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Refusal of the marketing authorisation for Deqtynet (copper (64Cu) oxodotreotide)

The European Medicines Agency has recommended the refusal of the marketing authorisation for Deqtynet, a diagnostic medicine intended for use with positron emission tomography (PET) imaging to detect well-differentiated neuroendocrine tumours (NETs) in adults. Neuroendocrine tumours are rare tumours that can develop in different parts of the body, such as the pancreas, intestines or lungs. Well-differentiated means that the cells look and behave like normal cells and grow slowly.

The Agency issued its opinion on 21 May 2026. The company that applied for authorisation, Cis Bio International, may ask for re-examination of the opinion within 15 days of receiving the opinion.

What is Deqtynet and what was it intended to be used for?

Deqtynet was developed as a diagnostic medicine used together with an imaging technique called a positron emission tomography (PET) scan in adults with confirmed or suspected well-differentiated NETs that have proteins called somatostatin receptors (targets) on their surface. Deqtynet was initially intended for a broader use, to detect neuroendocrine neoplasms (NENs) in adults.

Deqtynet contains the active substance copper (^{64}Cu) oxodotreotide and is a radiopharmaceutical (a medicine that emits a small amount of radioactivity). It was to be available as an injection into a vein.

Because the number of patients with NETs is low, the disease is considered 'rare' and Deqtynet was designated an 'orphan medicine' (a medicine used in rare diseases) on 9 December 2022. Further information on the orphan designation can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu-3-22-2727

How does Deqtynet work?

The active substance in Deqtynet, copper (^{64}Cu) oxodotreotide, was to be used with PET scans . It consists of radioactive copper (64Cu) that is attached to a somatostatin analogue, oxodotreotide. Most well-differentiated neuroendocrine tumour cells have a high number of somatostatin receptors on their surface and oxodotreotide will therefore bind to the tumour cells. The radioactive copper in Deqtynet can then be detected by PET. This helps to determine the tumours' location and if they have spread to other parts of the body.

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What did the company present to support its application?

The company submitted the results from a study involving 63 people including healthy volunteers and patients with confirmed or suspected NETs who received a single dose of Deqtynet and underwent a PET scan. The images were reviewed by independent experts who assessed whether tumours were present.

The scan results were compared with established methods such as other imaging techniques and evaluation of a tumour biopsy (sample) used to diagnose these tumours in the same participants.

What were the main reasons for refusing the marketing authorisation?

The study confirmed that Deqtynet was able to accurately detect, using PET imaging, well-differentiated NETs that produce high levels of somatostatin receptors and thereby determine whether a patient has the disease. Overall, Deqtynet was well tolerated with a safety profile that is in line with that of already authorised PET diagnostic medicines. The Agency therefore considered that the benefits of the medicine outweighed its risks for use with PET imaging to detect NETs that have somatostatin receptors on their surface.

However, the Agency concluded that the medicine cannot be granted marketing authorisation in the EU because of the ten-year market exclusivity that had been granted for SomaKit TOC, which was authorised in December 2016 for a comparable condition. Market exclusivity for orphan medicines is given as an incentive for companies to develop medicines for rare diseases, which may otherwise not be developed due to the high costs and small patient populations. The exclusivity means that another medicine cannot be authorised for the same condition if it is similar to the medicine already authorised. In this case, the Agency concluded that Deqtynet is similar to SomaKit TOC, as both work in the same way.

The agency also assessed whether any legal exemptions could justify authorising Deqtynet despite SomaKit TOC's market exclusivity. In particular, it considered whether Deqtynet could be regarded as clinically superior to SomaKit TOC or whether SomaKit TOC's manufacturer could supply sufficient quantities of the medicine. However, the Agency concluded that there is no robust evidence that Deqtynet would provide meaningful clinical advantages over SomaKit TOC, nor is there any indication of a systematic shortage of SomaKit TOC. The Agency therefore recommended the refusal of the marketing authorisation.

Does this refusal affect patients in clinical trials or compassionate use programmes?

The company informed the Agency that there are no ongoing clinical trials with Deqtynet in Europe. The company will continue with its ongoing compassionate use programmes pending discussions with national authorities that have granted approval for compassionate use.

If you are in a compassionate use programme and need more information about your treatment, speak with your doctor.