COMMUNICATION AGREED WITH THE EUROPEAN REGULATORY AUTHORITIES AND THE ITALIAN MEDICINES AGENCY (AIFA) CONCERNING A MARKETING CESSATION

16 November 2026

EMEND® (aprepitant)
"125 mg + 80 mg 1 hard capsule (125 mg) + 2 hard capsules (80 mg) in blister for oral use"
Marketing Authorization Number (AIC) 036167068

Permanent Marketing Cessation

Dear Healthcare Professionals,

MSD Italia S.r.l., as the local representative of Merck Sharp & Dohme B.V., Marketing Authorisation Holder (MAH) for EMEND® (aprepitant), in agreement with the Italian Medicines Agency (AIFA), is notifying healthcare professionals about the marketing cessation in Italy of EMEND® (aprepitant) "125 mg + 80 mg, 1 hard capsule (125 mg) + 2 hard capsules 80 mg in blisters for oral use", Marketing Authorisation Number 036167068.

Overview of situation

- **Merck Sharp & Dohme B.V. has made the decision to permanently cease the marketing and supply of all presentations of Emend 80 hard capsules, Emend 125 mg hard capsules and Emend 125 mg powder for oral suspension in the EU/EEA markets.**

- **This decision is based on commercial reasons and is not related to any safety, efficacy or quality concerns with Emend.**

- **The permanent cessation affects all EU/EEA countries where the product is available:**
  - **Austria, France, Germany, the Netherlands, Norway and Sweden for Emend 80 mg hard capsules.**
  - **Austria, France, Germany, Ireland, Norway and Sweden for Emend 125 mg hard capsules.**
  - **Austria, Belgium, Croatia, Czech Republic, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Slovakia, Slovenia and Sweden for Emend 125 mg+80 mg hard capsules.**
  - **Belgium, France, Germany and the Netherlands for Emend powder for oral suspension.**

- **The timing of permanent cessation will vary by country and presentation, depending on available supply. The current date for the permanent marketing cessation in Italy is 30 November 2026. For any updates, please refer to the list of medicines currently in shortage, available at the following link:** https://www.aifa.gov.it/farmaci-carenti.

Mitigation measures

In order to manage the product permanent cessation, Merck Sharp & Dohme B.V. is engaging with the European Medicines Agency and the National Competent Authorities to ensure that healthcare professionals have sufficient time to prepare.

In preparation for the permanent marketing cessation, healthcare professionals should:

- **Review current treatment plans and consider alternative therapies for affected patients.**

- **Alternatives may include another aprepitant-containing medicine or a medicine in the same therapeutic class such as fosaprepitant powder for solution for infusion.**

- **For children aged 6 months and older, no other alternative medicine is available as a powder for oral suspension. To ensure continuity of care for children and infants who require this formulation, healthcare professionals should follow relevant national guidance and consider suitable therapeutic alternatives where available. The European Directorate for the Quality of Medicines & HealthCare (EDQM) has issued official guidelines for the extemporaneous (magistral) preparation of an oral liquid alternative using adult capsules** (Aprepitant: Expert opinion on extemporaneous formulations).

- **Other therapeutic options, such as 5-HT3 receptor antagonists, are also available in paediatric formulations, although they are not equivalent in terms of mechanisms of action.**

For additional information and advice, consult EMA's shortage catalogue, the list of medicines in shortage published on the AIFA website at the following link https://www.aifa.gov.it/farmaci-carenti
or contact the Italian Medicines Agency for further information on the shortage.

To ensure continuity of supply and patient care, Merck Sharp & Dohme B.V. is offering to transfer the marketing authorisation to an interested third party or, in accordance with Article 10c of Directive 2001/83/EC, to allow a third party to use the relevant pharmaceutical, non clinical and clinical documentation to continue marketing the product.

Background on the medicine
Emend is an antiemetic agent that is available in hard capsules. Emend is used in combination with other antiemetic agents as follows:
Emend 80 hard capsules and Emend 125 mg hard capsules are indicated for the prevention of nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults and adolescents from the age of 12.

Company contact point
Should you have any questions regarding the information provided in this communication, please contact MSD Italia S.r.l. at the following email address: dpoc.italy@msd.com.

AIFA takes this opportunity to remind all healthcare professionals of the importance of reporting suspected adverse drug reactions, as an essential tool for confirming a favourable benefit-risk balance under real-world conditions of use.

Reports of suspected adverse drug reactions should be submitted to the Pharmacovigilance Officer of the healthcare facility to which the healthcare professional belongs.

This communication is also published on the AIFA website (https://www.aifa.gov.it/), which healthcare professionals are encouraged to consult regularly to stay informed and ensure the provision of appropriate information and services to the public.