



European Federation of Pharmaceutical  
Industries and Associations

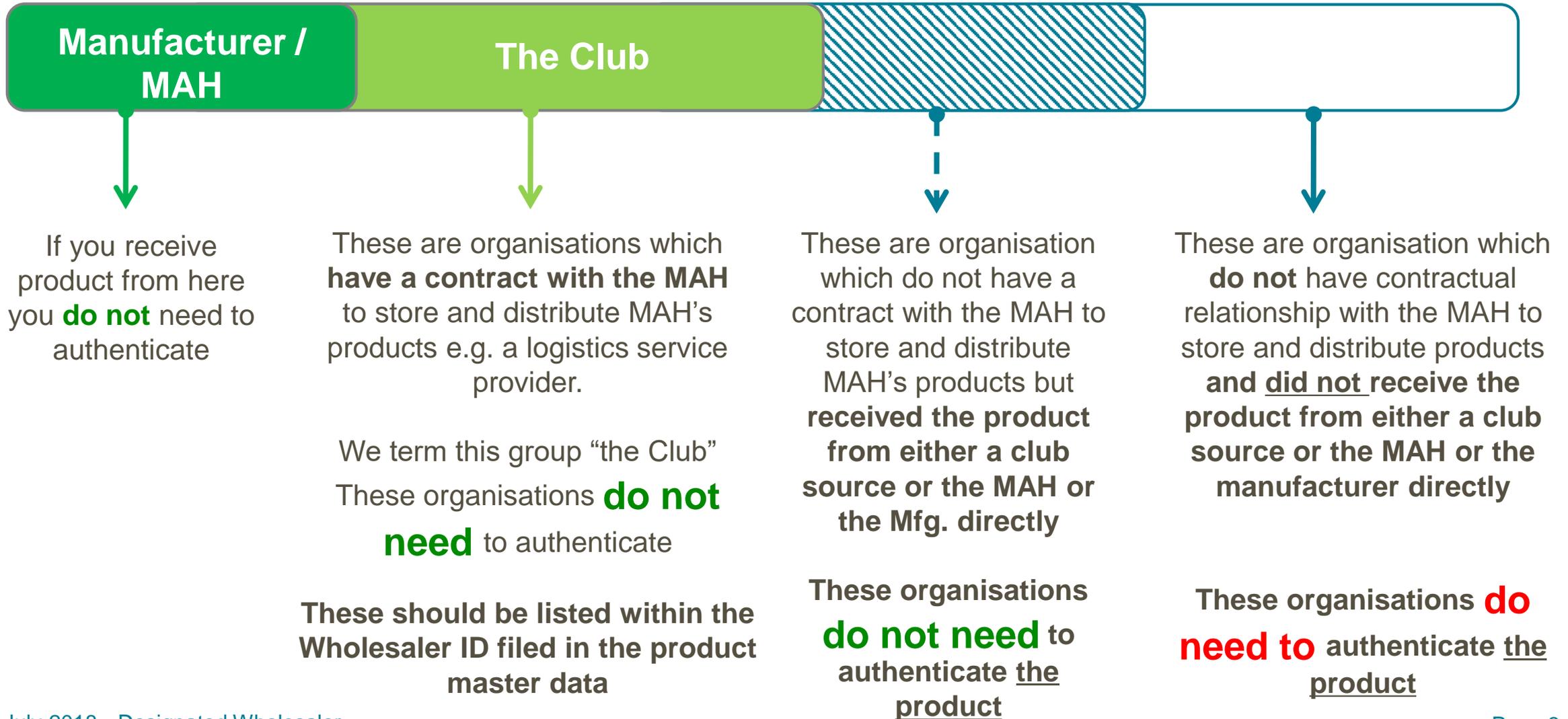
# **EMVO Master Data Guidance – Designated Wholesalers**

## **Update based on Baker McKenzie Memorandum**

**FMD Implementation Workshop  
Brussels, 13-July-2018**

Version 1

- 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)



## 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

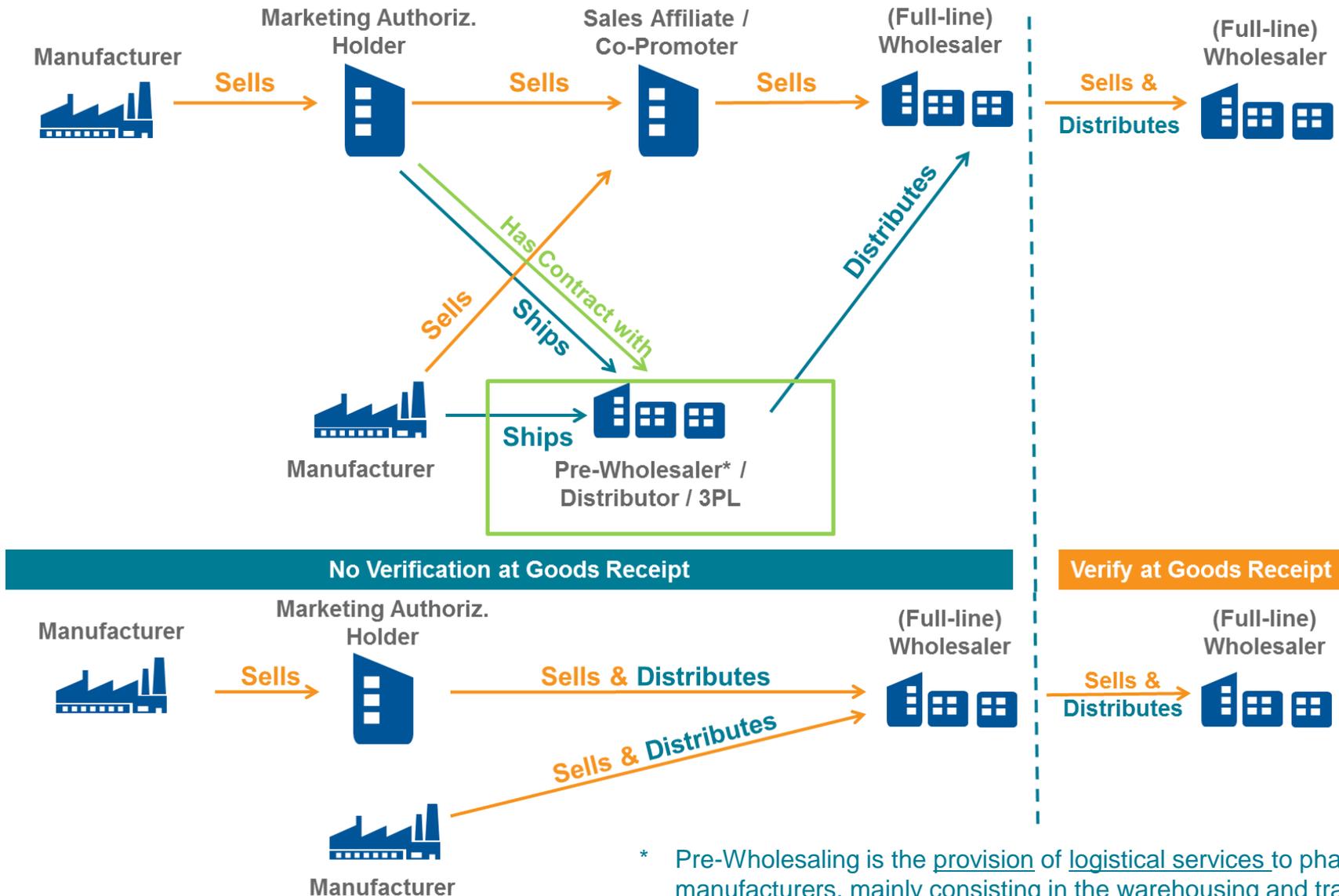
## Co-Marketer

- 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

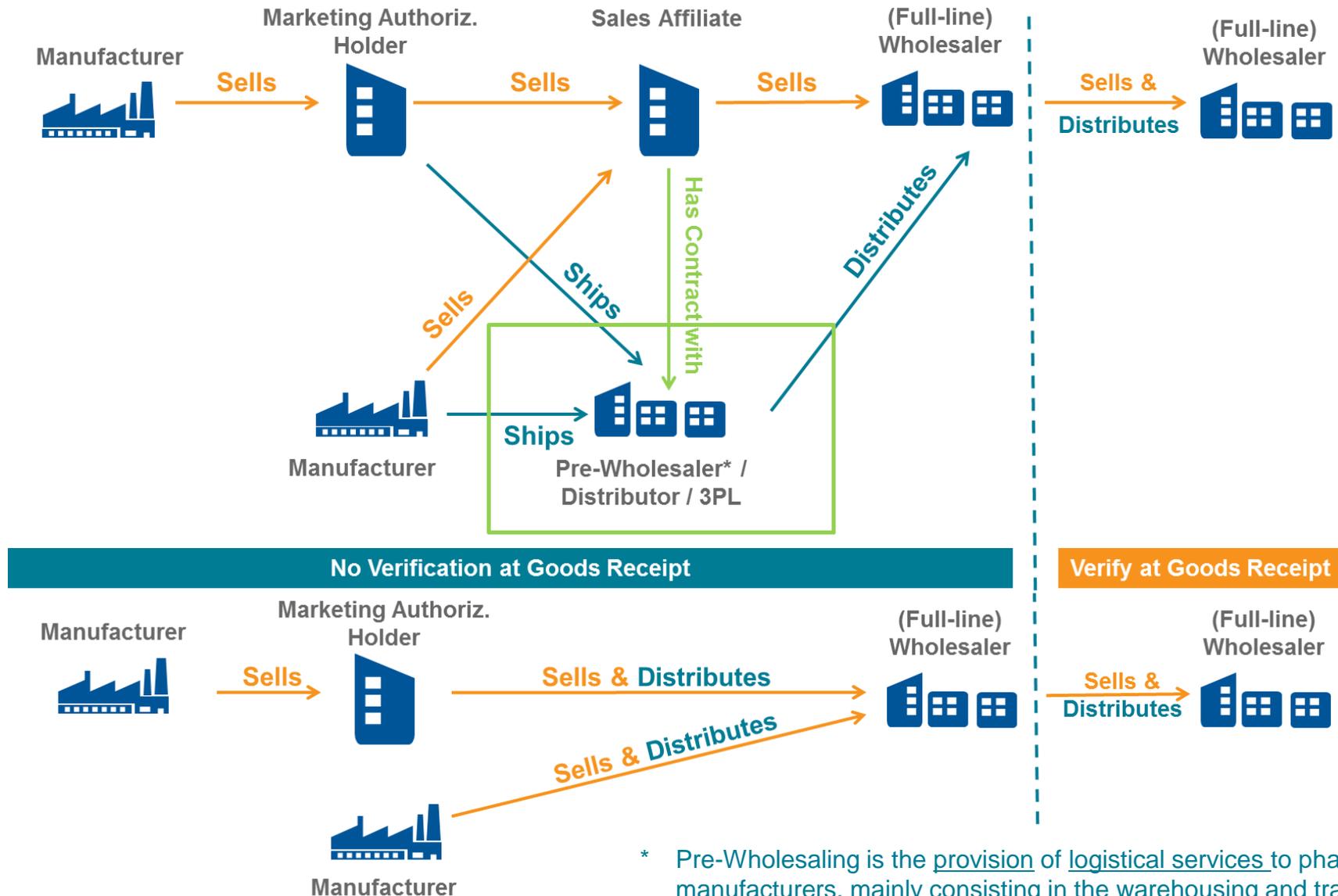
- Company operating under agreement with MAH or manufacturer and a license to commercialise same medicinal product under same trademark
- Term 'Co-Marketer' from previous presentations **replaced** by 'Co-Promoter'

# Theory: 'Green Box' Party to be declared 'Designated Wholesaler' to avoid verification by first Full-line Wholesaler (DR 2016/161)



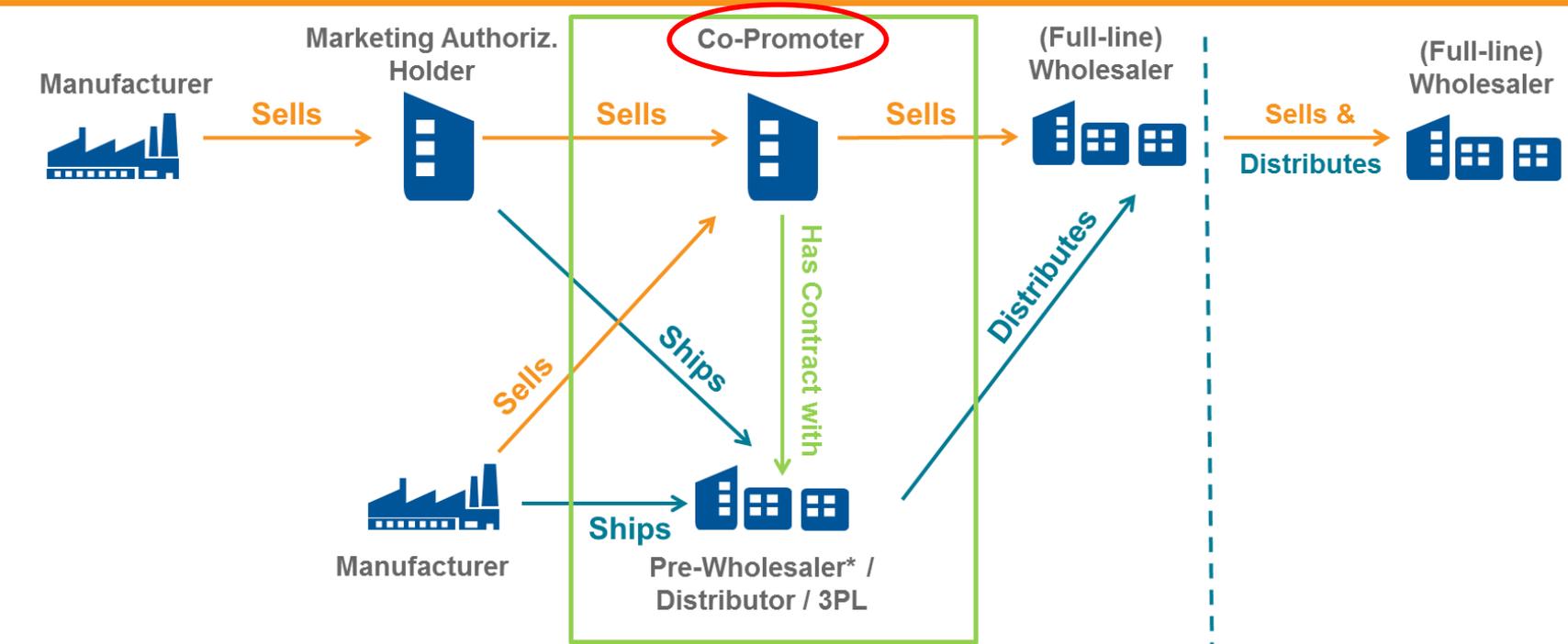
\* Pre-Wholesaling is the provision of logistical services to pharmaceutical manufacturers, mainly consisting in the warehousing and transportation of pharmaceutical products from the manufacturer to wholesalers, ...

# Sales Affiliate to be considered 'proxy' of MAH and thus not to be listed as 'Designated Wholesaler'



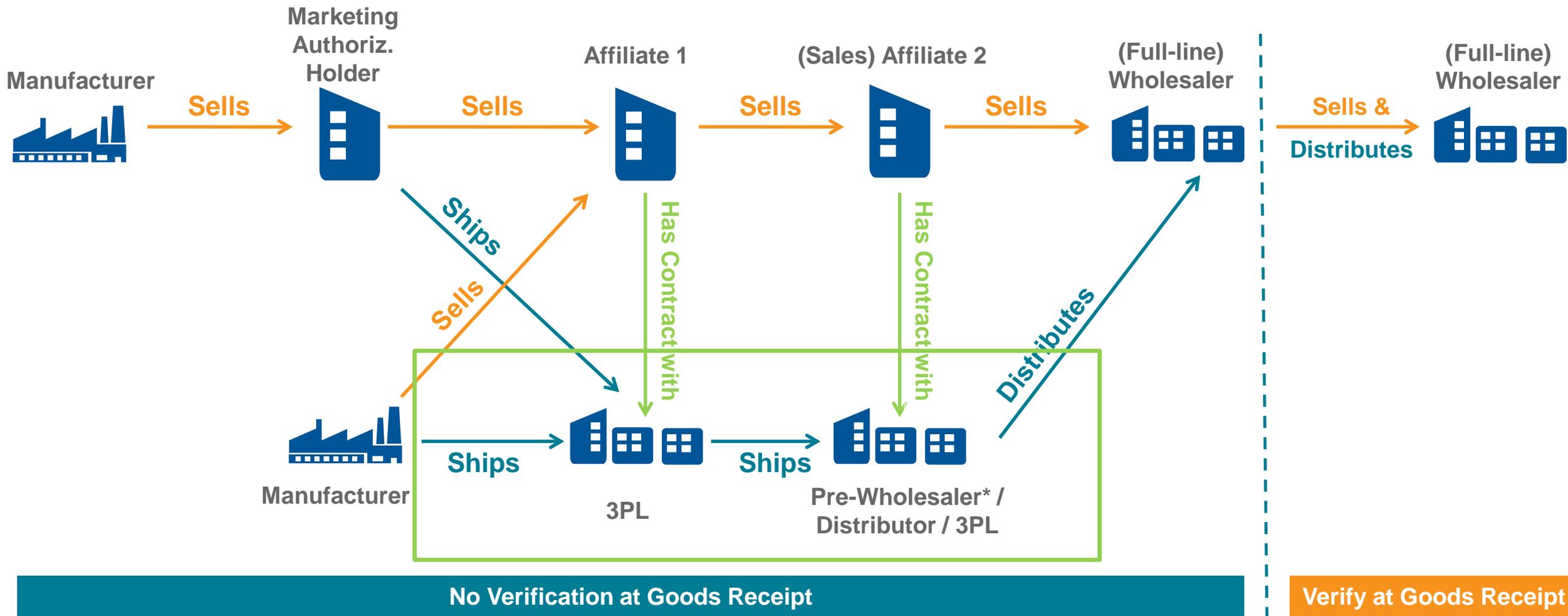
\* Pre-Wholesaling is the provision of logistical services to pharmaceutical manufacturers, mainly consisting in the warehousing and transportation of pharmaceutical products from the manufacturer to wholesalers, ...

# Co-Promoter *not* to be considered 'proxy' of MAH and thus to be listed as 'Designated Wholesaler'



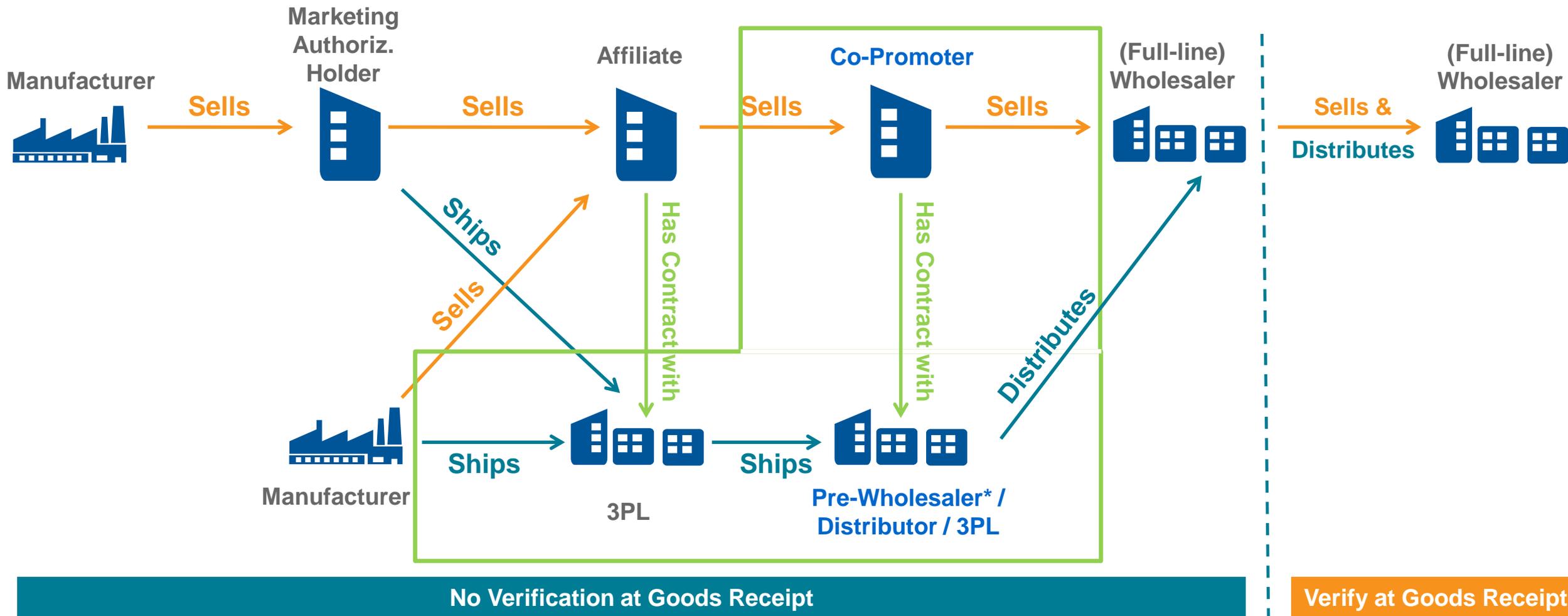
\* Pre-Wholesaling is the provision of logistical services to pharmaceutical manufacturers, mainly consisting in the warehousing and transportation of pharmaceutical products from the manufacturer to wholesalers, ...

# Multi-stage supply chains: Affiliates 1 & 2 to be considered 'proxy' of MAH and thus not to be listed as 'Designated Wholesaler'



\* 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, ...

- 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**



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**Thank You!**