Special License in Drug Supply

The registration of medicines is regulated by the 22nd article. The law of medicine and medical devices:

1. samples of medicines and bioactive products for registration;
2. donation and aid medicines;
3. medicines procured through international organizations, in accordance with Government agreement;
4. medicines, for which a trade contract could be made with only one entity, under the reason of protecting an intellectual right, and there is no body to replace the contracted entity;
5. orphan drugs;
6. medicines to be used in research and pharmacological and clinical experiments and analysis;
7. samples of medicines, medical devices and bioactive products to be launched at exhibitions and fairs;
8. supplementary medicinal substance;
9. raw materials of traditional medicine;
10. medicines to be used in emergency and the state of disaster;
11. medicines compounded in pharmacies as per doctor's prescription;
12. medicines for personal use of travelers.

Required materials for medicines registration for import:

1. The original official letter for registration in state registry of medicine of Mongolia approved by authorized person of manufacturer
2. Copy of the contract between Mongolian wholesaler and representative or manufacturer
3. Document from relevant drug regulatory authority certifying that the manufacturer is in compliance of the GMP requirements of the country
4. The Original pharmaceutical product certificate (CoPP) for Mongolia, WHO- type are attached (for WHO Certification Scheme).
5. Registration status in other countries, copy of registration certificate in 3 countries /with stamp of manufacturer/
6. Profile of the manufacturer /soft copy showed manufacturing process and hard copy translated in Mongolian briefly/
7. Product specifications, summary of main indications, brief summary of the main interaction with other medicaments and other forms of interaction, brief summary of the main adverse side effects
8. Original certificate /manufacturer's and contracted laboratory's/ and method of analysis of the finished product
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 clinical data on the toxicity (Not relevant to generic drug) the safety and efficacy of the product
14. Instruction of medicine for medical professions and package insert leaflet.
15. Primary and secondary packaging design such as label, pamphlet, carton.
16. Sample of medicine

Mongolian pharmaceutical sector implementing by the following laws and regulations, such us:

1. State policy on drug / 2011, issued in 2014 /
2. Health Law, Article 12-21
3. The law of medicine and medical devices / revised 2010 / which regulates pharmaceutical activities has come into effect. /Hereby I attached Law on Medicines and medical devices/.
4. The National Health Insurance Law
5. "Narcotic and Psychotropic Substances Control Act circulation / amended in 2011 /
6. State and local funds, goods and services, the purchase of law
7. Corporate Licensing Act
8. Our country joined the narcotic and psychotropic drugs of a number of international conventions
9. General Requirements for the pharmaceutical industry MNS 5524: 2005, MNS5524: 2011, MNS5524: 2014
10. For drug procurement organization in general MNS 5530: 2010
11. Drug fund for general MNS 5260: 2011
12. Prescription forms, prescribing MNS 5639: 2013
13. Bio-products for the Fed in general MNS 5260: 2011
14. Mongolian Government Resolutions
15. Minister of health
16. Other legal acts / Standard Insurance /