Required documents of registration

Company Name: **Mongol Emimpex Concern LLC**

Product name**:**

Strength of ingredients, Dosage form:

Name of manufacturer, Country:

Name of licence holder's:

Date of registration in country:

Registered status		**Registered status ATC**	**Guidelines Standards**		**Registered status**	**Manufactured in a national factory**		**Composition**	
	Expedited						Yes		Single ingredient
	Normal			Guidelines Standards			No		More than 4 ingredients

№	**Required documents**	**Completed**	**Explanation**	**Repeat submit**
1.	***Official letter***		***Original /validated by stamp of manufacturer/***	***Reciever name: Medicine and Medical device regulatory agency in Mongolia***
2.	***The final conclusion of Quality and Safety Guarantees for the Use of product***		***Original /validated by stamp of manufacturer/***	***Reciever name: Medicine and Medical device regulatory agency in Mongolia***
3.	***A post-market surveillance plan***	From MEIC		
4.	***An application submitted by an authorized individual from the manufacturer for the registration of medicine.***		***Original /validated by stamp of manufacturer/***	
5.	***Copy of the contract of the Pharmaceutical company or representative office of Mongolia with the manufacturer.***		***Notarized***	
6.	***Verification fromrelevant drugregulatory authority certifying GMP requirements of manufacturer.***		***Notarized***	
7.	***An Original pharmaceutical product certificate (CoPP), /A study of the required dosage forms in accordance with the recommendations of the World Health Organization/***		***Original or Notarized***	

8.	***Registration certificate of country of origin***		***Original or Notarized***	
9.	***A copy of each certificate of registration in 5 countries validated by stamp of manufacturer or FDA, EMA JMA certificate .***		***validated by stamp of manufacturer***	
10.	***Profile of the manufacturer hard and soft copy with manufacturer process of product in CD***		***Soft file***	
11.	***Certificate of analysis of finished products /Original form/***		***Original***	
12.	***Method of analysis, sample of medicine for registration, referents for analysis***		***Soft file***	
13.	***Source and Certificate of active and inactive ingredient(s)***		***Original***	
14.	***The analysis of sustainable quality that has been approved for the product storage period***		***Soft file***	
15.	***summary lot protocol of manufacturer process, Manufacturer's operating instructions and Scheme;*** **(summary lot protocol)** вакцины хувьд нийт цувралын тэмдэглэл ***For vaccine summary protocol of manufacturer*** **(summary lot protocol)**		***Soft file***	
16.	***For generic name bioequivalent analysis of quality /A study of the required dosage forms in accordance with the recommendations of the World Health Organization/***		***Soft file***	
17.	***For vaccines, the results of internationally recognized laboratory tests and a series of certificates issued by a competent authority or a certified copy of equivalent certificates issued by the competent authority of the State concerned***	=		
18.	***Report of preclinical studies (on side effects, mutation, oncology and toxicity through animal testing), clinical trials efficacy and safety (3 step study, side effects) /not related to generic name medicines/***		***Soft file***	
19.	***Certificate of analysis confirming the safer and more active effects of preparation with a mixed composition compared to a preparation with a single composition***		***Soft file***	

20.	***Instruction of medicine for health professionals and package insert leafletfor patients with translation into Mongolian language.***		***validated by stamp of manufacturer***	
21.	***Primary and secondary packaging design such as label, pamphlet, carton (specify the location of the Medication Conditions and Registration Number); / The manufacturer must be certified***		***validated by stamp of manufacturer***	
22.	***Certificate of analysis from Laboratory of Mongolia (not for fast track)***			
23.	***Comparative study of product prices of domestic wholesale prices with retail prices***	From MEIC		
24.	**Market Demand and Access to Medicines Produced by Registered Persons in National Pharmaceuticals**	From MEIC		
25.	***If necessary, analytical and shipping receipts for external accredited laboratories***	=		