

Who will onboard the Swedish system (SMVS)?

Do these instructions concern you and your company?

Organisation	Do you need to onboard the Swedish Medical Verification System (SMVS)?	Reference in the European Commission Delegated Regulation (EU) 2016/161	Reference in the Swedish Medical Product Agency Guidance of the European Commission Delegated regulation (EU) 2016/161
Holder of Pharmacy license			
Pharmacy chain	Onboarding required. Pharmacy chain head office responsible for onboarding of every single pharmacy in the chain.	Article 25	Chapter 2.1
Pharmacy (independent)	Onboarding required	Article 25	Chapter 2.1
Extempore pharmacy	Onboarding required if approved pharmaceuticals used in extempore manufacturing.	Article 25	Chapter 2.5

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Healthcare providers			
Hospital pharmacy	<p>Onboarding required</p> <p>The healthcare provider, or the company which by an agreement is assigned to act as the Hospital Pharmacy function, is responsible for onboarding.</p>	Article 23, 25 and 26	Chapter 2.2
Vaccination agencies	<p>Onboarding required if decommissioning is done by yourselves.</p> <p>If decommissioning takes place according to assignment agreement the supplier needs to be onboarded.</p>	Article 23, 25 and 26	Chapter 2.2 and 2.3
Health Clinics, Private healthcare providers, Outpatient healthcare	<p>Onboarding required if decommissioning is done by yourselves.</p> <p>If decommissioning takes place according to assignment agreement the supplier needs to be onboarded.</p>	Article 23, 25 and 26	Chapter 2.2 and 2.3
Prisons, Dental care, Nursing home,	<p>Onboarding required if decommissioning is done by yourselves.</p> <p>If decommissioning takes place according to</p>	Article 23, 25 and 26	Chapter 2.2

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School health service	assignment agreement the supplier needs to be onboarded.		
The Armed Forces	For information, please contact the Swedish Medical Product Agency	Article 23, 25 and 26	Chapter 2.4
Holder of Wholesale Distribution Authorisation (WDA)			
Wholesaler	Onboarding required if the wholesaler is responsible for physical handling of products which includes verification and decommissioning of packages.	Article 20-24	Chapter 2.3
Third party logistics (3PL)	Onboard if you have an agreement with MAH or Wholesaler which covers assignment to verify and/or decommission packages.	Article 20-24	n/a
Wholesaler not handling physical packages	Onboarding not required if packages not handled by the holder of Wholesale Distribution Authorisation.		
MAH/Manufacturer	No technical onboarding to SMVS for MAH/Manufacturer. Connection and uploading of safety features are done to the European hub.	Article 33	Chapter 2.3 and 2.5

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	If the company holds a Wholesale Distribution Authorisation and are physically handling products which includes verification and decommissioning, see "Wholesaler".		
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Links to document:

[Reference in the European Commission Delegated Regulation \(EU\) 2016/161](#)

[Swedish Medical Product Agency Guidance \(only in Swedish\)](#)

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