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Public statement

Qtrilmet

Withdrawal of the marketing authorisation in the European Union

On 14 August 2020, the European Commission withdrew the marketing authorisation for Qtrilmet (metformin hydrochloride / saxagliptin / dapagliflozin) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, AstraZeneca AB, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Qtrilmet was granted marketing authorisation in the EU on 11 November 2019 for the following indications in adults aged 18 years and older with type 2 diabetes mellitus:

- to improve glycaemic control when metformin, with or without sulphonylurea (SU), and either saxagliptin or dapagliflozin does not provide adequate glycaemic control

- when already being treated with metformin and saxagliptin and dapagliflozin.

The marketing authorisation was initially valid for a 5-year period. The product had not yet been marketed in the EU.

The European Public Assessment Report (EPAR) for Qtrilmet will be updated to indicate that the marketing authorisation is no longer valid.

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