



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Hemoprostol

Procedural steps taken and scientific information after the authorisation

| Application number | Scope                                                                                            | Opinion / Notification <sup>1</sup> issued on | Commission Decision Issued <sup>2</sup> / amended on | Product Information affected <sup>3</sup> | Summary                           |
|--------------------|--------------------------------------------------------------------------------------------------|-----------------------------------------------|------------------------------------------------------|-------------------------------------------|-----------------------------------|
| IAIN/0003          | C.I.10 - Change in the frequency and/or date of submission of PSURs for human medicinal products | 26/03/2015                                    |                                                      | Annex II                                  |                                   |
| PSUV/0002          | Periodic Safety Update                                                                           | 09/01/2015                                    | n/a                                                  |                                           | PRAC Recommendation - maintenance |

<sup>1</sup> Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.

<sup>2</sup> A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

