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Questions and answers on Nanotop and associated names (human albumin colloidal particles, kit for radiopharmaceutical preparation)

Outcome of a procedure under Article 29(4) of Directive 2001/83/EC

On 19 December 2013, the European Medicines Agency completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Nanotop. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Nanotop outweigh its risks, and that the marketing authorisation granted in Germany can be recognised in other Member States of the EU.

What is Nanotop?

Nanotop is a kit for the preparation of a radioactive suspension for injection. It contains particles of the human protein albumin which are attached to radioactive technetium (^{99m}Tc) before use.

Nanotop is for diagnostic use. When injected, it passes through in the lymphatic system (a network of vessels that transport fluid from tissues through the lymph nodes and into the bloodstream). During a scan the radioactive technetium can be detected, which help to obtain a clear image of the lymphatic system and to detect whether tumours have spread to the lymph nodes in patients with breast cancer or malignant melanoma (a type of skin cancer).

Why was Nanotop reviewed?

ROTOP Pharmaka AG submitted Nanotop for mutual recognition on the basis of the initial authorisation granted by the German medicines regulatory agency on 8 December 2011. The initial authorisation was based on a well-established-use application, which relied on published data with a similar product named Nanocoll. The company wanted the authorisation of Nanotop to be recognised in Austria, Finland, France, Italy, Norway, Portugal, Spain, Sweden and the United Kingdom (the 'concerned Member States').

However, the Member States were not able to reach an agreement and the German medicines regulatory agency referred the matter to the CHMP for arbitration on 26 September 2013.

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The grounds for the referral were concerns raised by Sweden that Nanotop could not be considered comparable in quality to Nanocoll, particularly because of supposed differences in particle sizes between the two products. Particle size is critical for the way the medicine works as it affects how well the medicine is taken up by the lymphatic system.

What are the conclusions of the CHMP?

The CHMP assessed additional supportive data provided by the company comparing the particle size of Nanotop with that of Nanocoll and the variability in particle size between different batches of each medicine. Based on the evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that particle size and its batch variability are similar for Nanotop and Nanocoll. The CHMP therefore considered that these medicines can be considered comparable in quality and that the benefits of Nanotop outweigh its risks. It recommended that Nanotop be granted marketing authorisation in the concerned Member States.

The European Commission issued a decision on 28 February 2014.