Dear colleagues!

Within the expertise for state registration of the medicinal product in the Republic of Armenia, the following are carried out:

1) Confirmation of manufacturers involved in the manufacturing process based on the following documents:

a) Application for registration/re-registration,

b) Data submitted in the Part 3.2.P.3.1 "Manufacturer(s)" of the registration dossier in registration, and in re-registration, the data provided in part 3.2.P.3.1 "Manufacturer(s)" in the previously approved registration dossier,

c) Data provided in the certificate (CPP) of the medicinal product (in some cases).

Based on the results of the expertise of submitted documents, the manufacturers involved in the five main manufacturing operations: 1) bulk 2) production, 3) primary packaging, 3) secondary packaging, 4) quality control (physicochemical, microbiological non-sterile/ microbiological sterile, biological) and 5) batch production are confirmed. In this regard, correct presentation of the information in these documents is very important for the smooth proceeding of the registration/re-registration expertise.

Inconsistencies in the data on manufacturers between the application and other documents in the dossier are requiring a confirmation by applicant leading to delay of the expertise.

2) Expertise of the GMP compliance of the approved manufacturing sites using the valid GMP certificates issued by the competent authority of the country of manufacturer submitted in the dossier, and in some cases, reviewing available web based electronic platforms (e.g. EudraGMDP).

Based on the results of the GMP compliance expertise of manufacturers involved in the medicines production a report is drawn up including the list of approved manufacturers, and, afterwards, the name of the manufacturer/manufacturers in the state registration certificate of the medicinal product in the Republic of Armenia are subsequently formed (Table 1).

Table 1

Bulk production	*Name of manufacturer* Site address: *bld. No/street/city/postal code/state*
Primary packaging	*Name of manufacturer* Site address: *bld. No/street/city/postal code/state*
Secondary packaging	*Name of manufacturer* Site address: *bld. No/street/city/postal code/state*
Quality control (physical-chemical/ microbiological)	*Name of manufacturer* Site address: *bld. No/street/city/postal code/state* *Name of manufacturer* Site address: *bld. No/street/city/postal code/state*
Batch release	*Name of manufacturer* Site address: *bld. No/street/city/postal code/state*

In some cases, in addition to the five main production steps, additional manufacturers may be involved in the production process. For example, in case of hard capsules are composed by soft-shell capsules or pellets the manufacturers of soft-shell capsules and pellets are, also, fixed and in this case three manufacturing sites should be fixed (Table 2).

Table 2

Bulk production 1, 2	*Name of manufacturer* Site address: *bld. No/street/city/postal code/state*
Primary packaging	*Name of manufacturer* Site address: *bld. No/street/city/postal code/state*
Secondary packaging	*Name of manufacturer* Site address: *bld. No/street/city/postal code/state*
Quality control (physical-chemical/ microbiological)	*Name of manufacturer* Site address: *bld. No/street/city/postal code/state*
Batch release	*Name of manufacturer* Site address: *bld. No/street/city/postal code/state*

[1] *Production of shell capsules:*

Name of manufacturer
Site address: *bld. No/street/city/postal code/state*

[2] *Production of pellets:*

Name of manufacturer
Site address: *bld. No/street/city/postal code/state*

In another case, several manufacturers in the quality control are involved (Table 3)

Table 3

Bulk production	*Name of manufacturer* Site address: *bld. No/street/city/postal code/state*
Primary packaging	*Name of manufacturer* Site address: *bld. No/street/city/postal code/state*
Secondary packaging	*Name of manufacturer* Site address: *bld. No/street/city/postal code/state*
Quality control (physical-chemical/ microbiological)	-Denk Pharma GmbH & Co.KG, Germany *Name of manufacturer* Site address: *bld. No/street/city/postal code/state* *Name of manufacturer* Site address: *bld. No/street/city/postal code/state*
Batch release	*Name of manufacturer* Site address: *bld. No/street/city/postal code/state*

In this case, all manufacturers involved in the quality control process should be mentioned, as the quality control carried out for the purpose of releasing the product into the market is considered to manufacturing process.

During registration, approval of all manufacturers is a requirement raising from Government Decree No. 162-N of February 28, 2019[1] and considering that before adoption of Decree, manufacturers involved in the manufacturing process of the medicinal product to be registered in RA may not be approved for all stages of production, please submit relevant corrections and clarifications by September 30 of this year, taking into account the above mentioned.

Thank you for your collaboration!

[1] On approval of procedures for state registration and re-registration of medicinal products, renewal of certificates, as well as refusal of registration, re-registration of medicinal products and renewal of certificates, suspension and revocation of registration, procedures for expertise in the above cases, and submission and expertise of post-registration changes and list of necessary documents, list of changes not requiring new registration, procedures for pharmaceutical inspections and recognition of reports of competent authorities of other countries