Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

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Information for Healthcare Professionals

CAR T-CELL THERAPY

Start of Signal Analysis Procedure for CAR T-Cell Therapies

Cancer immunotherapy with CAR T cells is a promising therapeutic strategy for haematological diseases. The European Commission authorised the first CAR T-cell medicinal product in 2018. The European Medicines Agency (EMA) has received a number of reports of T-cell lymphoma cases following CAR T-cell therapy that could potentially be related to treatment. The reports were collected as part of regular post-authorisation surveillance. The number of cases is small, but they require closer investigation and assessment. It should be emphasised here that the benefit-risk ratio is currently still regarded as positive in view of the therapeutic success in treating the affected patients' severe underlying conditions.

In total there are six centrally authorised CAR T-cell products in Germany: Abecma, Breyanzi, Carvykti, Kymriah, Tecartus and Yescarta. The Paul-Ehrlich-Institut has assumed a leading role at the EMA as a rapporteur in the Pharmacovigilance Risk Assessment Committee (PRAC) or in the Committee for Human Medicinal Products (CHMP) for five of these products. As a rapporteur, the Paul-Ehrlich-Institut is involved in the comprehensive assessment of the reported cases and the benefit-risk ratio of the CAR T-cell products and works closely with the representatives of the other Member States. The signal analysis procedure is coordinated by the EMA, as is customary with centrally authorised products.

Physicians who are supervising treatment with CAR T-cell therapies are asked to report any suspected side effects. If a patient is suspected to have CAR T-cell-associated lymphoma, a genetic examination of the tumour cells is crucial for processing. The examination is carried out by the manufacturers.

The signal analysis procedure began during the last PRAC session week in January 2024 with the dispatch of a questionnaire to the manufacturers involved in producing the medicinal products. After the responses have been received in early February, the analysis will take place over the course of the following two months.

Further information on the status and content of the signal analysis procedure can be found on the EMA's website[1].

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[1] https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-8-11-january-2024