Documentation/information submitted with a request for listing

1. The identity of the national body responsible for registration/authorisation API manufacturers and carrying out inspections in those sites.

2. Contact details of person at operational level for technical follow-up questions.

3. The national legislation, implementing provisions and other relevant information relating to the manufacture of APIs (including the registration/authorisation of manufacturers) in order to ensure quality and purity of the active substances. Copies of legislation and implementing provisions should be provided and the relevant sections highlighted. If the legislation is not in one of the working languages of the Commission (English, French or German), a translated version should be provided.

4. Information as to whether these provisions are identical with internationally-agreed guidelines, such as those of the ICH Q7 or WHO and, if not identical, where precisely they differ.

5. The national legislation, implementing provisions and other relevant information relating to inspections of API manufacturers, including the risk prioritisation process for selecting sites to be inspected and the frequency of inspections.

6. The total number and list of registered API manufacturers in the country and (where numbers are available) those exporting APIs to the EU. Please also list those sites which have been inspected in the last calendar year and in this calendar year to date.

7. The total number of inspectors and the average number of API sites inspected annually per inspector.

    - the minimum qualifications required of inspectors;
    - the professional training required to be followed by inspectors;
    - the inspection procedures;
    - the format of the inspection report;
    - actions taken to follow-up inspections findings;
    - the enforcement powers and sanctions available.

8. Information (and reference) whether the legislative and implementing provisions referred to in points 3 and 5 apply to sites manufacturing APIs *exclusively* destined for export.

9. The legislative and implementing provisions relating to the importers and the import of APIs into your country.

10. (In the case there is an MRA in place which covers APIs) An overview of any legislative and implementing provisions which have been adopted or which have entered into force subsequent to conclusion of the MRA.

11. The prospective timetable for the inspections of API manufacturers for the next 12 months (to plan the on-site visit).

12. (Where already in place) The mechanisms in order to ensure regular and rapid provision of information by the third country to the EU in relation to non-compliant producers of APIs.

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