CHMP Chairman
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

27th April 2026

Attn: xxxxx

Subject: Withdrawal of Budesonide/Formoterol fumarate, 160/4.5 mcg and 320/9 mcg, inhalation powder. EMEA/H/C/2348 and EMEA/H/C 3890

Dear Sir or Madam,

I would like to inform you that, at this point of time, Teva Pharma B.V. has taken the decision to withdraw the application to add an optional treatment option for anti-inflammatory reliever use.

This withdrawal is based on the following reasons:

- Major identification of clinical issues as highlighted by the Rapporteur Team during assessment.
- At this point in time, the applicant does not have sufficient information to address the issues as raised.
- The consequence of withdrawal does not affect any future post-approval activities concerning the medicinal products.

We reserve the right to make further application for these Marketing Authorisation submissions at a future date in this or other therapeutic indication, or other variation applications for these Marketing Authorisations.

I agree for this letter to be published on the EMA website.

Yours faithfully,

xxx