. **Application for the medicinal product registration (appendix № 1);**

1. Type of medicinal product registration procedure (to mark necessary)

– registration

– re-registration

– registration of amendments made to the registration documents of early registered medicinal products

2.Customer, country

3.Manufacturer, country

4.Address of manufacturer

5.Medicinal product license holder (upon request)

6.Pharmaceutical substance manufacturing company

7.Medicinal product trade name

8.Active ingredient(s) (international nonproprietary name, dose)

9.Auxiliary substance(s)/quantity

10.Pharmaceutical product form, standard package (preliminary and final) with indication of quantity of doses per pack

11.Medicinal product basic synonyms

12.Medical product type

a) generic

b) original

c) if medical product is generic original medical product's name have to be pointed out: _____

13.Route of administration (orally, injection, etc.)

14.Therapeutical indication for use

15.ATC code

16.Shelf life

17.Storage condition

18*To indicate any change while making amendment since medicinal product registration

19*Date and registration number of medicinal product at the last registration in the Azerbaijan Republic

20**Type of amendments made to the medicinal product registration documents

Notes:

1.Customer is responsible for efficacy, safety and quality of medicinal product and also for the correctness of information included into the registration materials.

2.*Points 18 and 19 are to be filled at the re-registration of medicinal products with expired term of registration.

3.*Point 20 is to be filled at the registration of amendments made to the registration documents of early registered medicinal product.