



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 September 2019  
EMA/HMPC/453279/2019  
Committee on Herbal Medicinal Products (HMPC)

## Overview of comments received on 'Procedure on management of proposals submitted by Interested Parties for European Union List Entries or European Union herbal monographs' (EMA/HMPC/328575/2007 Rev.2)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
1	AESGP (Association of the European Self-Care Industry), 7 avenue de Tervuren, B-1040 Brussels

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1. General comments – overview

Stakeholder no.	General comment (if any)	Outcome (if applicable)
	None	

## 2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
93-95		<p>Comments: Considering EU Member States and EEA-EFTA States are members of the HMPC, we consider they should not be included in the definition of 'Interested Parties'.</p> <p>Proposed change: Interested Parties: parties concerned with the use of medicinal products such as pharmaceutical industry associations, health care professional groups, scientific, consumers and patients' associations, governmental institutions. <del>as well as EU Member States and EEA-EFTA States.</del></p>	<p>Not accepted.</p> <p>In the context of proposals for EU list entries or EU monographs, EU Member States and EEA-EFTA States are regarded as interested parties regardless of the fact that they are represented in HMPC. The same 'Procedure on management of proposals...' shall apply to both proposals coming from EU Member States and EEA-EFTA States/HMPC members and proposals from other interested parties e.g. non-governmental institutions.</p>
173-176		<p>Comments: HMPC should also provide a short explanation of why the proposal was not included in the in the HMPC priority list.</p> <p>Proposed change: <b>In case of a negative decision, the HMPC Secretariat will provide a short explanation as to why the decision was negative.</b></p>	<p>Accepted.</p> <p>The request to provide more transparency concerning HMPC decisions is comprehensible as such and an additional sentence is included in the procedure.</p> <p>Moreover, the reasons for negative decisions are included in HMPC minutes.</p>