*Un official translation from Mongolian*

**Health minister’s order**

September 9, 2019 No A/295 Ulaanbaatar city

Approval of product registration procedures

of medicines, raw materials and biological active products

Based on Sections 24.1.8 and 24.2 of the Article No. 24, Law on Government of Mongolia and Section 22.6, Article 22 of the Law on Drugs and Medical Devices, I hereby ORDER:

1. To approve “Procedure on registration of medicines, raw materials, diagnostics, biological active products” by Appendix 1, “Procedure on fees, cost reference expenditure, and spending procedure for registration of medicines, raw materials, diagnostics, biological active products” by Appendix 2, “Application form for registration of medicines, raw materials, diagnostics” by Appendix 3, “Sample of registration certificate for medicines, biological active products and diagnostics” by Appendix 4.
2. To assing the Centre for Health Development (D.Gantsetseg) to organize the implementation of this procedure, to work towards providing continuous coordinative activities in relation to registration, quality and safety of medicines, biological active products, to include and obtain approval on administrative costs and fees in the annual budget of the Centre for Health Development as “Payments and fees for work performed by others”’ to support financially activities in regards with continuously.
3. To assign the State Secretary (B.Byambadorj) to oversee the implementation of the order and control the reporting and appropriate exhaustion of revenue obtained from the fees.
4. To discard the Health Minister’s Order No. 13, 2015 in connection of endorsement of this order,

Minister D. Sarangerel

Appendix 1,

Health Minister’s Order A/ 295

September 9, 2019

**Product registration procedures of medicines,**

**raw materials and biological active products**

One. General provisions

* 1. In accordance with the “State Policy on Health”, “Law on Medicines and Medical Devices”, the registration of Mongolian medicines (hereafter referred to as ‘registration’) shall be the regulation to register medicines, bio preparations, vaccines (hereafter referred to as “medicine”) of high efficiency, safe, assured quality and used for provision of health care services for the population, to make amendments in the registration, extend the registration period, remove/ revoke from the registry, to conduct surveillance and assessments of quality and safety of registered medicines.

1.2. Decisions on medicine registration, extention and withdrawal shall be discussed and decided by the Human Drug Council (hereinafter referred to as "HDC").

1.3. Medicines label and package form shall be considered as registered in the Statel Registry, unless it is specified in the Article 22.7 of Law on Medicines and Medical Devices and medicines with amendments, revisions disapproved by the HDC and medicines with different labelling, packaging shall be considered as unregistered.

1.4. The registrant (hereafter referred to as ‘registrant’) applying for registration shall be a licensed Mongolian entity to conduct professional activities, as well as a legally authorized representative of international supplier, manufacturer and local manufacturer with quality management system for medicines, raw materials, diagnostics, biologically active products

1.5. The list of medicines to be registered in accordance with the policy shall be approved by the HDC, Ministry of Health (hereafter referred to as ‘MOH’) based on the recommendations and offer provided by the Drug Therapeutic Committees of General Hospital, specialized hospitals, specialized centers, as well as decisions made by the professional sub-committees within first half of the year.

1.6. To avoid the risk of distrupted or faulty health care service due to medicines shortage without appropriate substitutive alternatives, those medicines of high efficiency, quality, safe and very essential for provision of hospital care, included in the guidelines and standards of treatment and diagnostics shall be registered based on the policy.

1.7. Activities in regards with fast-track registration of medicines (hereafter referred to as ‘fast-track registration’) from countries with stringent authority shall be discussed and decided by the HDC.

1.8. Pharmaceutical products of same ingredient, dose, and dosage form shall not be registered by more than 10 manufacturers (This provision does not apply to fast-track registrations).

1.9. Pharmaceutical product of same manufacturer, similar ingredient, equal dose and dosage form shall not be registered under 2 trade names.

1.10. For registration of diagnostics shall complete documents identified in 4.28 and 4.29 of this Procedure.

1.11. The registration, alteration, extension, and delisting of diagnostics shall be discussed and decided by the Sub-committee on Biopreparations and the Diagnostics (hereinafter referred to as the "SCBD").

1.12. Label and package form of diagnostics shall be considered as registered in the State Registry, and diagnostics with amendments, revisions that not approved by the SCBD and diagnostics with different labelling, packaging shall be considered as unregistered.

1.13. Biologically active product (BAP) is used to support normal functioning of human body, to replace required minerals and calories, it shall not be used with a purpose of treatment or diagnostics.

1.14. The registration, amendment, extension, and delisting of the BAP will be resolved by the Sub-Committee for Biologically active products (hereafter referred to as ‘SCBAP’).

1.15. Label and package form of BAP shall be considered as registered in the State Registry, and BAP with amendments, revisions that not approved by the SCBAP and diagnostics with different labelling, packaging shall be considered as unregistered.

1.16. In addition to the Provisions 22.7 specified in the Law on Medicines and Medical Devices, the product listed in the food category of manufacturer’s country shall be not registered in BAP registry .

Two. General requirements for registration

2.1. HDC shall make decisions in regards with registration of pharmaceutical products based on the following criteria:

2.1.1. Whether the manufacturer meets the requirements of "Good Manufacturing Practice" (GMP);

2.1.2. Results of analytical results performed by an independent accredited laboratory;

2.1.3. Conclusion of expert in registration;

2.1.4. Registration status of a medicine in Mongolia, availability, access, needs and cost;

2.1.5. Evidence of inferiority in relation to quality and safety for combination medicines as opposed to medicines with single composition;

2.1.6. Proof of bioequivalency for generic drugs;

2.1.7. Decisions from any country in regards with prohibition to use the medicine or ingredient, restrictions related to age or dose;

2.1.8. Whether the pharmaceutical product is included in Alert list of the World Health Organization (hereinafter referred to as "WHO");

2.1.9. If necessary, conclusions and proposals from specialized health organizations and professional sub-committees of MOH;

2.2. The registrant authority of a pharmaceutical product listed in the State Registry shall submit the report of the drug safety information within the following timeframe:

2.2.1. Every half year after the registration within 3 years;

2.2.2. Every year for the subsequent 2 years;

2.2.3. Every time for extension of registration;

Three. Requirements for the pharmaceutical product

3. Pharmaceutical products to be registered in the State registry shall meet the following requirements: These include:

3.1.1. The pharmaceutical manufacturer meets the requirements of "Good Manufacturing Practice" (GMP) and manufacturer of diagnostics shall comply with ISO 13485 standard;

3.1.2 A manufacturer or license holder (hereinafter referred to as "the manufacturer") has a certificate of pharmaceutical products approved by the authorized body of the country;

3.1.3 The drug activity, composition, dosage and stability are determined accurately by scientific experiment;

3.1.4 Treatment and safety profiles of medicine are confirmed by pre-clinical and clinical studies;

3.1.5 The effectiveness, quality and safety of registering medicines are superior to similar state-registered pharmaceuticals, which are certified by experts' conclusions and surveillance studies;

3.1.6 Medication indication, contra-indication, side effects, drug interactions, and dose limits are proven by clinical trials;

3.1.7. The quality of the vaccine is certified by internationally recognized laboratory test results, lot release certificate issued by a competent authority of the country or equivalent document assigned by the relevant competent authority in the country;

3.1.8. Narcotics and psychotropic substances to be included in the State Regsitry shall be included in the list approved by International Conventions in 1961, 1971 as well as the pharmaceutical product shall be included in the Mongolian List of narcotics and psychotropic substances to be used for medical purposes;

3.1.9. Proof of bioequivalency for generic drugs

3.2. Registration of pharmaceutical products with quality assurance certification, provided by the international suppliers with quality management system in place with a purpose to provide hospital care under the health care insurance against service risks shall be discussed and resolved by the HDC.

3.3. Registration documents and sample shall meet the following requirements. These include:

3.3.1. Registration documents shall be in either Mongolian, English or Russian.

3.3.2. If the document is in other languages, a translation of any of the above 3 languages shall be required.

3.3.3. Secondary packaging of the pharmaceutical product shall include appropriate information, coding and labelling in accordance with requirements specified in Provision 18.5, Article 18 of the Law on Medicines and Medical Devices, labelling shall be either in Mongolian, English, and Russian or may be combined with an additional one language.

3.3.4. Only the labelling, packaging samples submitted for registration may be in form of adhesive sticker.

3.3.5. The medicines’ instructions to use shall contain the information specified in Provision 18.5, Article 18 of the Law on Medicines and Medical Devices.

3.4. Pharmaceutical product for importation shall be registered at least for three years in the manufacturing country, registered in at least 5 different countries, or registered in a country with stringent authorities, diagnostics shall be registered in the country of origin in the ‘diagnostics category’.

3.5. Vaccines, tuberculisis medicines included in category of WHO prequalification, shall be listed in ‘WHO List of prequalified medicinal products’

3.6. For pediatric pharmaceutical products, the dossier shall be approved by the Professional Sub-Committee and other relevant committees and the pediatric dose, dosage form and packaging shall be verified, in addition exclusion of conta-indicated raw materials, excipients shall be confirmed.

3.7. Registration of pharmaceutical products manufactured and approved in countries with Stringent Regulatory Authorities shall follow the ‘fast-track’ registration within 3 months. (This indication shall not be applied for biopreparations, vaccines, diagnostics and biologically active products)

3.8. Pharmaceutical products for fast-track registration shall be included in the WHO or National Essential Drug List, strandard treatment guidelines and recommendations and shall be used in hospital settings or prescription only medicines.

3.9. Stringent regulatory authorities are the countries in the WHO approved list (<https://www.ich.org/about/members-observers.html>), including the United States Food and Drug Administration, European Medicines Agency, European Commission, Ministry of Health, Labour and Welfare of Japan, Swiss Agency for Therapeutic Products (Swissmedic), Health Canada, ANVISA-Brazil National Health Surveillance Agency, The Ministry of Food and Drug Safety of South Korea, [Health Sciences Authority of Singapore, China National Medical Product Administration, Taiwan Food and Drug Administration](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=2ahUKEwj69MHgjZDhAhXJzmEKHUu1CEcQFjAAegQIBhAD&url=https%3A%2F%2Fwww.hsa.gov.sg%2F&usg=AOvVaw36w_LksV_VSOQZLzJa4Qy2), The Therapeutic Goods Administration, Australia.

3.10. BAP for registration shall comply with following requirements:

3.10.1. The manufacturer shall operate in compliance with the "Good Manufacturing Practice" (GMP) or "Quality Management System", "Food Security System", "Food Production Hazard Analysis and Critical Control Points" (ISO 9001, ISO 22000, ISO 17025: 2018, HACCP ), shall meet equivalent requirements of the country;

3.10.2. Product shall be listed in the BAP category in the country of origin;

3.10.3. Imported BAP shall be used in the country of origin;

3.10.4. Product labelling and packaging are listed in either Mongolian, Russian or English.

3.10.5. Instructions for use shall be in Mongolian

Four. Registration procedure

4.1. Procedures for registration of pharmaceutical product, raw material, diagnostic, BAP shall be organized by a competent authority (hereafter referred to as ‘Secretariat’). These shall include:

4.1.1. To check and receive the registration documents that are verified and supplied by the manufacturer;

4.1.2. To send samples for quality control test to an independent, accredited laboratory (not applicable for fast-track registration and diagnostics);

4.1.3. To obtain a report of the expert's review;

4.1.4. If necessary, to obtain conclusions and proposals from specialized agencies and professional sub-committees of the Ministry of Health;

4.1.5. To discuss registration issues at the relevant council meeting;

4.1.6. In case of disputed cases, to have an expert team and working group nominated by HDC to make conclusions;

4.1.7. To receive depository units of registered documents in paper and electronic form;

4.1.8. Research projects on assessing the demand, availability and accessibility of pharmaceutical products to be registered by policy shall be conducted in collaboration with health organizations, non-governmental organizations, registrant entities and researcher teams;

4.2. Registration process of pharmaceutical products, raw materials, diagnostics and BAP shall be completed via Licemed- Registration System.

4.3. The Secretariat shall provide access code to the system for registrant entities of pharmaceutical products, raw materials, diagnostics and BAPs.

4.4. The registrant who is authorized to acces the system shall submit the following information according to the register of medicines electronically, and submit hardcopied of the documents specified in the Provisions 4.24, 4.25, 4.26, 4.27, 4.28, 4.29, 4.30 of this Regulation.

4.4.1. Trade name of pharmaceutical product;

4.4.2. International non-priopriety names;

4.4.3. Ingredients (active and excipients);

4.4.4. Dose and dosage form;

4.4.5. Anatomical Therapeutic Classfication, barcode;

4.4.6. Wholesaling price, (warehouse prices for local manufacturers);

4.4.8. Manufacturer’ and country name;

4.4.9. License holder;

4.4.10. Description of pharmaceutical product;

4.5. The applicant of diagnostics with access to the registration system shall submit the following information on the registration electronically and documents specified in 4.31 and 4.32 of this Regulation shall be submitted on paper.

4.5.1. Name of the diagnostic;

4.5.2. Number of the catalogue;

4.5.3. Type of the test;

4.5.4. Type of the diagnostic test;

4.5.5. Packaging information

4.5.6. Wholesaling price (warehouse price for local manufacturers);

4.5.7. Name of the manufacturer and country;

4.5.8. Indication for use;

4.5.9. Specificity and sensitivity;

4.6. The applicant authorized and has an access to the BAP registration system shall submit the following information electronically and the documents specified in 4.33 and 4.34 of this Regulation shall be submitted on paper.

4.6.1. The name of the BAP;

4.6.2. Ingredients (active and excipients);

4.6.3. Dose and dosage form;

4.6.4. Wholesaling prices (warehouse prices for local manufacturers);

4.6.5. Manufacturer and country name;

4.6.6. The names of countries where BAP is consumed;

4.7. The Registrant shall be responsible for the accuracy and authenticity of the registration documents submitted by the manufacturer.

4.8. The Registrant shall be responsible to submit the reagents, solvents and materials required for specific product analysis to the accredited laboratory.

4.9. The manufacturer and /or the registrant of pharmaceutical product, raw materials, diagnostics and biologically active products shall be fully responsible for the expenses incurred relevant to test analysis performed by external accredited laboratory at the time of application for registration and during post-marketing surveillance.

4.10. The decision to register the drug shall include international non-proprietory names and trade names, dose and dosage form, the quantity of the package, conditions to dispense, the validity of the registration, the manufacturer's name, the country of manufacturer and the license holder.

4.11. The decision to register the diagnostic shall include the name of the diagnostic product, catalogue number, type of test, the quantity/size of the package, the manufacturer's name, the country of manufacturer.

4.12. The decision to register a BAP shall include the name of the product, the manufacturer's name, the dosage form and quantity/ size of the package, the country of manufacturer.

4.13. Pharmaceuticals, medicinal raw materials, diagnostics, BAPs shall be registered for 5 years and a license shall be issued.

4.14. The applicant shall complete an application form for pharmaceutical products, raw materials, diagnostics and BAPs specified in Appendix 3 and shall submit both hard-copy and electronic copies of relevant documents that are certified by an authorized representative of the manufacturer, quality and safety assurance information, periodic safety update reports to the Secretariat.

4.15. In accordance with the ‘Regulation on usage and issue a reference for archived documents’, the applicant shall submit hard copy and electronic copy of depository registration documents, as well as the applicant shall submit electronic copies primary and secondary package of the product within 5 days after decision for a meeting has been announced to the Secretariat.

4.16. Prior to registration, instructions for use of a pharmaceutical product shall be discussed and approved by the Subcommittee on Pharmacology, and an application for registration shall be submitted. The registered pharmaceutical product shall be marketed with approved information regarding instruction of use.

4.17. Prior registration, instructions for use of a BAP shall be reviewed and approved by an expert and application for registration shall be submitted. The registered BAP shall be marketed with approved information regarding instruction of use.

4.18. If deemed necessary, the Secretariat is entitled to request authorized entities/ competent authority for reference and clarification regarding the documents submitted by the manufacturer and all incurring costs shall be bourne by the applicant.

4.19. The Secretariat shall consider the application submitted by a drug manufacturer as valid and the documents provided via facsimile and email shall be deemed as ineligible.

4.20. If a clinical observation was deemed as necessary by the HDC, the clinic/ hospital, number of subjects shall be determined in detail. Results of the observation shall be introduced and discussed at the HDC and a decision for registration shall be reached.

4.21. Registration of vaccines, biopreparations shall be introduced at Sub-committee on Biopreparations and the Diagnostics, consequently discussed at the HDC.

4.22. If a non-compliant result from laboratory tests as indicated in the Provision 4.1.2 of this Procedure was obtained in the course of registration of pharmaceuticals, medicinal raw materials and BAPs, the registration process for that product shall be discontinued, registered in the registration database and relevant actions shall be discussed at the HDC meeting and undertaken.

4.23. The registration shall be completed in the following steps and timeframes

|  |  |  |
| --- | --- | --- |
| **Activity** | **Timeline** | **Responsibility** |
| Initial assessment of registration documents | Within 5 working days from receipt of registration documents | Secretariat |
| Registration fee, invoice, payment | Within 5 working days from initial assessment of registration documents | Secretariat ,applicant |
| Submission of samples to laboratory tests (not relevant to fast track registration and diagnostics) | Within 1 month from receipt of registration documents | Secretariat ,applicant |
| Issuance of expert’s review | After laboratory test completed (within 1 month, each) | Secretariat, Experts |
| Discuss at HDC, SCBD, SCBAP | Within 1 month from experts review | Secretariat |
| Submission of decision | Within 5 working days from final meeting protocol/ decision | Secretariat, applicant |
| If rejected or postponed by the meeting, to present and discuss registration documents again by the meeting | Within 2 months | Secretariat, applicant |
| Issuance of State registration license | Within 5 working days from issuance of final decision made by HDC, SCBD, SCBAP | Secretariat |
| Information entering in to the “Licemed” system | Within 5 working days from issuance of license | Secretariat |

4.24. Regular and fast registration of imported medicines shall include the following documents:

4.24.1. Official request from the registrant company, conclusions relevant to quality, safety and quality assurance during product use, working plan on periodic safety update reports.

4.24.2. Original copy of application to register their product in Mongolia that is certified by the authorized representative of the manufacturer’s name signature and seal;

4.24.3. Original copy of contract made between the manufacturer and a wholesaling company in Mongolia or distributor to register their product in Mongolia

4.24.4. Certificate of Good Manufacturing Practice (GMP) (certified copies of manufacturer);

4.24.5 Original certificate of pharmaceutical product or verified copy of certificate by an authorized authority (shall include description of a pharmaceutical product in accordance with WHO recommendation);

4.24.6. A copy of the registration certificate verifying that product is registered in the manufactured country (the registration shall be valid, the copy of the valid certificate shall be verified by the seal of the manufacturer or license holder);

4.24.7. Registered in a country with stringent authority or registered in 5 different countries (product shall be registered in a different country, registration shall be valid, copies of valid certificate shall be verified by manufacturer’s seal and submitted);

4.24.8. Introduction of the manufacturer (the production process shall be presented in a media form on CD-ROM, and 1-2 pages containing information regarding the production process that is translated into Mongolian shall be submitted);

4.24.9. The original test results for the final product of the manufacturer and the method of analysis;

4.24.10. The analytical test results of manufacturer active ingredient and excipients;

4.24.11. Stability test results proving the storage period and conditions;

4.24.12. Production operating procedure, production protocol and scheme (including intermediate product control) for whole batch, summary lot protocol for vaccines

4.24.13. For generic medicines, proof bioequivalency test results (required for WHO recommended dosage formulations);

4.24.14. For the vaccination, the tests results of internationally accredited laboratory and a lot release certificates issued by a competent authority or a certified copy of equivalent certificates issued by the competent authority of that country;

4.24.15. Toxicity of pharmaceutical product (not necessary for generic medicines), activity and safety study results;

4.24.16. For combination drugs, proof of quality, activity and safety inferiority over single drug;

4.24.17. Instruction for use, accompanied by an approved Mongolian translation by the Subcommittee for Pharmacology;

4.24.18. Colored pamphlet and samples of the primary and secondary packaging (spaces designated for the condition for the pharmaceutical product and registration number shall be indicated);

4.24.19. Test results performed by an accredited and contracted laboratory (it shall not apply for fast track registration).

4.24.20. Comparative study between the costs of registration product, wholesale and retail costs of locally manufactured products;

4.24.21. Survey on market demand and access of locally manufactured products by registrants;

4.24.22. Where necessary, evidence of payment for test analysis performed by external accredited laboratory and shipment fees for transportation;

4.25. The following documents will be submitted to the registration of drugs to register under the policy. These include:

4.25.1. Official application by the registrant organization, study results and conclusions regarding quality, safety assurance of the product during its use;

4.25.2. A post-market surveillance plan, periodic safety update reports;

4.25.3. Original application for registration of the product in Mongolia certified by the authorized official of the manufacturer; signature and seal;

4.25.4. Certificate of Good Manufacturing Practice (GMP) (certified copies of manufacturer);

4.25.5. Original or verified certificate of pharmaceutical product by an authorized organization or free trade certificate;

4.25.6. A copy of the registration certificate registered in the country of origin (the registration shall be valid, the copy of not-expired certificate is issued by the manufacturer or verified by the seal of the license holder);

4.25.7. Introduction to the manufacturing company (information regarding the production process is provided on the CD and information shall be provided on 1-2 pages in Mongolian language);

4.25.8. Original tests result of final product performed by the manufacturer and a method of analysis

4.25.9. The results of analytical tests on the active ingredient and excipient;

4.25.10. Stability tests results conforming the storage conditions;

4.25.11. For generic drugs, proof bioequivalency test results (required for WHO recommended dosage formulations);

4.25.12. Drug toxicity information (not relevant for generic drugs)

4.25.13. Intructions for use, accompanied by a Mongolian copy approved by the Subcommittee for Pharmacology

4.25.14. Colored pamphlet and samples of the primary and secondary packaging (spaces designated for the condition for the pharmaceutical product and registration number shall be indicated);

4.25.15. Test results performed by an accredited and contracted laboratory (it shall not apply for fast track registration).

4.25.16. Where necessary, evidence of payment for test analysis performed by external accredited laboratory and shipment fees for transportation

4.26. The following documents shall be submitted for the registration of pharmaceutical products, supplied by the international suppliers with quality management system in place with a purpose to provide hospital care under the health care insurance:

4.26.1. Offical application by the registrant organization, study results and conclusions on the quality and safety assurance of medicine during its use;

4.26.2. A post-market surveillance plan, periodic safety update reports;

4.26.3. Original application of registration for the product in Mongolia, verified by the International Supplier Organization name, signature and seal;

4.26.4. Original copy of contract made between the manufacturer and a wholesaling company in Mongolia or distributor to register their product in Mongolia;

4.26.5. Description of pharmaceutical product;

4.26.6. Copies of the test results of the final product performed by the manufacturer;

4.26.7. Instruction for use in foreign language, accompanied by a Mongolian translation approved by the Subcommittee for Pharmacology;

4.26.8. Colored pamphlet and samples of the primary and secondary packaging (spaces designated for the condition for the pharmaceutical product and registration number shall be indicated);

4.26.9. Comparative study between the costs of registred product, with wholesale and retail costs of locally manufactured products;

4.26.10. An official statement in regards with overtaking the full responsibility of quality and safety by the international supplier or distributor in Mongoia;

4.26.11. Where necessary, evidence of payment for test analysis performed by external accredited laboratory and shipment fees for transportation;

4.27. The following documents shall be submitted for registration of locally manufactured products:

4.27.1. Official application for registration, study results and conclusions of the quality safety of the drug during its use, plan for post-market surveillance/ periodic safety update reports;

4.27.2. The original application for the registration of a product certified by the authorized official person of the manufacturer, signature and seal;

4.27.3. Copies of intellectual property certificates verified by the competent authority (if any);

4.27.4. Approved copies of verified authorizations when using genetic resources;

4.27.5. Introduction of the pharmaceutical organization;

4.27.6. Special permission for drug manufacturing;

4.27.7. Certificate of Good Manufacturing Practice (GMP) (verified copies by the manufacturer);

4.27.8. Certified copy of a valid, not expired pharmacopeaiel monograph that is approved by the Committee for Pharmacopeaie (if the drug was not included in National Pharmacopeaie of Mongolia);

4.27.9. Test results performed by an accredited and contracted laboratory (it shall not apply for fast track registration).;

4.27.10. Results of analysis of active ingredients and excipients (external and internal);

4.27.11. Drug stability test results;

4.27.12. Results of the pharmacological activity, potency of medicines by preclinical and clinical studies (excludes generic medicines);

4.27.13. Instructions for use approved by the Subcommittee for Pharmacology;

4.27.14. Colored pamphlet and samples of the primary and secondary packaging (spaces designated for the condition for the pharmaceutical product and registration number shall be indicated);

4.27.15. Comparative study between wholesale and retail costs of registration product;

4.27.16. Where necessary, evidence of payment for test analysis performed by external accredited laboratory and shipment fees for transportation;

4.28. The following documents shall be submitted for registration of imported traditional and homeopathic medicines. These include:

4.28.1. Official application for registration, study results and conclusions of the quality safety of the drug during its use, plan for post-market surveillance/ periodic safety update reports;

4.28.2. The original application for the registration of a product certified by the authorized official of the manufacturer, signature and seal;

4.28.3. Certificate of Good Manufacturing Practice (GMP) (verified copies by the manufacturer);

4.28.4. Original certificate of pharmaceutical product or verified copy of certificate by an authorized authority (shall be in accordance with WHO recommendation);

4.28.5. Information about the manufacturing company (both hard and soft copies shall be submitted);

4.28.6. Product description, indication for use, information regarding drug interactions and other dosage forms, in addition other adverse effects of the product;

4.28.7. Results (original) of analysis of the final product performed by the manufacturer and method of analysis;

4.28.8. Origin of raw materials and tests results;

4.28.9. Stability study of the product;

4.28.10. Results of pre-clinical studies (acute and chronic toxicity, adverse effects, teratogenicity, carcinogenicity and mutagenicity tested on animals), clinical efficacy and safety (results and side effects identified in Phase I and II);

4.28.11. Information regarding the source of the prescription to prove the authenticity of traditional prescriptions (not relevant to homeopathic products);

4.28.12. Instruction for use, accompanied by an approved Mongolian translation by the Subcommittee for Pharmacology;

4.28.13. Colored pamphlet and samples of the primary and secondary packaging (spaces designated for the condition for the product and registration number shall be indicated);

4.28.14. Test results performed by an accredited and contracted laboratory;

4.28.15. Comparative study between wholesale and retail costs of registration product;

4.28.16. Where necessary, evidence of payment for test analysis performed by external accredited laboratory and shipment fees for transportation;

4.29. The following documents shall be submitted for registration of locally manufactured traditional medicines:

4.29.1. Official application for registration, study results and conclusions of the quality safety of the drug during its use, plan for post-market surveillance/ periodic safety update reports;

4.29.2. The original application for the registration of a product certified by the authorized official of the manufacturer, signature and seal

4.29.3. Approved copies of verified authorizations if genetic resources were utilized;

4.29.4. Introduction of the drug manufacturer (both hard and soft copies);

4.29.5. Copy of certificate of special permission for drug manufacturing;

4.29.6. Certificate of Good Manufacturing Practice (GMP) (verified copies by the manufacturer);

4.29.7. Test results of the final product performed by the manuafacturer;

4.29.8. Origin of raw materials contained in the product;

4.29.9. Test results performed by an accredited and contracted laboratory;

4.29.10. For newly formulated products, results of pre-clinical studies (acute and chronic toxicity, adverse effects, teratogenicity, carcinogenicity and mutagenicity tested on animals), clinical efficacy and safety (results and side effects identified in Phase I and II);

4.29.11. Information regarding the source of the prescription to prove the authenticity of traditional prescriptions;

4.29.12. Instructions for use approved by the Subcommittee for Pharmacology;

4.29.13. Colored pamphlet and samples of the primary and secondary packaging (spaces designated for the condition for the traditional medicine and registration number shall be indicated);

4.29.14. Comparative study between wholesale and retail costs of registration product;

4.29.15. Where necessary, evidence of payment for test analysis performed by external accredited laboratory and shipment fees for transportation;

4.30. The following documents shall be submitted for registration of raw materials:

4.30.1. Official application for registration, study results and conclusions of the quality safety of the raw material during its use, plan for post-market surveillance/ periodic safety update reports;

4.30.2. The original application for the registration of a product certified by the authorized official of the manufacturer, signature and seal

4.30.3. Introduction of the manufacturer (both hard and soft copies);

4.30.4. Certificate of Good Manufacturing Practice (GMP) (verified copies by the manufacturer);

4.30.5. Description of origin for raw materials derived from animals, plants, mineral and other natural sources;

4.30.6. Original copy of test results of laboratory for raw materials;

4.30.7. Test results performed by an accredited and contracted laboratory;

4.30.8. Colored foldable pamphlet of the primary and secondary packaging

4.30.9. Where necessary, evidence of payment for test analysis performed by external accredited laboratory and shipment fees for transportation;

4.31. The following documents shall be submitted for registration of imported diagnostics:

4.31.1. Official application for registration, study results and conclusions of the quality safety of the diagnostic during its use, plan for post-market surveillance/ periodic safety update reports;

4.31.2. Original copy of the application for registration of the diagnostic in Mongolia certified by the authorized official of the factory; signature and seal;

4.31.3. Introduction of the manufacturer (both hard and soft copies);

4.31.4. Manufacturer's Quality Management System Certificate (ISO13485) (shall be approved by the manufacturer);

4.31.5. Documents verifying the product classified as "diagnostic" in the country of origin;

4.31.6. General description of the diagnostics and specific characteristics;

4.31.7. Test results of the diagnostic and performance test of samples;

4.31.8. Results and conclusions of analytical risk and control;

4.31.9. Technical documentation and validation related to diagnostic production and design;

4.31.10. Clinical evaluation and research results;

4.31.11. Instructions for use for health professionals with Mongolian translations;

4.31.12. Colored foldable pamphlet of the primary and secondary packaging;

4.31.13. Where necessary, evidence of payment for test analysis performed by external accredited laboratory and shipment fees for transportation;

4.32. The following documents shall be submitted for registration of locally manufactured diagnostics:

4.32.1. Official application for registration, study results and conclusions of the quality safety of the diagnostic during its use, plan for post-market surveillance/ periodic safety update reports;

4.32.2. Original copy of the application for registration of the diagnostic in Mongolia certified by the authorized official of the factory; signature and seal;

4.32.3. Copy of special permission to manufacture;

4.32.4. Introduction of the pharmaceutical organization (both hard and soft copies);

4.32.5. Product input, composition and safety parameters;

4.32.6. If necessary, the specificity and sensitivity characteristics of the diagnostic;

4.32.7. Instructions for use;

4.32.8. Conclusions made by the relevant expert regarding the specificity and sensitivity of the diagnostic;

4.32.9. Colored foldable pamphlet of the primary and secondary packaging;

4.32.10. Where necessary, evidence of payment for test analysis performed by external accredited laboratory and shipment fees for transportation;

4.33. The following documents shall be submitted for registration of imported BAP:

4.33.1. Official application for registration, study results and conclusions of the quality safety of the BAP during its use, plan for post-market surveillance/ periodic safety update reports;

4.33.2. Original copy of the application for registration of the BAP in Mongolia certified by the authorized official of the factory; signature and seal;

4.33.3. Introduction of the manufacturer (both hard and soft copies);

4.33.4. A copy of special permission to import, sell, supply BAPs of the registrant

4.33.5. The manufacturer shall submit good manufacturing practice (GMP) or "Quality Management System", "Food Security System", "Food Production Hazard Analysis and Critical Control Points" (ISO: 9001, ISO: 22000, ISO17025: 2018, HACCP) certificate (manufacturer's certified copy);

4.33.6. Certification of the product is listed as “BAP” in the country of origin (manufacturer's certified copy);

4.33.7. Export authorization of the BAP or Free Trade Certificate (manufacturer's certified copy);

4.33.8. Original test results of the final product performed by manufacturer;

4.33.9. Test results performed by an accredited and contracted laboratory;

4.33.10. Product composition, safety data, indications, adverse reactions and methods of analysis;

4.33.11. Description of manufacturer in regards whether genetically modified component was used;

4.33.12. If a microorganism was used in a product, manufacturer’s description of the product patent including the names of family and species of microorganism in Latin

4.33.13. Description of the manufacturer in regards with no substance of abuse was being used in the product;

4.33.14. Certificate of origin of raw materials, their quality and safety;

4.33.15. Instruction for use in Mongolian (according to the approved format);

4.33.16. Colored foldable pamphlet of the primary and secondary packaging;

4.33.17. Where necessary, evidence of payment for test analysis performed by external accredited laboratory and shipment fees for transportation

**The following documents shall be submitted for registration of locally manufactured BAPs:**

4.34. The following documents shall be submitted for registration of locally produced BAP:

4.34.1 Official application for registration, study results and conclusions of the quality safety of the BAP during its use, plan for post-market surveillance/ periodic safety update reports;

4.34.2 Approved copies of verified authorizations from competent authority when using genetic resources

4.34.3. Copy of Special permission certificate to manufacture BAPs;

4.34.4 Original copy of the application for registration of the BAP in Mongolia certified by the authorized official of the factory; signature and seal;

4.34.5 Test results of the final product performed by the manuafacturer;

4.34.6 Test results performed by an accredited and contracted laboratory;

4.34.7 If BAP is derived from plants, family, genus and species shall be indicated in Latin, description for production and dosage forms shall be submitted.

4.34.8 Certificate of origin for raw materials, documentation including the list of raw materials, relating verifying information about their quality and safety profiles.

4.34.9 Product composition, safety parameters, effecasy, interaction, side effects and method of analysis

4.34.10 Manufacturers declaration relarding if genetic resources were utilized;

4.34.11 If a microorganism was used in a product, manufacturer’s description of the product patent including the names of family and species of microorganism in Latin;

4.34.12 Description of the manufacturer in regards with no substance of abuse was being used in the product;

4.34.13 Instruction for use in Mongolian (according to the approved format);

4.34.14 Colored pamphlet of the primary and secondary packaging; samples

4.34.15 Where necessary, evidence of payment for test analysis performed by external accredited laboratory and shipment fees for transportation;

4.35. Medicines, raw materials, diagnostics, BAPs deemed as ‘not registered’ by relevant council meetings shall not be considered for re-discussion. If a decision to re-assess and postpone until next meeting was made in order to provide additional information and clarification, the Council shall consider reviewing and deciding about the registration of proposed product.

Five. Registration number

5.1. The drug registration number shall include information in regards wiith the source, date of registration, anatomical therapeutic classification (ATC) code, conditions and individual number.

5.2. The registration of pharmaceutical products shall be numbered in the following manner and the following abbreviations shall be used: F / T / - Date of first registration - ATC - Condition of application - Unique drug number (FT20161001AP00050)

|  |  |  |
| --- | --- | --- |
|  | **Abbreviation** | **Description** |
| Source | **F**  **FT**  **L** | Foreign  Fast track  Local |
| Year of first registration in Mongolia | **0000** | For instance: 2006 |
| Day monthof first registration in Mongolia | **0000** | For instance: 1001= 1st of October |
| ATC code | **A** | Аlimentary tract and metabolism |
| **B** | Blood and blood forming organs |
| **C** | Cardiovascular system |
| **D** | Dermatologicals |
| **G** | Genito urinary system and sex hormones |
| **H** | Systemic hormonal preparations, excluding sex hormones and insulins |
| **J** | General antiinfective for systemic use |
| **L** | Antineopalastic and immunomodulating agents |
| **M** | Musculo skeletal system |
| **N** | Central nervous system |
| **P** | Antiparasitic products, insecticides and repellents-Паразит, шавжийн эсрэг бэлдмэл |
| **R** | Respiratory system |
| **S** | Sensory organs |
| **T** | Traditional medicine |
| **V** | Raw material and others |
| **Ho** | Homeophaty |
| Conditions | **Р**  **O**  **N**  **Ps**  **Н** | Prescription only  OTC  Narcotic  Psychotropic  Hospital |
| Number of the pharmaceutical product | **00000** | 00050; 00051;  in 5 numbers |

* 1. Numbering of diagnostics shall be based on the following abbreviations. F- first date of registration- classification based on diagnosis- number of diagnostics (F20161001Bi00050)

|  |  |  |
| --- | --- | --- |
|  | **Abbreviation** | **Description** |
| Source | **F**  **L** | Foreign  Local |
| Date of first registration | **0000-00-00** | For instance: 1001= 1st of October |
| Classification based on the type of diagnostic test | **Bi**  **Cc**  **He**  **Im**  **Ih**  **Mb**  **Mi**  **Pt**  **O** | **Bi-**Biochemistry  **Cc-**Clinical chemistry  **He-** Hematology  **Im-** Immunology  **Ih-**Immunohematology  **Mb-**Molecular biology  **Mi-**Microbiology  **Pt-**Pathology  **O-**Other |
| Number of the diagnostic | **00000** | 00050; 00051; in 5 numbers |

* 1. Registration number of BAP shall include source of the BAP, the date of the registration, letter and unique number for BAP.
  2. When allocating a registration number for registered BAP, the following abbreviations shall be used. F- date of first registration, letter- product number (F20161001Supp00050)

|  |  |  |
| --- | --- | --- |
|  | **abbreviation** | **description** |
| Source | **F**  **L** | Foreign  Local |
| First date of registration | **0000-00-00** | For instance: 1001= 1st of October |
| letter abbreviation | **Supp** | Supplement |
| Тухайн БИБ-ний дугаар/ Unique number for BAP | **00000** | 00050; 00051; in 5 numbers |

5.6. The registration certificate shall be issued in a single copy, issued to the applicant and the copies will be archived with the Secretariat.

5.7. The certificate of registration for pharmaceutical product shall be signed by the Chairman of HDC, registration certificate for diagnostics shall be signed by the Director of the HDC based on the approval by SCBD meeting, certificate BAP shall be signed by the Director of HDC based on the approval by SCBAP meeting and sealed by the MOH.

Six. Extension, amendment and withdrawal of registration

6.1. The amendment, extension of registration certificates of pharmaceuticals, raw materials and diagnostics, BAP shall be submitted in form of official request by the initial registrant to the Regulatory Authority.

6.2. Extension of registration for pharmaceutical products, raw materials, diagnostics and BAP shall be requested two months prior the expiration of the registration deadline.

6.3. The following documents shall be submitted for extension of registration of drugs:

6.3.1. Official request for extension of registration;

6.3.2. The original application for extension of registration for pharmaceuticals, raw materials, signed and sealed by a competed representative official of the manufacturing company;

6.3.3. Original certificates verified by competent authority specified by the WHO recommendations or officially certified copies (excluding raw materials);

6.3.4. Certificate of Good Manufacturing Practice (GMP) (verified copies of manufacturer);

6.3.5. Test results performed by an accredited and contracted laboratory;

6.3.6. Instructions for use, approved by the Subcommitte for Pharmacology (excluding raw materials);

6.3.7. Original copy of the expired registration certificate;

6.3.8.Colored pamphlet and samples of the primary and secondary packaging (spaces designated for the condition for the pharmaceutical product and registration number shall be indicated, excluding raw materials);

6.3.9. Study results on market demand and access to locally manufactured medicines by the registrant organization (excluding raw products);

6.4. The following documents will be submitted for extension of the registration of diagnostics:

6.4.1. An official request to extend the registration period;

6.4.2. Original copy of application to register for extension for their diagnostic product that is certified by the authorized representative of the manufacturer’s name signature and seal;

6.4.3. Manufacturer's Quality Management System Certificate (ISO13485) (shall be verified by the manufacturer);

6.4.4. Results of the diagnostic tests and tests performed for samples;

6.4.5. Colored images of primary and secondary packaging (first registered and current product);

6.4.6. Instruction of use for health professionals (shall be verified by the SCBD);

6.4.7. Original copy of the expired registration certificate;

6.5**.** The following documents will be submitted for extension of BAP:

6.5.1. Official request for extension of registration;

6.5.2. Original copy of application to register for extension for their BAP that is certified by the authorized representative of the manufacturer’s name signature and seal;

6.5.3. Information on BAP safety;

6.5.4. Instructions for use of BAP (verified by the SCBD);

6.5.5. Original copy of the expired registration certificate;

6.5.6. Color images of primary and secondary packaging;

6.5.7. Test results performed by an accredited and contracted laboratory;

6.6. The Secretariat shall collect reports on side effect and safety from the Subcommittee for Pharmacology, quality and safety of the product from the Government Agency for Specialized Inspection, violation of advertisement from the Association for Fair Competition, Consumer Protection and present to the HDC on a quarterly basis.

6.7. Any change related with production technology, research, treatment outcome and market demands of the fnal product with purpose of improving the quality of the product shall be informed by the manufacturer to the Secretary and discussed by the HDC.

6.7.1. Changes in primary and secondary packaging (labelling, design, packaging, size, material changes, bar codes, logos, labels, batch number, registration numbers, changes in manufactured and expiration date order, notice, warning, adverse reaction, side effect user information, add or remove photos, and other information);

6.7.2. To alter the labelling, indication, signs, ink on medications such as tablets, capsules, suppositories;

6.7.3. Additional Packaging;

6.7.4. Changes in instruction of use (in cases where the new indication was not added in the instruction of use);

6.7.5. Changes in the condition of the drug dispensing;

6.7.6. Changes in analytical method and methodology of final product and active ingredient;

6.7.7. Results of stability studies, changes in storage terms and conditions;

6.7.8. The manufacturer's name and address change (the name or address of the manufacturer is changed, in case of country of origin is not changed);

6.7.9. Change of the license holder's name;

6.7.10. Change of composition of excipients and dyes, change of dose (eg, replace with internationally accepted substance);

6.7.11. Changes in the production process of pharmaceutical products;

6.7.12. Changes in the name of the trade of pharmaceutical products (in the case of active ingredient and excipient, corresponding dose were not changed);

6.8. The following documents will be submitted to change the registration:

6.8.1. Official request of the manufacturer to make changes in the registration;

6.8.2. The original application to change the registration of a product certified by the authorized official of the manufacturer, signature and seal;

6.8.3. Detailed description of the amendments and related documents (if the primary and secondary packaging changes, the comparison of the old and new design colors, if analysis method of final product and active ingredient was changed, attach test results performed by the accredited and contracted laboratory);

6.8.4. Expert conclusions on the results of stability studies, changes in storage terms and conditions;

6.8.5. For the change of trade name, complete documents for new registration shall be submitted.

6.9. In the following cases, the HDC, Subcommittees shall revoke registration of medicines, medicinal raw materials, diagnostics and BAPs:

6.9.1. Drugs, medicines, diagnostics, BAPs which have been removed or revoked from Drug Registry List in the country of origin;

6.9.2. An official request has been submitted to the registrant and manufacturer for termination;

6.9.3. As a result of surveillance studies non-compliant or non-satisfactory quality and safety of the product were confirmed by either accredited or reference laboratory analysis and other documents and research findings and professional organization's conclusions.

6.9.4. Review and conclusion of experts, legal authority has been issued in regards with falsified documents submitted to registration, and applied to extend or change the registration.

6.9.5. The complaints received from health organizations and community related with the quality, efficacy and safety of the product were traced and assessed by professional inspection agencies and request for revokal has been made;

6.9.6. Death, long-term treatment, disability and loss of ability to work were caused due to significant adverse events and quality of pharmaceutical product and proved by legal authorities.

6.9.7. The pharmaceutical product was removed from treatment and diagnostics standards, guidelines and recommendations, and they are no longer used;

6.9.8. Decisions on WHO and the country's drug and food regulatory authorities to prohibit the use of the product;

6.10. In the event of a decision to withdraw or recall the product from the market, the legal authorities shall be informed within 7 working days after the issuance of decision and relevant changes shall be made in the electronic databases.

6.11. If postmarketing surveillance for registered pharmaceutical products, raw materials, diagnostics and BAPs are required, HDC shall approve the terms of reference and assign the surveillance team.

6.12. If the application for extension is not submitted within the deadline specified in the Article 6.2 of this Procedure, the registration of the product shall be revoked from the last day of registration period and Secretary shall annotate the product as unregistered in the database.

Seven. Miscellanious

7.1. Documents and application regarding the registration of medicines, raw materials, diagnostics and BAP by the HDC, Subcommittees shall be prepared and verified in accordance with the documentation standards and the Secretariat shall submit these documents to Secretary of relevant Subcommittees 5 working days prior and include them in the meeting schedule.

7.2. The applicant shall work towards ensuring the provision of accurate and authentic study results, reports on assurance of quality and safety of the products to the HDC and the Subcommittees.

7.3. The Registrar shall be obliged to pay the registration fee for specified period and is ineligible to revoke the application once the the expert's conclusion has been made or assessment started.

7.4. It is prohibited to import, distribute, or use in the medical care in Mongolia if a valid registration certificate was not received by the applicant.

7.5. The registrant shall be responsible to cover all costs associated with removing of products from the market in case of a decision to revoke and recall has been made by the HDC.

7.6. The manufacturer and the supplier shall be held liable to cover all costs associated with any negative outcome on health, death and finances due to usage of product which are confirmed by legal authorities.

Eight. Storage and usage of registration documents

8.1 The Secretariat shall be responsible for maintaining and keeping the confidentiality and integrity of database on registered drugs, raw materials, diagnostics, BAPs, as well as registration archives and all documents shall be kept under the "Law on Archives".

8.2 Archived documents shall be used for official use only in accordance with the "Regulation on use of archives and issuance of reference documents".

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Appendix 2,

Health Minister’s Order A/ 295

September 9, 2019

regulation on expend, model expenditure and registration fees for pharmaceutical product, raw materials, diagnostics and biologically active products

One. Registration fees for medicines, raw materials, diagnostics and biologically active products, model expenditure

1.1. Procedural costs associated with registration of medicines, raw materials, BAPs and diagnostics (hereinafter referred to as "registration fee") shall be paid to the state budget irrespective type of the ownership.

1.2. The registrant shall be responsible for the registration of drugs, raw materials, BAP and diangostics, and the product registration fees shall be paid to the state budget prior to the HDC, SCBAP and SBD meeting.

1.3. Payments in foreign currencies shall be calculated on the exchange rate of the day, Mongolbank. The foreign transfer fee shall be borne by the paying entity.

1.4. The registration fee shall be non-refundable and in the following estimates:

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **Registration** | **Extension of registration** |
| 1 | Fast track registration of imported medicines | 900,000 | 600,000 |
| 2 | Regular registration of imported medicines | 800,000 | 600,000 |
| 3 | Registration of locally manufactured medicines | 400,000 | 250,000 |
| 4 | Registration of raw materials | 500,000 | 300,000 |
| 5 | Registration of combination medicines with 4 or more ingredients | 1,600,000 | 600,000 |
| 6 | Registration of imported medicines locally manufactured | 1,600,000 | 600,000 |
| 7 | Registration of medicines to be supplied upon HDC policy | 300,000 | 600,000 |
| 8 | Registration of imported BAP | 800,000 | 600,000 |
| 9 | Registration of locally manufactured BAP | 400,000 | 250,000 |
| 10 | Registration of imported diagnostics | 300,000 | 250,000 |
| 11 | Registration of locally manufactured diagnostics | 200,000 | 150,000 |
| 12 | Change of registration for medicines, BAP | 300,000 | - |
| 13 | Бүртгэлийн өөрчлөлт оношлуур/ Change of registration for diagnostics | 200,000 | - |

1.5. Assignment of registration experts. The following model shall be referenced to reimburse members of HDC and Subcommittees for time spent in meetings.

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|  |  |  |  |
| --- | --- | --- | --- |
| **№** | **Type of activity** | **Unit** | **Reimbursement /MNT** |
| 1 | Incentive for members of HDC, Subcommittees | 1 person/ hour | 20,000 |
| 2 | Incentive for members of Pharmacopeaie Committee | 1 person/ hour | 20,000 |
| 3 | Incentive for members of Professional Committees, MOH | 1 person/ hour | 20,000 |
| 4 | Incentives for editorial board members of Drug Information journal | 1 хүн/цаг  1 person/ hour | 20,000 |
| 5 | Эм зүй, эмнэлзүйн шинжээчийн ажлын хөлс/  Incentive for pharmaceutical, clinical experts | 1 expert/ medicine | 150,000 |
| 6 | Incentives for experts diagnostics | 1 expert/ diagnostic | 100,000 |
| 7 | Incentives for experts in BAP | 1 expert/ BAP | 100,000 |
| 8 | Incentives for experts in GMP | 1 expert/ plant | 100,000 |
| 9 | Expenditure for meetings and operations | 1 person | 5000 |

Two. Expense of registration fees of pharmaceutical products, raw materials, diagnostics and biologically active products

2.1. The registration fees shall be included and approved in the budget of the Regulatory Authority and shall be used for the following activities:

2.1.1. Get acquainted with foreign and local plants, conduct research and risk assessments, and obtain references of manufacturers;

2.1.2. Conduct regular market surveillance studies on efficacy, quality and safety of medicines;

2.1.3. Expenses required to contract an expert and assessment team for surveillance studies;

2.1.4. Costs of activities related to the informing and registering adverse effects;

2.1.5. Payment for membership of the International Monitoring Center for Drug Safety, Adverse Reactions to inform and exchange information (Uppsala Monitoring Center);

2.1.6. To provide wages for experts in registration;

2.1.7. Training costs for experts and regulators;

2.1.8. Publish a certificate of registration;

2.1.9. To publish GMP certificates;

2.1.10. For required instances, to hire international consultants and experts;

2.1.11. To provide support to members of the Human Drug Council, relevant specialists and experts to attend international exhibitions, conferences, short-term training seminars and business travels;

2.1.12. To publish books, brochures, manuals, Drug information journal and indicators that are required for implementation and used for legal and regulatory purposes;

2.1.13. Information and training on appropriate use of medicines;

2.1.14. Costs associated with maintain regular activities of the Medicines Databases, provision of bar codes and renewal;

2.1.15. Obtain professional foreign and domestic books, journals, booklet, information, ordering, and internet access;

2.1.16. Expenses required to implement the State Policy on Health;

2.1.17. Costs associated with meetings and organizational activities of HDC and the Subcommittee, Committee for Pharmacopoeia, Professional Committee for Pharmacy and Pharmacology;

2.1.18. Costs associated with monitoring the implementation of the regulations;

2.1.19. Other activities related to the implementation of pharmaceutical activities indicated in the State Policy on Health;

2.1.20. Processing, printing and enhancing national pharmacopoeia;

2.2. The Secretariat shall report the revenues and expenditure of the state registration to the Division of Pharmaceuticals, Medical Devices, Manufacturing, Department of Pharmaceuticals, Manufacturing and Technology, Ministry of Health within the first quarter of every year and present the report to the Human Drug Council meeting.

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