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- to determine that the MAH has staff, systems and facilities in place;
- to meet their PV obligations;
- to identify, record and address non-compliance which may pose a risk to public health;
- to use the inspection results as a basis for enforcement action, where considered necessary.

2. Types of Inspections

By object:

- Entire PV system
- PV in relation to an individual drug

By initiation procedure:

- Planned;
- Unplanned
- Repeated (if a significant number of nonconformities are identified)

By specific of planning conducting:

- Announced/planned
- Sudden / unscheduled

By location:

- At the place of main PV activity
- At the place of delegated activity
- On the territory of the country of registration of drugs

3. Conduction Mode

Inspections can be carried out both on site and remotely.

a) Scheduled inspections

- Have a preliminary inspection program
- They are systemic in nature, assessing the risk of non-fulfillment of PV obligations by the MAH
- May be selective based on the drug

The inspection plan (IP) can be found on the websites of the RAs of the countries where the drug is authorized.

[Monitoring procedure of the RA's website](#) in the respective country (s) is ensured in accordance with the SOP-PV-007 «RI Monitoring».

In the absence of an IP on the websites of the RA, the MAH is notified of the inspections 4-6 weeks before