Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 10-13 June 2024

13/05/2024

Review of painkiller metamizole started

Review will look into risk of agranulocytosis, a sudden drop in white blood cells that can lead to serious infections, and measures to minimise it.

EMA has started a review of medicines containing the painkiller metamizole following concerns that the measures in place to minimise the known risk of agranulocytosis may not be effective enough.

Metamizole-containing medicines are authorised in a number of EU countries for treating moderate to severe pain and fever. The authorised uses vary from country to country, ranging from the treatment of pain following surgery or injuries to the treatment of cancer-related pain and fever.

Agranulocytosis is a known side effect of metamizole-containing medicines. It involves a sudden and sharp drop in a type of white blood cell called neutrophils. This can lead to serious infections which can be fatal. It is listed as a rare (may affect up to 1 in 1,000 people) or very rare (may affect up to 1 in 10,000 people) side effect in the product information of the various authorised products. Measures to minimise this risk vary across countries.

More information is available in EMA's public health communication.

CAR T-cell medicines: PRAC identifies risk of secondary malignancies of T-cell origin

Patients treated with CAR T-cell medicines should be monitored life-long for secondary malignancies

The PRAC has concluded that secondary malignancies of T-cell origin (a new cancer, different from the previous one, that begins in a type of white blood cells of the immune system called T-cells) may occur after treatment with chimeric antigen receptor (CAR) T-cell medicines.

The committee evaluated data on 38 cases of secondary malignancy of T-cell origin, including T-cell lymphoma and leukaemia, reported among approximately 42,500 patients who have been treated with CAR T-cellmedicines. Tissue samples were tested in half of the cases, revealing the presence of the CAR construct in 7 cases. This suggests that the CAR T-cell medicine was involved in disease development. The secondary malignancies of T-cell origin have been reported within weeks and up to several years following administration of CAR T-cell medicines. Patients treated with these medicines should be monitored life-long for new malignancies.

CAR T-cell medicines belong to a type of personalised cancer immunotherapies where one type of a patient's white blood cells (T-cells) are reprogrammed and reinjected to attack the cancer.

Six CAR T-cell products are approved in the European Union (EU): Abecma, Breyanzi, Carvykti, Kymriah, Tecartus and Yescarta. These medicines are used to treat blood cancers such as B-cell leukemia, B-cell lymphoma, follicular lymphoma, multiple myeloma and mantle cell lymphoma in patients whose cancer has come back (relapsed) or has stopped responding to previous treatment (refractory).

Since approval, the product information has advised that patients treated

with these products may develop secondary malignancies. The product information and the risk management plans will be updated to include the new information concerning secondary malignancy of T-cell origin.

New safety information for healthcare professionals: risk of secondary malignancies of T-cell origin

The PRAC also discussed a direct healthcare professional communication (DHPC) regarding CAR T-cell medicines.

The DHPC will inform healthcare professionals of the PRAC's review conclusion on secondary malignancies of T-cell origin, including chimeric antigen receptor (CAR)-positive malignancies.

The DHPC will remind healthcare professionals about the need for life-long monitoring of patients for cases of secondary malignancies.

The DHPC for Abecma, Breyanzi, Carvykti, Kymriah, Tecartus and Yescarta will be forwarded to EMA's human medicines committee (CHMP). When adopted, the DHPC will be disseminated to healthcare professionals by the marketing authorisation holders, according to an agreed communication plan, and published on the Direct healthcare professional communications page and in national registers in EU Member States.

Agenda

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