*** (dosage, frequency, route, etc)
- ***Relevant safety data*** (including AEs and corrective measures, should they occur)
- ***Relevant (quantifiable) data supporting the evidence that the ATMP-HE is beneficial for the patient***
- ***Contact coordinates of the treating physician***

Follow-up of the patients (2)

-> The **Hospital** (through its treating HCPs) **is responsible for the protection of these personal data**.

-> they are **anonymised (code for each patient) before being transmitted** to the Holder of the ATMP-HE and the FAMHP.

-> Moreover, the **transfer of personal data from the treating physician (Hospital) to the Holder of the ATMP-HE/the FAMHP or from the Holder of the ATMP-HE to the FAMHP requires the agreement of the Sector Committee of Social Security and of Health.** This agreement can be solicited once the content of the application dossier has been validated by the FAMHP.

-> **Follow-up data** from patients should be **kept and store for minimum 30 years** (**no longer than 50 years in any case**).

Annual Report

-> reference in CHAPTER IX of the Royal Decree

-> THE ATMP-HE SHOULD BE RE-EVALUATED YEARLY AT THE LATEST 3 MONTH AFTER THE REFERENCE BIRTH DATE

The **Holder of an ATMP-HE should submit an annual report 2 months before the birth date**, which should contain the following information:

- The **number of treatments** prepared;
- The **number of patients** treated;
- A **motivated statement, justifying the maintenance of the treatment as an "exemption"** (including the fact that the treatment is not routinely prepared);
- **Relevant clinical data** (showing benefit of the treatment);
- **Relevant safety/pharmacovigilance data** (showing the acceptable safety profile of the ATMP-HE);
- A **brief discussion about the B/R balance** of the treatment for the patient;
- **All modifications** to the application dossier occurring during the period which are considered **"not substantial"** (substantial modifications to be notified immediately)

Only **anonymous data** (patients identified by codes) **are provided in the annual report**.

Traceability

-> reference in CHAPTER X of the Royal Decree

-> TRACEABILITY OF THE PREPARED ATMP-HE

The **Holder should implement and manage a Registry to ensure the traceability** of all substances used during the manufacturing, the conditioning, the storage, the transport and the delivery of the ATMP-HE to the place where it will be administered to the patient.

In this Registry, the patient should be anonymous and identified by the means of its ATMP-HE prescription number (responsibility of the Holder of an ATMP-HE to ensure that the data remain anonymous).

-> **Traceability data should be kept and store for minimum 30 years** after the limit date for use, or longer is the FAMHP considers it appropriate (**no longer than 50 years)**.

-> IN CASE OF **ABROGATION OR OTHER TYPE OF CESSATION OF THE ATMP-HE, TRACEABILITY DATA ARE TRANSMITTED TO THE FAMHP** (which becomes responsible for the protection of these personal data).

Thank you for your attention

Your medicines and health products, our concern

10 years famhp .be