Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for polystyrene sulfonate, the scientific conclusions are as follows:

In the view of available data on polystyrene sulfonate use in patients with impaired gastrointestinal motility due to medical conditions, surgical history, and concomitant medication affecting motility from the literature and spontaneous reports where most cases indicate a close temporal relationship, there is a reasonable possibility that postoperative patients and patients using medications affecting gastrointestinal motility may be at increased risk of experiencing gastrointestinal disorders. Thus, polystyrene sulfonate administration should be avoided in patients with impaired gastrointestinal motility.

The PRAC Lead Member State concluded that the product information of products containing polystyrene sulfonate should be amended accordingly. In case the product information already includes a stricter information (i.e.., contraindication in adults with compromised gastrointestinal motility is listed), the stricter advice remains valid and no update of PI is needed.

The CMDh agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for polystyrene sulfonate the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing polystyrene sulfonate is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing polystyrene sulfonate are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~)

Summary of Product Characteristics

- Section 4.4

A warning should be added as follows:

Due to the risk of severe gastrointestinal disorders (such as bowel obstruction, ischaemia, necrosis or perforation) the use of polystyrene sulfonate is not recommended in patients with compromised gastrointestinal motility (including immediate post-surgery or drug-induced).

Package Leaflet

- Section 2

Warnings and precautions

Talk to your Doctor or pharmacist before taking the < invented name>if

…

you have abnormal bowel movements due to your medical condition (including conditions after surgery or drug usage) as these may cause a variety of disorders including bloating, severe constipation, reduced blood supply to your gut or ruptured bowel.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	May 2023 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	10 July 2023
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	07 September 2023