24 February 2022
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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): nivolumab

Procedure No. EMEA/H/C/PSUSA/00010379/202107

Period covered by the PSUR: 3 July 2020 to 3 July 2021

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for nivolumab, the scientific conclusions of the CHMP are as follows:

The PRAC agreed to update the Summary of Product Characteristics (SmPC) section 4.8 to move the adverse reactions: "lymphopenia, leucopenia, neutropenia, thrombocytopenia and anaemia", from "Investigations" to "Blood and lymphatic system disorders", and to move the adverse reactions: "hyperglycaemia, hypoglycaemia and weight decreased", from "Investigations" to "Metabolism and nutrition disorders". In addition, to ensure that patients are fully informed of what diabetic ketoacidosis (DKA) is and of the particular signs to be aware of, the risk of DKA and relevant symptoms, should be reflected in the Package Leaflet.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for nivolumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing nivolumab is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.