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Public statement

Enzepi

Withdrawal of the marketing authorisation in the European Union

On 19 July 2017, the European Commission withdrew the marketing authorisation for Enzepi (pancreas powder) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Allergan Pharmaceuticals International Ltd, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Enzepi was granted marketing authorisation in the EU on 29 June 2016 as an enzyme replacement treatment for exocrine pancreatic insufficiency due to cystic fibrosis or other conditions. The marketing authorisation was initially valid for a 5-year period.

There is no impact on patients expected as Enzepi was not commercially available in Europe.

The European Public Assessment Report (EPAR) for Enzepi will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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