Checklist for Mäkler* or Agents*

In order to evaluate the quality assurance system prior to the initial inspection due to a Swissmedic licence: not exhaustive

The Checklist is based on Chapter 3.4 of the Technical Interpretation.

Contracts between Mäkler* and / or Agents* with the contract giving pharmaceutical company	
1.	Are contracts (quality agreements) with all pharmaceutical companies on behalf of the Mäkler* or Agents* acts in place?
2.	Are the responsibilities regarding the distributed medicinal products clearly defined between contract giver (licenced pharmaceutical company) and contract acceptor (Mäkler* or Agents*)?
3.	Have the pharmaceutical companies (contract giver) appropriate establishment licences for manufacturing and/or distribution of medicinal products? If the contract givers of Mäkler* or Agents* are located in foreign countries that do not issue licenses: Can the proof be provided that the contract giver's place of business does not require an official permit to trade with medicinal products?
Quality management and quality risk management	
4.	Is an effective QA system in place covering the type and scope of the activities carried out?
5.	Is there a systematic process for assessing, controlling, communicating and reviewing risks related to the quality of medicinal products (quality risk management, QRM) which is in line with the level of risk?
6.	Are the management and the responsible person of the contract giver (pharmaceutical company) actively involved in this system? Are their responsibilities clearly described in the QA system? Is there a review of the effectiveness of the QA system by the management of the contract giver (management review)?
7.	Are the SOPs regularly checked and, if necessary, updated?
8.	Is an effective change control system in place?
9.	Are deviations from defined and approved processes documented and investigated? Are appropriate corrective and preventive actions (CAPA) taken? Do the deviations and their CAPAs flow into the PQR of the contract giving pharmaceutical company, that is the owner of the brokered medicinal products?
10.	Does the QS system ensure in an appropriate manner that: - supplier of medicinal products have the necessary licences and are qualified by the Mäkler* or Agents*? - medicinal products are only delivered to authorized customers? - complaints are handled properly? - deliveries can be traced and a distribution pedigree of the whole chain from manufacturer to the Mäkler* and Agents* is available? - a recall can be initiated promptly and at time (SOP, written recall plan, realisation, information system, records and documentation, annually mock recall)? - the competent authority and the marketing authorisation holder are informed immediately of medicinal products suspected of being counterfeit?
Personnel	
11.	Is every employee involved in the GDP activities of medicinal products regularly trained with regard to the applicable legal regulations?
12.	Is the personnel training documented?

Documentation	
13.	Do the purchase and sales invoices created for the procurement of the brokered medicinal products contain the following information? - date - name and quantity of the distributed medicinal product - name and address of supplier and customer - batch number - confirmation of entitlement to delivery (for deliveries from wholesalers) such as licence
Are the necessary SOPs available and records kept of?	
14.	- handling of complaints? - informing competent authorities and marketing authorisation holders of suspected falsified medicinal products? - recalls of medicinal products? - ensuring that finished medicinal products distributed have a marketing authorisation? - verifying that Mäkler* or Agents* supplying wholesale distributors hold a distribution authorisation, their supplying manufacturers or importers hold a manufacturing authorisation and their customers are authorized to supply medicinal products in the target market?
15.	Are records kept for at least 5 years?
16.	Are records of blood products, preparations of other substances of human origin, human blood sera and genetically engineered blood components, replacing missing blood components, kept for at least 30 years?
17.	Change control: Is it ensured that subsequent documentary changes are detected (changes to the documentation such as handwritten notes, comments or markings are signed with date and signature)? Is the original document legible?
Traceability over the whole chain from Manufacturer to the Mäkler* or Agents*	
18.	Is a distribution pedigree of the whole chain from Manufacturer to the Mäkler* and Agents* available in order to protect the distribution channel for falsified medicines and medicines with quality defect?