Chief Pharmaceutical Inspectorate

Inspection in third countries

1. General information

GMP Inspectors from the Chief Pharmaceutical Inspectorate are able to conduct a GMP Inspection in a manufacturing site in companies located in third countries only if manufactured there active substances are available in the Polish market or are imported by a Polish importer of active substances.

The application for the inspection should be send by:

- Polish importer of API or
- by Marketing Authorization Holder who is located in Poland and a medicinal product which contains this active substance is manufactured by polish manufacturer, or
- by Polish manufacturer who uses this active substance.

Paper documents should be delivered personally or by mail to the Chief Pharmaceutical Inspectorate.

All documents are verified on both formal and substantive aspects.

If any deficiencies are found, call to supplement with an indication of legal basis is formulated.
If applicant does not complete formal deficiencies within 7 days from the date of receiving the call, the application remains without consideration – according to art. 64 § 2 of the Code of Administrative Proceedings.

In case of difficulty with completion the application within period specified in art. 64 § 2 of the Code of Administrative Proceedings, the applicant may request to the authority for suspension of proceedings. According to art. 98 § 2 of the Code of Administrative Proceedings authority may suspend the proceedings, if it is requested by the applicant, there is no other Parties objection and there is no threat of interests of society.

If documents are complete, applier is written informed about exact inspection term and cost in 45 days before planned inspection.

The costs of the inspection are calculated according to the Regulation of the Minister of Health from March 2, 2015 on the amount and manner of the covering of costs related to carrying out an inspection at the manufacturer, importer or distributor of active substances or the manufacturer of excipients by GMP inspectors of the Chief Pharmaceutical Inspectorate. Written notice include notification about the inspection specifying leading inspector.

The applicant shall pay the fee for the inspection indicated in the written notice on the Chief Pharmaceutical Inspectorate account within 14 days from the date of receiving the notice. Receipt for payment should be sent by fax to number 22 635 99 57. Receipt for payment for the hotel and for the airline tickets should be delivered no later than 30 days before the scheduled start of the inspection.

2. List of required documents

Application must contain:

- Exact name and address of the manufacturer and manufacturing site
- DUNS number of manufacturing site
- Detailed information on the active substances which inspection will concern
- Information on inspections of the other competent authority of the European Union in the manufacturing site

Application must be signed by person authorized to represent the entity according to the law in force or by an agent acting under a power of attorney signed by a person mentioned above.

To the application must be attached:

- Site Master File in English and Polish language (detailed proceeding and actualization of SMF is described in the Statement of the Chief Pharmaceutical Inspector number 6/2012)
- Receipt for payment stamp duty in the amount of 51 PLN (17 PLN per certificate, wherein the Party receives two certificates – first in Polish language, second in English language and additional certificate in English receives inspected manufacturer.
- Receipt for payment stamp duty in the amount of 17 PLN for power of attorney, if applicable.

3. Time limit for completion

Chief Pharmaceutical Inspector shall issue certificate confirming the compliance with the Good Manufacturing Practice or refusing decision within 90 days of the inspection completion date.

4. Payment

- The costs of planned inspection is calculated according to the Regulation of the Minister of Health on the amount and manner of the covering of costs related to carrying out an inspection at the manufacturer, importer or distributor of active substances or the manufacturer of excipients by GMP inspectors of the Chief Pharmaceutical Inspectorate dated 2 March 2015.

- Certificate cost – stamp duty in the amount of 51 PLN (17 PLN per certificate, wherein the Party receives two certificates – first in Polish language, second in English language and additional certificate in English receives inspected manufacturer) payed at the cash desk of Śródmieście District of Warsaw office, Nowogrodzka 43, 00-691 Warsaw or by transfer to account number 60 1030 1508 0000 0005 5001 0038.

- Power of attorney cost - stamp duty in the amount of 17 PLN payed at the cash desk of Śródmieście District of Warsaw Office, Nowogrodzka 43, 00-691 Warsaw or by transfer to account number 60 1030 1508 0000 0005 5001 0038.

5. Additional information

According to the Regulation of the Minister of Health on the amount and manner of the covering of costs related to carrying out an inspection at the manufacturer, importer or distributor of active substances or the manufacturer of excipients by GMP inspectors of the Chief Pharmaceutical Inspectorate dated 2 March 2015, the applicant is responsible for ensure the hotel accommodation and airline tickets for inspectors.

In order to clarify any doubts concerning the organization of inspection, the manufacturer contacts the designated Leading Inspector.

The certificate confirms the compliance of the manufacturing conditions with the Good Manufacturing Practice requirements found during the mentioned above inspection. The certificate cannot be used after the expiration of 3 years from the date of the last day of the inspection. After this period, the manufacturer is obliged to contact the Chief Pharmaceutical Inspectorate or other competent authority of the European Union, to conduct the next inspection.

6. Contact person

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