Appendix 3
to the Rules of state registration,
re-registration of medications, including medical products and rules of amendments in registration dossier of medication agent, including medical products in the Republic of Kazakhstan.

List of registration dossier documents, presented during state registration, re-registration of medication agents in the Republic of Kazakhstan.

МИБП – медицинские изделия биологического происхождения – MPBO - medical products of biological origin

No	Name of documents	Medication agent							
					MPBO				
		Medication preparations	Medication preparations in bulk	Medication substances	Used on living organism	Used out of living organism	raw material of herbal medicine	Homeopathic Preparations	Para-pharmaceuticals
1	2	3	4	5	6	7	8	9	10
	Part I General Documentation								
I A.	**Administrative data**								
1.	Application in accordance with approved form (in paper and in electronic format)	+	+	+	+	+	+	+	+
2.	Inventory –act about receiving and transfer of registration dossier documentation	+	+	+	+	+	+	+	+
3.	**Certificate for pharmaceutical (medical product) according to recommendations of WHO. In case of absence following represented:	+	+	+	+	+	+	+	+

	1) registration certificate in manufacturing country or copy of registration certificate in manufacturing country (verified by stamp of applicant); 2) GMP certificate; 3) Free Sale Certificate, permitting free sale (export)	+	+	+	+	+	+	+	+
6.	Data about registration of medication in other countries with indication of number and date of registration certificate (copy of registration certificates)	+	+	+	+	+	+	+	+
7.	Certificate of analysis of active substance	+	+	+	+	+	+	+	+
8.	Certificate of analysis of Finished Product (on three batches)	+	+	+	+	+	+	+	+
9.	Certificate of prionic safety for substances with animal origin (Lactosa, Magnesium Stearat)	+	+	+	+	+	+	+	+
10	Copy of registration certificate in the Republic of Kazakhstan during re-registration	+	+	+	+	+	+	+	+

11	Information about refusal of registration, withdrawal from market by competent authority or by applicant, about termination of registration certificate or suspension of it by competent organ (with indication of reason)	+	+	+	+	+	+	+	+
I.B.	**Brief characteristics (description) of medication preparation (SPC) in English.	+	+	-	+	+	+	+	+
1.	** Translation of the brief characteristics of medication preparation (SPC) into Russian.	+	+	-	+	+	+	+	+

2.	**Instructions on clinical use for specialists in English.	+	-	-	+	+	+	+	+
3.	Draft of instruction on clinical use for specialists in Russian (in paper and in electronic formats)	+	-	-	+	+	+	+	+
4.	**Instructions for user (loose leaf information for user) in English	+	-	-	+	+	+	+	+
5.	Draft of instruction for users (patients) (loose leaf information for user) in official language (in paper and in electronic formats)	+	-	-	+	+	+	+	+
6.	Draft of instruction for users (patients) (loose leaf information for user) in Russian language (in paper and in electronic formats)	+	-	-	+	+	+	+	+
7.	Color model of packages and labels in paper and electronic formats (if above indicated are not available, a sample in final primary package without final marking.	+	-	-	+	+	+	+	+
	Sample in final primary and secondary packages must be presented additionally, as soon as it becomes available)								
8.	Packaging materials specification	+	+	+	+	+	+	+	+
9.	Copy of title of protection	+	+	+	+	+	+	+	+
I.C.	**Conclusions of experts relating to chemical, pharmaceutical, microbiological, pharmacological, toxicological and clinical data (summary of basic properties of a preparation) for MPBO – diagnostic effectiveness (sensitivity, specificity)	+	+	-	+	+	-	-	+
	Part II. Chemical, Pharmaceutical and Biological documentation								
II.									
IIA.	Qualitative and quantitative	+	+	-	+	+	+	+	+

	composition of medication preparation (active substance, adjuvant substance)								
IIB.	1. Information about manufacturer: 1) manufacturing formula 2) description of production technology 3) control during manufacturing process 4) validation of manufacturing processes 2. Draft of normative document and explanatory note to it	+	+	+	+	+	-	+	+
IIC.	Original substances control techniques with enclosure certificates of analysis	+	+	+	+	-	+	+	+
IID.	Intermediate products analysis techniques	+	+	+	+	+	-	-	+
IIE.	Finished Product Specification and quality control methods with validation (in Russian and in English)	+	+	+	+	+	+	+	+
IIF.	Stability data of not less then on three batches in natural conditions in long time storage	+	+	+	+	+	+	+	+
IIG.	Bioavailability data (for generics)	+	+	-	+	+	-	-	+
IIH.	Data about probable danger for environment of preparation, containing genetically modified organisms.	+	+	-	+	+	-	-	+
IIQ.	Other additional information, which confirms effectiveness, safety and quality	+	+	+	+	+	+	+	+
	Part III. Pharmacological and Toxicological documentation								
III.	Content (composition)	+	+	-	+	+	+	+	+

IIIA.	Toxicity in single dose administration and in repeated dose administration	+	+	-	+	-	+ (for new)	+ (for new)	+
IIIB.	Toxicity in single dose administration and in repeated dose administration	+	+	-	+	-	+ (for new)	-	+
IIIC.	Data on embryotoxicity and teratogenicity	+	+	-	+	-	+ (for new)	-	+
IIID.	Data on mutagenicity	+	+	-	+	-	(for new)	-	+
IIIE.	Data on carcinogenicity	+	+	-	+	-	+ (for new)	-	+
IIIF.	Pharmacodynamics	+	+	-	+	-	(for new)	-	+
IIIG.	Pharmacokinetics	+	+	-	+	+	+ (for new)	-	+
IIIH.	Data on local irritation action	+	+	-	+	-	(for new)	-	+
IIIQ.	Other additional information, which confirming effectiveness, safety and quality	+	+	-	+	+	+	-	+
	Part IV. Clinical documentation								
IV.	Content	+		-	+	+	+	+	+
IVA.	Data n clinical pharmacology (Pharmacodynamics, Pharmacokinetics)	+		-	+	+	+ (for new)	-	+
IVB.	Clinical trials results, scientific publications, reports	+		-	+	+	+ (for new)	+	+
IVQ.	Other additional information, which confirming effectiveness, safety and quality	+		-	+	+	+	+	+
1.	Samples of medicine (minimum 200 tablets or capsules)								
2.	Standards for determination of foreign impurities								
3.	Samples of active substances for performing thrice-repeated analysis								