

CHAPTER VII

ESTABLISHMENT, MANAGEMENT AND ACCESSIBILITY OF THE REPOSITORIES SYSTEM

Article 31

Establishment of the repositories system

1. The repositories system where the information on the safety features shall be contained, pursuant to Article 54a(2)(e) of Directive 2001/83/EC, shall be set up and managed by a non-profit legal entity or non-profit legal entities established in the Union by manufacturers and marketing authorisation holders of medicinal products bearing the safety features.
2. In setting up the repositories system, the legal entity or entities referred to in paragraph 1 shall consult at least wholesalers, persons authorised or entitled to supply medicinal products to the public and relevant national competent authorities.
3. Wholesalers and persons authorised or entitled to supply medicinal products to the public are entitled to participate in the legal entity or entities referred to in paragraph 1, on a voluntary basis, at no cost.
4. The legal entity or entities referred to on paragraph 1 shall not require manufacturers, marketing authorisation holders, wholesalers or persons authorised or entitled to supply medicinal products to the public to be members of a specific organisation or organisations in order to use the repository system.
5. The costs of the repositories system shall be borne by the manufacturers of medicinal products bearing the safety features, in accordance with Article 54a(2)(e) of Directive 2001/83/EC.

(Legal text of the Delegated Regulation)

Commission perspective on EMVO participation by hospital pharmacy:

*"I can confirm that the persons authorised to supply to the public (e.g. hospital pharmacist) are entitled to participate in the legal entity **at no costs.**"*

(Email to EAHP from Agnes Matthieu, 14th December 2016)

EMVO perspective:

*"With the purpose of permitting EAHP and HOPE to join, the constituency approach may also be applied for an affiliate membership of both organisations, which would, in case both are joining, lower the rate of 50%. Any further progress on this level may also be achieved by direct tripartite discussions (EMVO, EAHP, HOPE), which should be organised in early 2017. In general, we are confident that this measure would be taken as a step forward in order to recognise the role of the hospital sector within the project. **However and without wanting to anticipate any agreement possible between all partners, any new EMVO member has to participate, in one way or another, in the governance costs of the organisation.**"*

(Email to EAHP from Andreas Walter, 7th December 2016)