

Divergent positions to CMDh position

Procedure under Article 107i of Directive 2001/83/EC

Pholcodine containing medicinal products

Procedure number: EMEA/H/A-107i/1521

Divergent statement

The below named CMDh Members consider the benefit-risk balance of pholcodine-containing products negative, however do not consider that revocation is a risk proportionate measure taking into account limitations of available evidence from ALPHO study (i.e. power of the study, issue of identifying exposition to pholcodine, validity of final analysis model) and that a feasible condition for lifting the suspension can be identified. Benefit-risk balance of pholcodine-containing products could be reconsidered in case of identification of subpopulation in which risk of sensitisation to neuromuscular blocking agents (NMBAs) due to pholcodine use is adequately minimised, such as patients with certain conditions who are unlikely to receive a NMBA.

CMDh Members expressing a divergent opinion:

- Sabina Uzeirbegović (Croatia)
- Paula Cardona Xuereb (Malta)