AZERBAIJAN REPUBLIC
Ministry of Health
ANALYTICAL EXPERTISE CENTER FOR MEDICINES
34 J.Jabbarli str., baku AZ1065
Tel/Fax: (994 12) 596 05 20
e-mail: mnl@azdata.net

No. 04/4341

To the plenipotentiaries and representation of the pharmaceutics companies acting in Azerbaijan Republic

There have been done definite changes in the rule of presentation of the dossier accepted to the expertise to the Analytical Expertise Center for Medicines with the purpose to register the medicines.

The definite parts of the dossier must be presented in two copies in the electron carrier and each page of the required document must be showed:

In paper carrier (in two copies):

1. The application compiled in Azerbaijani for the registration of the medicines.
2. Appeal letter compiled in definite rule.
3. Information about the official status of the medicines:

The document about registration of the medicines in the producing country (the original or the copy certified in the notarial rule);

The document about the registration of the medicine in other countries certified by the manufacturer of the medicines (if it needs, the copy of the registration cards certified in the notarial rule);

For the medicine issued according to the license - the copy of the permission of the licensing certified in the notarial rule;

The license for the production of the medicine and (or) the document certifying the manufacture proper to the reliable manufacture practice (the original or the copy certified in the notarial rule);

The examples of the quality certificate certified by the manufacturer given to a series of the ready medicine (to the consecutive series for the immunobiological medicines).

In the Electron carrier:

1st disc (in two copies)
Instruction about the use of the medicine

2nd disc (in two copies):
The marked examples of the packages, etiquette and their sketches in Azerbaijani and in English, use instructions

3rd disc (in two copies):
Documents about the chemical, pharmacological and biological tests:

1. The exact composition showing all the ingredients including to a form of medicine based on normative documents (monograph, pharmacopeia, the document of the manufacturer), at the same time the assistant matters, colouring matters, aromatizers, stabilizers and so on;
2. The short scheme of the production process of the medicines;
3. The normative documents on the control to the quality of the assistant matters and medicine substance. The demands to the quality of the strain and substratum used in the manufacture of the immunobiological medicines and the full and detailed description of the control method (the cultivation lines of embryos, cells);
4. If the normative documents on the quality of the ready medicine aren't suitable for the quality parameters intended for the medicine form, the information about the tests held in intermediate stages of the manufacture processes;
5. Normative documents on the control to the quality of the ready medicines.
6. The reference about the conducting the validation of the method on the control to the quality;
7. The quality certificate given to a series of the ready medicine and medicine substance (to the consecutive series for the immunobiological medicines)
8. The marked examples of the packages, etiquette and their sketches in Azerbaijani and in English, use instructions;
9. The tests results about the stability of the medicine (2 series).

4th disc (in two copies):

1. The documents about the investigations (analogues of the medicines – for the generics) conducting for the determination of the bioappropriation (of the bioequivalent) certified by the manufacturer (information about the mutual interchangeability for the immunobiological medicines);
2. The calculation of the clinical tests certified by the manufacturer (scientific publication and information). The documents about the clinical, immunological, prophylactic effectiveness of the used "İn vivo" immunobiological medicines and about the diagnostic effectiveness of the used "İn vitro" immunobiological medicines;
3. The account about the conducting of the clinical test of the medicine (for the original medicines)