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 the Marketing Authorization Holder applies for: marketing authorization or amendment of the marketing authorization because of change of the manufacturer located in the third country, or GMP Certificate when the medicinal product is imported into Republic of Poland from a third country.

All documents should be delivered on paper personally, by mail or by Post 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 the 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 Pharmaceutical Law – Act of September 6, 2001, the section 47 b and the Regulation of the Minister of Health dated 10 March, 2015 on the amount and manner of the covering of costs related to carrying out an inspection at the manufacturer of medicinal product by GMP inspectors of the Chief Pharmaceutical Inspectorate. Written notice includes notification about the inspection specifying lead 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:

- Information what application should be recognized by the Chief Pharmaceutical Inspectorate
- Exact name and address of the manufacturer and manufacturing site
- DUNS number of the manufacturing site or GPS details, or any other geographic location system
- Detailed information on the medicinal product which will be concerned by the inspection (general name, formulation, dose, marketing authorization number, if applicable)
- Information whether other European Union competent authorities carried out an inspection of the manufacturing site.

Furthermore, application must be signed by a person authorized to represent the entity according to the law in force or by a plenipotentiary acting under the power of attorney signed by the person mentioned above.

Documents to be attached to the application:

- When the inspection is to be carried out in a manufacturing site, certified copy of manufacturing authorization (manufacturing license) issued by the competent authority of the country where the medicinal product is manufactured (translated into Polish or English)
- Certified copy of marketing authorization or statement claiming application for marketing authorization issued by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
- Site Master File in English or Polish language (the SMF is to be draw up according to templates included in the Volume 4 – Good Manufacturing Practice, Part III or in the Regulation of the Minister of Health dated 15 November 2015 on the Good Manufacturing Practice Requirements, respectively).
- Receipt for payment stamp duty in the amount of 17 PLN for each 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 noncompliance statement within 90 days of the inspection completion date.

4. Payment

- Inspection cost – transfer to Chief Pharmaceutical Inspectorate bank account of – National Bank of Poland office in Warsaw, account number 30 1010 1010 0056 2722 3100 0000
- Certificate cost – stamp duty payment at the cash register of *Śródmieście District* of *Warsaw* Head *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 payment at the cash register of *Śródmieście District* of *Warsaw* Head *Office,* Nowogrodzka 43, 00-691 Warsaw or by transfer into account number 60 1030 1508 0000 0005 5001 0038

5. Additional information

According to the Regulation of the Minister of Health dated 10 March 2015 on the amount and manner of covering costs related to carrying out an inspection of the manufacturer or importer of medicinal products by the GMP Inspectors from Chief Pharmaceutical Inspectorate the applicant ensures the hotel accommodation and airline tickets for GMP inspectors.

In order to clarify any doubts concerning the organization of inspection, the manufacturer should contact the designated lead inspector.

The GMP certificate confirms the compliance of the manufacturing conditions with the Good Manufacturing Practice requirements found during the inspection mentioned above. The certificate cannot be used after the expiration of 3 years from the date of the last day of the inspection. For an extension the manufacturer must apply to the Chief Pharmaceutical Inspectorate or other competent authority of the European Union, to conduct the next inspection in advance.

6. Contact

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