a. *Pharmaceuticals registration*

Requirements of registration

Following requirements need in state registration list for medicine and medical devices. Herewith:

- To meet requirements on Medicine manufacturers are in "Regulation of medicine manufacture" (GMP), and medical devices manufacturers are in European and USA standard (CE, FDA, FDA-510 K);
- Export country should have medicine product certificate approved by authority organization;
- Determined precisely by sciences expertise of Medicine effectiveness, ingredients, dose and medical devices quality;
- Ensured by clinical medicine baseline survey and analytic conclusion;
- Ensured by expert expertizes and surveillance conclusion for medical reaction, quality and safety with advantage effectiveness than same registered medicine in state (not belong to intensive registration)
- Medicine use, prohibition, side effects, pharmaceuticals mutual reaction and dosage proved by pharmacology expertise;
- Package of pharmaceuticals and medical devices should be with international bar code and translated into with Mongolian, English, Russia any of them which it must be meet to "Law of medicine and medical devices" requirements;
- Import medicine should be registered in at least three county's medicine registration. (not belong to traditional medicine);
- Import medicine should be registered in present country at least 3 years past and export country use it;
- Tuberculious medicine should be registered in "WHO List of prequalified medicinal products";
- Package of pharmaceuticals and medical devices should be with international line code with sticker design and it must be meet to "Law of medicine and medical devices" requirements which is register in intensive registration. Oganization which is going to register their medicine should responsible to security of sticker;

Required documents for licensing and pharmaceuticals registration as Minister order 41/2012:

1) An application submitted by an authorized individual from the manufacturer for the registration of medicine.
2) A Copy of the contract between the manufacturer and Mongolian wholesaler/manufacturer's representative.
3) Verification from relevant pharmaceuticals regulatory authority certifying GMP requirements of manufacturer.
4) An Original pharmaceutical product certificate (CoPP) for Mongolia, /WHO- type/.
5) A copy of each certificate of registration in 3 countries validated by stamp of manufacturer.
6) Profile of the manufacturer in CD format where the manufacturing process is shown along with a copy of printed profile in the Mongolian language.
7) Product specifications, summary of main indications, brief summary of main interaction with other medicines, brief summary of main side effects.
8) An original certificate of finished products by manufacturer.
9) Source and Certificate of active and inactive ingredient(s)
10) Stability study data justifying the shelf life of the medicinal product
11) Master manufacturing formula of including details of batch size, manufacturing process (including in-process quality control)
12) Bioavailability studies

13) Summary of clinical data on the toxicity (Not relevant to generic pharmaceuticals) efficacy and safety of the medicinal product
14) Instruction of medicine for health professionals and package insert leaflet for patients with translation into Mongolian language
15) Primary and secondary packaging design such as label, pamphlet, carton and so on.
16) Sample of medicine

b. Licensing for import Drugs and BAP

1. An application submitted by an authorized individual from the manufacturer for the registration of medicine

2. A Copy of the contract between the manufacturer and Mongolian wholesaler/manufacturer's representative

3. Verification from relevant pharmaceuticals regulatory authority certifying GMP requirements of manufacturer
4. An Original pharmaceutical product certificate (CoPP) for Mongolia, /WHO- type/

5. A copy of each certificate of registration in 3 countries validated by stamp of manufacturer
6. Profile of the manufacturer in CD format where the manufacturing process is shown along with a copy of printed profile in the Mongolian language.

7. Product specifications, summary of main indications, brief summary of main interaction with other medicines, brief summary of main side effects

8. An original certificate of finished products by manufacturer, Source and Certificate of active and inactive ingredient(s)
9. Stability study data justifying the shelf life of the medicinal product

1. Master manufacturing formula of including details of batch size, manufacturing process (inclusion in-process quality control)
2.

11. Bioavailability studies
12. Summary of clinical data on the toxicity (Not relevant to generic pharmaceuticals) efficacy and safety of the medicinal product

13. Instruction of medicine for health professionals and package insert leaflet for patients with translation into Mongolian language.

14. Primary and secondary packaging design such as label, pamphlet, carton and so on

15. Sample of medicine

Import BAP

1. Aplication to register in state registration;
2. Notarized copy of "State registration certificate of company";
3. Original Copy of contract with manufacturer of export country or official distributer;
4. Notarized copy of registered certificate in origin country;
5. Evidence of export license of BAP or license of free trade;
6. Conclusion of examination and definition of manufacturer on quality of product, active biology and indicator of safety;
7. Label, instruction;
8. Information of product's ingredients, compound, indicators of safety, influence, side affects;
9. Product's patent of microzoon, name of micro zoon, its type, latin name and and defination of how to develop micro zoon;

10. Evidence of biological active product made by mix of genetically changes and definition of mix is not include in biological active product
11. Defination document of name of plant, type with translated into Latin and its recipe;
12. Evidence of manufacturer not used doping for sportsmen and people who are work with tie up to support their increase of muscles in ingredients of biological active product;
13. Documents to meet requirements from related authorized inspection organizations such as bring into WHO industrial practice standard (GMP) , Analysis of safety and critical moment /HACCP/, international standard /ISO/, or same official documents from manufactured country;
14. Information of methodology examination of industrial technology compound of ingredient to influence health
15. Quality certificate, names raw materials, sources of products and evidence of its quality and safety;
16. Sample and design of the product sufficiently for examination;

c. Fee for service and customer taxes

1. Despite of different types of property, perspiration of registration (hereafter regulation fee) should pay in registration activity.
2. Applicants responsible to relevant activity of registration on medicine, diagnostic kit and biological active product.

3. Foriegn payment shall be calculate Mongolian Bank USD rate present day. Payer organization shall be responsible to foreign transaction.

4. Fees of registration activity is not pay back condition:
4.1 To register import medicine in state registration and its prolongation 350 000 ₮;
4.2 To register diagnostic kit in state registration and its prolongation 50 000 ₮;
4.3 To register biological active product in state registration and its prolongation 250 000 ₮;
4.4 To register rapid import medicine 500 000 ₮;
4.5 Planned primary register from Counsil on Human medicine and to register import medicine in list but still not registered 100 000 ₮;
4.6 To register and prolong national manufacture medicine 100000 ₮;
4.7 To register and prolong raw materials of medicine100 000 ₮;
4.8 To register and prolong import traditional medicine- 200 000 ₮;
4.9 To register and prolong national traditional manufacture medicine - 50000 ₮;
4.10To make change in registration- 50 000 ₮;
4.11 Same form of medicine registered in over 10 medicine manufacture before and its fees should be more 2 times. It is spend into comparable examination and survey.

5. **Registration fees** proved by in centralized measure expences of DoH budget and it is spend in following activity.
5.1 To provide registration activity continuously;
5.2 To publish registration certificate;
5.3 To provide required equipments for registration activity;
5.4 To develope registration database;
5.5 Invite to work professional expert,
5.6 To organize expert training;
5.7 To plan expences for international consultant an expert in required activity;
5.8 To make conclusion of laboratory and expertize;
5.9 To invole international references and laboratory examination;
5.10 Activity expences of council on human medicine and sub committee;
5.11 To prove use of instruction;
5.12 To conduct survey regularly medicine market and its quality, safety;

5.13 To take referencesof manufacturer;

5.14 To plan expences on duty travel for study tour on manufacture ;
5.15 To involve member of counsil on Human medicine, relevant professionals and experts in international exhibition, conference and training
5.16 To order international professional book, booklet and publishments
5.17 To advertise and publisize of medicine proper use;
5.18 To develope and publish national pharmacopey;
5.19 To cooperate with contractor for intensive registration activity and surveillance;
5.20 Other activity related to adhiring and implementing policy from government.

6. Below mentioned standard should follow for invite to work expert, to transfer medicine, diagnostic kit, biological active product, to translate medicine instruction, article of pharmacopey and incentives for member of Counsil on Human Medicine and sub Counsil attended in official meeting .

Background of expences	Unit of measures	Payment tariff
Incentives for members of Counsil on Human medicine and sub committee	1 hour	8000 ₮
Incetives for members of Pharmacopey committee	1 hour	8000 ₮
To develope newly of Pharmacopey	A4, 12 font size, track 1, every pages	30000 ₮
Incentives for pharmacology expert	New medicine (with trade name)	50000 ₮
	To register intensively of general name, motherland medicine and raw materials	30000 ₮
Incentive for diagnostic expert	Each item	30000 ₮
Incentive for laboratory expert	Each form and item of diagnostic kit	30000 ₮
Incentive for biological active product expert	Each biological active product	30000 ₮
To involve sample of medicine, biological active product in laboratory examination and to ininvolve diagnostic kit in test	Each medicine and diagnostic kit	Along the laboratory rate