EMVO Master Data Guidance – Designated Wholesalers

Update based on Baker McKenzie Memorandum

FMD Implementation Workshop
Brussels, 13-July-2018

Version 1
‘Designated Wholesaler’ – Definition

- Defined in DR 2016/161 as a wholesaler who is
  
  ... designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf.

- Needs to be read in conjunction with DR 2016/161, Art. 20

  A wholesaler shall verify the authenticity of the unique identifier of at least the following medicinal products in his physical possession: (a) ... (b) medicinal products he receives from a wholesaler who is neither the manufacturer nor the wholesaler holding the marketing authorisation nor a wholesaler who is designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf.

- A ‘Designated Wholesaler’ is
  
  - Neither the manufacturer
  - Nor the Marketing Authorization Holder (MAH)
  - Nor a wholesaler buying from the manufacturer or MAH (because in this case there will be no contract between buyer and manufacturer or MAH that covers storage and distribution of products)
Authenticating a Product at Goods Receipt – A very Simplistic Overview

If you receive product from here you do not need to authenticate

These are organisations which have a contract with the MAH to store and distribute MAH's products e.g. a logistics service provider.

We term this group “the Club”

These organisations do not need to authenticate

These should be listed within the Wholesaler ID filed in the product master data

The Club

These are organisation which do not have a contract with the MAH to store and distribute MAH's products but received the product from either a club source or the MAH or the Mfg. directly

These organisations do not need to authenticate the product

These are organisation which do not have contractual relationship with the MAH to store and distribute products and did not receive the product from either a club source or the MAH or the manufacturer directly

These organisations do need to authenticate the product
**Terminology**

**Sales Affiliate of MAH**
- Company focussing on sales which is controlled by MAH or which is subject to control by the same legal entity as the MAH

**Co-Marketer**
- Company commercializing a product under different trademark
- Co-marketer holds own marketing authorization different from that of the other marketing authorization holder (MAH)
  → Co-marketer to be considered MAH in their own right

**Co-Promotor**
- Company operating under agreement with MAH or manufacturer and a license to commercialise same medicinal product under same trademark
  → Term ‘Co-Marketer’ from previous presentations replaced by ‘Co-Promoter’
Theory: ‘Green Box’ Party to be declared ‘Designated Wholesaler’ to avoid verification by first Full-line Wholesaler (DR 2016/161)

Pre-Wholesaling is the provision of logistical services to pharmaceutical manufacturers, mainly consisting in the warehousing and transportation of pharmaceutical products from the manufacturer to wholesalers, …
Sales Affiliate to be considered ‘proxy’ of MAH and thus not to be listed as ‘Designated Wholesaler’

* Pre-Wholesaling is the provision of logistical services to pharmaceutical manufacturers, mainly consisting in the warehousing and transportation of pharmaceutical products from the manufacturer to wholesalers, …
Co-Promoter *not* to be considered ‘proxy’ of MAH and thus to be listed as ‘Designated Wholesaler’

*Pre-Wholesaling is the provision of logistical services to pharmaceutical manufacturers, mainly consisting in the warehousing and transportation of pharmaceutical products from the manufacturer to wholesalers, …*
Multi-stage supply chains: Affiliates 1 & 2 to be considered ‘proxy’ of MAH and thus *not* to be listed as ‘Designated Wholesaler’

No Verification at Goods Receipt

* Pre-Wholesaling is the provision of logistical services to pharmaceutical manufacturers, mainly consisting in the warehousing and transportation of pharmaceutical products from the manufacturer to wholesalers, …
Co-promoter not belonging to MAH’s group of companies to be listed as ‘Designated Wholesaler’

Pre-Wholesaling is the provision of logistical services to pharmaceutical manufacturers, mainly consisting in the warehousing and transportation of pharmaceutical products from the manufacturer to wholesalers, …
Baker McKenzie – Key Statements

• Affiliates should be considered proxies of the MAH and not to be listed as ‘Designated Wholesaler’
• Co-Marketers considered MAH in their own right and not to be listed as ‘Designated Wholesaler’
• Co-Promoters should be considered ‘Designated Wholesaler’
• Products received from a country warehouse can only be considered to have been directly received from the manufacturer where the manufacturer owns or controls the warehouse (i.e. no designation foreseen for manufacturers (author’s comment))
• Recommended to document in writing the delegation of ‘Designated Wholesaler’ appointments to sales affiliates and other legal representatives
Thank You!