Types of inspections: Competencies of inspectorates

Type of inspection [1]	Company type	Products manufactured or distributed	Legal basis [2]	Competent authority
1. General (routine) GMP/GDP inspections as well pre-approval inspections related to essential changes to facilities, equipments or procedures	Manufacturer	Unspecified medicinal products only [3]	Art. 60 TPA Art. 41 MPLO	Inspectorate of the Cantons on request of Swissmedic or acc. to regional schedule
	Manufacturer	Specified medicinal products only [3]	Art. 34 para. 3 TPA Art. 60 para. 2 TPA Art. 41 MPLO	Swissmedic
	Wholesaler	Unspecified medicinal products only [3]	Art. 60 TPA Art. 41 MPLO	Inspectorate of the Cantons on request of Swissmedic or acc. to regional schedule
	Wholesaler	Specified medicinal products only [3]	Art. 60 TPA Art. 41 MPLO	Swissmedic
	Manufacturer	Both specified and unspecified medicinal products [3]	Art. 34 para. 3 TPA Art. 60 TPA Art. 41 MPLO	Swissmedic and/or Inspectorate of the Cantons [4]
	Wholesaler	Both specified and unspecified medicinal products [3]	Art. 34 para. 3 TPA Art. 60 TPA Art. 41 MPLO	Inspectorate of the Cantons

[1] All types of inspections include follow up inspections (re-inspections)

[2] Medicinal Products Licensing Ordinance (MPLO; SR 812.212.1); Therapeutic Products Act (TPA; SR 812.21); Therapeutic Products Licensing Requirements Ordinance (TPLRO; SR 812.212.22); Therapeutic Products Ordinance (TPO; SR 812.212.21)

[3] Unspecified medicinal products simply consist of medicinal products that fall not under the specified medicinal products according to art. 60, para. 2 TPA. The specified medicinal products are defined as follows:
- immunological medicinal products (vaccines, sera, toxins)
- medicinal products derived from human blood and human plasma (labile and stable blood products)
- rarely used technologies requiring highly specific know-how

[4] Manufacturers of specified and unspecified medicinal products: The competent authority is determined on a case by case basis. A joint responsibility is favoured

Type of inspection [1]	Company type	Products manufactured or distributed	Legal basis [2]	Competent authority
2. „Pre-approval“ and „Post-approval“ inspections related to marketing authorization	Manufacturer	All medicinal products	Art. 10 TPA Art. 23 TPLRO Art. 59 TPO	Swissmedic
3. „For cause“-inspections [5]	Manufacturer / Wholesaler	All medicinal products	Art. 60 para. 1 MPLO Art. 59 TPO	Swissmedic [5] or Inspectorate of the Cantons
4. Inspections abroad	Manufacturer	All medicinal products	Art. 60 para. 2 MPLO	Swissmedic [6]
5. Escort of foreign inspections	Manufacturer	All medicinal products	Art. 64 a TPA	Swissmedic [7]

[5] When a competent authority (Swissmedic or Inspectorate of the Cantons) decides to perform a for cause inspection, this competent authority contacts the other authority before performing the inspection, in order to coordinate the inspection process (e.g. building of inspection’s team)

[6] The responsibility and decision for performing inspections abroad remains with Swissmedic. The inspection team is formed on a case by case basis and it can include inspectors from Swissmedic and from Inspectorate of the Cantons

[7] The responsibility for the coordination of the escort of foreign inspections remains with Swissmedic. The inspection team is formed on a case by case basis, and it may include inspectors from Inspectorate of the Cantons and from Swissmedic