## Submission of comments on the revised guidelines on good distribution practice of medicinal products for human use

## **Comments from:**

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## 1. General comments

Stakeholder number	General comment (if any)	Outcome (if applicable)
	In the previous GDP some flows were specifically excluded. The following was stated in the former GDP in Section 2 - Scope of the document:	
	"This document does not cover materials such as pharmaceutical starting materials (active pharmaceutical ingredients (API) and excipients), reagents, solvents, process aids, intermediate products, packaging materials and labelling materials"	
	In the new GDP guidelines there is no more "scope"	

Stakeholder number	General comment (if any)	Outcome (if applicable)
	section and we would like to request clarification whether with the new GDP guidelines these materials are still not covered or are now in scope?	