REGULATION

From the Turkish Medicines and Medical Devices Agency:

HOMEOPATIC MEDICAL PRODUCTS LICENSE REGULATION

FIRST PART
Purpose, Scope, Basis and Definitions

Aim

ARTICLE 1 – (1) The purpose of this Regulation; It is to determine the procedures and principles to be applied in licensing, packaging and distribution processes in order to ensure that homeopathic medicinal products have the desired effectiveness, safety and required quality, and the practices regarding licensed homeopathic medicinal products.

Scope

ARTICLE 2 – (1) This Regulation covers industrially prepared homeopathic medicinal products produced by a traditional or industrial method, and natural and legal persons who have applied for a license and/or been granted a license.

(2) Without prejudice to the provisions of the Regulation on Clinical Trials of Pharmaceuticals and Biological Products published in the Official Gazette dated 13/4/2013 and numbered 28617, medicinal products intended to be used in research and development studies, homeopathic medicinal products prepared for animals and plants, and magistral homeopathic medicinal products. products are outside the scope of this Regulation.

Rest

ARTICLE 3 - (1) This Regulation; To the Pharmaceutical and Medical Preparations Law No. 1262 dated 14/5/1928, Subparagraph (k) of the first paragraph of Article 3 of the Health Services Basic Law dated 7/5/1987 and numbered 3359, and the Official Gazette dated 15/7/2018 and numbered 30479. It has been prepared on the basis of Articles 508 and 796 of the Presidential Decree No. 4 on the Organization of Ministries, Related, Related Institutions and Organizations and Other Institutions and Organizations.

Definitions

ARTICLE 4 – (1) In this Regulation;

a) Packaging information: Information on the inner or outer packaging,

b) Packaging sample: A two-dimensional, full-color, two-dimensional drawing of the packaging that will be put on the market when cut and folded, providing a clear copy of the inner and outer packaging in a way to ensure that the three-dimensional presentation of the text of the packaging information prepared with the information based on the license, after cutting and folding when necessary, can be created,

c) Main tincture: The solution prepared in accordance with the homeopathic main tincture manufacturing procedure defined in the Pharmacopoeia,

ç) Ministry: The Ministry of Health,

d) Starting material: The source used to prepare the homeopathic stock and included in the pharmacopeia or Materia Medica,

e) Medicinal product for human use:

1) Presented as having therapeutic or preventive properties for human disease or,

2) Used or applied to humans for the purpose of restoring, improving or changing physiological functions or medical diagnosis by showing a pharmacological, immunological or metabolic effect,

substance or combination of substances,

f) Herbal drug: Mostly dried, sometimes fresh, whole, shredded or cut plants of medicinal plants used in unprocessed condition to be given together with the botanical name, genus, species, subspecies, variety, herb and scientific name of the plant part used according to the binomial system. or plant parts, algae, fungi, lichens and some exudates not subjected to special treatment,

g) Finished product: A ready-to-use homeopathic medicinal product in its final package, which has passed all production stages,

ğ) Braille alphabet: The internationally widely used reading and writing system for visually impaired people with complete or partial vision loss or impairment,

h) Dilution: The process of reducing the concentration by using the appropriate solvent and method during the preparation of the homeopathic medicinal product,

ı) Pharmacopoeia: Turkish Pharmacopoeia or European Pharmacopoeia, or the official pharmacopoeia of the European Union member countries where it is not included in these Pharmacopoeia, or the pharmacopoeia approved by the Institution in cases where these pharmacopeias are not applicable,

i) Pharmaceutical form: The presentation form of the homeopathic medicinal product produced in accordance with its intended use,

j) Homeopathic stock: Used in the preparation of potencies of the homeopathic medicinal product; preparations that can be the main tincture or macerate formed with the starting material and/or the carrier material,

k) Homeopathic medicinal product: A medicinal product for human use prepared from homeopathic stock, in compliance with the homeopathic production procedure defined in the Pharmacopoeia,

l) Homeopathic Medicinal Product Information (HÜB): The document containing written information prepared for the user, presented with the homeopathic medicinal product,

m) Name of the homeopathic medicinal product: The trade name of the homeopathic medicinal product that has been invented or the name of the homeopathic medicinal product together with the name of the license holder of the homeopathic medicinal product, as mentioned in the pharmacopeia or Materia Medica,

n) Good agricultural practices: The processes required to make the agricultural production system socially viable, economically profitable and efficient, protecting human health, giving importance to animal health and welfare and the environment,

o) Law: Law No. 1262,

ö) Institution: Turkish Medicines and Medical Devices Agency,

p) Licensor Firm:

1) The company that authorizes the natural or legal person for the registration and sale of the imported homeopathic medicinal product in Turkey, or

2) The company that authorizes the natural or legal person for the manufacture, licensing and sale of the homeopathic medicinal product manufactured with a license in Turkey,

r) Materia Medica: A reference book accepted by the Institution, containing information on the therapeutic indications, posology and use of homeopathic stocks,

s) Nosod: Homeopathic preparations prepared using products obtained from human or animal disease processes, pathogens or their metabolic products, degradation products of animal organs or cultured microorganisms,

ş) Priority Evaluation Board: Established with the aim of giving priority to the applications for human medicinal products of strategic importance, which are the first in treatment or diagnosis, bring innovation, or are needed in terms of public health in order to ensure the sustainability of access to the drug or the rapid delivery of the drug to the society, in the Institution's business and operations. ; The Board, whose working procedures and principles are determined in accordance with the relevant guide,

t) Package transfer system: The application that enables the transfer of data matrix of all products transferred between the stakeholders and the hierarchy information of the transport units containing these products,

u) Lot: The amount of a homeopathic medicinal product obtained in a single production cycle during production and ensuring homogeneity,

ü) Potency: The level of potentiation of the homeopathic medicinal product,

v) Potentization: The process carried out by trituration or succussion together with dilution from the homeopathic stock during the preparation of a homeopathic medicinal product,

y) License: The document issued by the Institution showing that a homeopathic medicinal product can be produced and put on the market with a certain formula, in a certain pharmaceutical form and potency, in accordance with the accepted product information,

z) Licensing: The examination and approval procedures carried out by the Authority for a homeopathic medicinal product to be put on the market,

aa) License holder: The natural or legal person holding the license of the homeopathic medicinal product,

bb) Sarcode: Homeopathic preparations of healthy organs, tissues or metabolic factors obtained from healthy organisms (human or animal),

cc) Responsible technical staff: The person assigned by the applicant, graduated from one of the higher education institutions providing education in pharmacy or medical sciences, received homeopathy training approved by the Ministry and is responsible for the production of the homeopathic medicinal product in accordance with the relevant legislation, including good manufacturing practices,

çç) Sukkusion: Mixing by shaking with a certain power and violence,

dd) Carrier material: Substances used in the preparation of the homeopathic stock or in the potentiation process,

ee) Trituration: Mixing by crushing with a certain power and violence,

ff) Production place: The place where the pharmaceutical form of the homeopathic medicinal product is produced before the inner packaging,

gg) Product: Homeopathic medicinal product,

ğğ) Variation:

1) In the content of the information specified in the guide on the variations in the 8th, 9th and 10th articles and the licensed homeopathic medicinal products, or,

2) Conditions, obligations or restrictions affecting the licensing of HUB and homeopathic medicinal product, or packaging information and/or in HÜB,

changes made,

hh) Excipient: Substances included in the composition of the homeopathic medicinal product, excluding the homeopathic stock, carrier substance and packaging material,

means.

SECOND PART
License Application

Licensing Obligation

ARTICLE 5 – (1) No homeopathic medicinal product that is not licensed by the Agency in accordance with the provisions of this Regulation can be placed on the market.

License application and application form

ARTICLE 6 – (1) Real or legal persons residing in Turkey apply for a license to the Agency in accordance with this Regulation and the Guidelines on Homeopathic Medicinal Products Licensing Application in order to obtain a license for placing a homeopathic medicinal product on the market.

(2) Except for cases deemed necessary by the Institution, force majeure or obligatory cases; License applications are only accepted electronically and all correspondence during the licensing process is carried out electronically only.

Persons who can apply for a license

ARTICLE 7 - (1) Pursuant to Article 5 of the Law, those wishing to obtain a license to put the homeopathic medicinal product on the market;

a) real persons; Having graduated from one of the higher education institutions providing education in the fields of pharmacy, medicine or chemistry and having the authority to practice their profession in Turkey,

b) Legal persons; Employing someone who has the qualifications specified in subparagraph (a) as an "authorized person",

is essential.

(2) Real persons belonging to the dentistry profession and authorized to practice their profession in Turkey also have the right to apply for a license for homeopathic medicinal products used in dentistry.

THIRD PART
Information and Documents to be Submitted in License Application

Product information

ARTICLE 8 – (1) The natural or legal person wishing to obtain a license for a homeopathic medicinal product applies to the Agency with the documents prepared in accordance with the Guidelines on the Application for the Registration of Homeopathic Medicinal Products and containing the following items regarding the product:

a) Name of the homeopathic medicinal product.

b) Pharmaceutical form.

c) The route of administration.

ç) Content of the finished product.

d) Packing size.

e) Potency of the homeopathic stock contained in the finished product.

f) Quantitative amount of auxiliary/carrier substances in the finished product.

g) Shelf life.

ğ) Information on safe potentiation.

(2) It is obligatory to notify the Institution about the updated information in this article.

Administrative information

ARTICLE 9 – (1) A natural or legal person wishing to obtain a license for a homeopathic medicinal product applies to the Agency with the documents containing the administrative issues listed below, which have been prepared in accordance with the Guidelines on the Application for a Homeopathic Medicinal Product Registration Application:

a) The applicant's diploma or notarized copy showing that he is a member of one of the professions specified in Article 7, or a graduation certificate from the Higher Education Council.

b) If the applicant is a legal person, the Turkish Trade Registry Gazette stating the partners of the company and the duties and titles of the responsible persons.

c) Approved document showing that the applicant is authorized to make the application.

ç) Applicant's name or company name, permanent address, registered e-mail (KEP) address, telephone and e-mail address.

d) Name, permanent address, telephone number and e-mail address of the place of manufacture.

e) In case of importation of a homeopathic medicinal product, a document issued by the licensing company showing that the real or legal person making the import is the only authorized representative for the importation, licensing and sale of the said product in Turkey.

f) In case the homeopathic medicinal product is produced under license, a document issued by the licensing company showing that the real or legal person making the production is the only authorized representative for the licensing, production and sale of the said product in Turkey.

g) For the imported or licensed homeopathic medicinal product for which the application has been made, the list of other countries/countries where the product is put on the market, and a copy of the license/permit approved by the health authority of one of the countries in the list, and the list of other countries for which a license/permit application has been made, if any.

ğ) Name, address, telephone and e-mail address of the places where inner-outer packaging, batch release and batch control/analysis are made.

h) In case the applicant is not a manufacturer of homeopathic medicinal products to be manufactured in Turkey, the contract for contract manufacturing with a manufacturer that meets the conditions specified in the Regulation on Manufacturers of Medicinal Products for Human Use published in the Official Gazette dated 21/10/2017 and numbered 30217, and the registration certificate of the parties. .

ı) Regarding the homeopathic stock production places of the homeopathic medicinal product; For the homeopathic stock taken under the scope of the inspection by the Agency, the document issued by the Agency for the homeopathic stock production site(s), showing that the production is made in accordance with the good manufacturing practices guidelines, or the production site permit for the homeopathic stock production site(s) operating in Turkey; A document issued by an authorized health authority for homeopathic stock production sites that are not within the scope of inspection by the Institution, showing that the homeopathic stock is produced in accordance with internationally accepted good manufacturing practices, or in cases where this document is not physically issued,

i) A document approved by the Authority showing that the finished product has been produced in accordance with the internationally accepted good manufacturing practices guidelines issued by an authorized health authority for all production steps of the production site, given by the Authority, or for production steps for which no document is issued by the Authority, or In cases where the document is not physically issued, the information or document accepted by the Authority showing that production is made in accordance with the internationally accepted good manufacturing practices guides, or a document issued by the official authorities of the countries that have mutual recognition agreement with our country, showing that it can produce within the framework of good manufacturing practices, or to be manufactured in Turkey manufacturing site permit for homeopathic medicinal products.

j) The diploma or notarized copy of the diploma or notarized copy of the responsible technical staff, showing that he has graduated from one of the higher education institutions providing education in the fields of pharmacy or medicine, or the graduation certificate from the Higher Education Council or the original or notarized copy of the equivalence certificate approved by the Ministry.

k) The original or notarized copy of the homeopathy training certificate of the responsible technical personnel or the document showing that he has received equivalent training.

l) Curriculum vitae, address, telephone, e-mail address of the product safety officer and representative within the scope of pharmacovigilance practices and the document describing the duty of this person.

m) Document defining the science service within the scope of the Regulation on Promotional Activities of Medicinal Products for Human Use published in the Official Gazette dated 3/7/2015 and numbered 29405, and the address, KEP address, telephone, e-mail address of this service.

n) The homeopathic medicinal product applied for; If the license application has been rejected by the competent authority of other countries or withdrawn by the applicant, or if the licensed/permitted product has been withdrawn or its license/permit has been suspended, stating the list of these countries together with the name of the product in the country in question, the date and justification of the transactions.

o) Package samples of HÜB and homeopathic medicinal product prepared in accordance with the 13th, 14th and 17th articles in the size and design to be presented to the market, and in case of importation or licensed production of the product, also approved by the competent authorities of the other country or countries where the product is put on the market, if any, and approval, if any. Current original HUB and packaging samples of the product showing the date.

ö) In case of importation or licensed production of the homeopathic medicinal product, the packaging sample of the product approved by the competent authority, HÜB and its sworn Turkish translation or, in cases where sworn translation cannot be made in our country, a sworn translation document translated into Turkish or English in another country.

p) Package samples of the size and design to be presented to the market of the HÜB and homeopathic medicinal product prepared in accordance with the relevant guide on the packaging, HÜB and tracking system in accordance with the 13th, 14th and 17th articles, and in case of import or licensed production of the product, as well as other other products where the product is put on the market, if any. HUB and packaging samples of the current reference product of the product, approved by the competent authorities of the country or countries and showing the approval date, if any.

r) Considering the potential risks posed to the environment by the homeopathic medicinal product for which the registration application has been made, the storage of the product, its application to patients, and the disposal of waste products in accordance with the provisions of the Waste Management Regulation published in the Official Gazette dated 2/4/2015 and numbered 29314. precautions and safety measures to be taken.

(2) All official documents included in the application and obtained from abroad must be apostille annotated or approved by the consulate. It is essential that all documents are submitted in Turkish. Parts deemed appropriate by the institution may be presented in English. However, those prepared in languages other than English must be submitted with a sworn Turkish translation. In cases where sworn translation cannot be made in our country, a sworn translation document translated into Turkish or English in another country may be accepted.

(3) It is obligatory to notify the Institution about the updated information in this article.

Control of starting materials and homeopathic stocks, production method, information about the finished product

ARTICLE 10 – (1) The following information about the control of starting materials and homeopathic stocks, production method and finished product controls is submitted in accordance with the Guidelines on the Application for the Registration of Homeopathic Medicinal Products:

a) Scientific name of starting materials, pharmacopoeial name of homeopathic stock.

b) Information on where starting materials were obtained.

c) On the basis of adequate bibliography describing how the homeopathic stock was obtained; documents explaining the rationale for its homeopathic use.

ç) Specifications, analysis control methods and acceptance limits of starting materials and homeopathic stocks.

d) Documents proving that there is no risk of biological contamination according to the characteristics of the homeopathic medicinal product.

e) If the homeopathic medicinal product contains substances of animal origin, the applicant's statement that there is no risk of causing Transmissible Spongy Encephalopathy (TSE) and the submission of the official authority letter, if any, and viral contamination tests if it contains human origin starting material.

f) The accuracy of the formulation of the homeopathic medicinal product and its analysis in the Institution's laboratory or in a laboratory accepted by the Institution for this purpose, in order to determine the applicability of the methods according to the pharmacopoeia method and specifications used by the manufacturer to control the product, if not, according to the company's method and specification.

g) Description of the production method.

ğ) Potency information and production flow chart of the homeopathic stock.

h) Production method specific (in-process) controls.

i) Reproducibility of production methods specified in the pharmacopoeia, validation of the methods if not included in the pharmacopoeia.

i) Stability for main tincture or homeopathic stocks.

j) Finished product specifications.

k) Finished product control methods and reproducibility of production methods specified in the pharmacopoeia, validation of methods if not included in the pharmacopoeia.

l) Data on the stability of the finished product.

m) Description of the control methods used by the manufacturer and, where applicable, presented in accordance with the pharmacopoeia.

n) In case the finished product is prepared from toxic compounds, experimental data in which the diagnosis and amounts of all toxic compounds are determined.

o) Results of physicochemical, biological or microbiological tests.

(2) The definition of the homeopathic stock used to prepare the homeopathic medicinal product is justified by reference to the pharmacopoeia. Where it is not in the pharmacopoeia, it can be justified by reference to Materia Medica.

(3) Detailed summaries of the documents related to the results of physicochemical, biological or microbiological tests specified in subparagraph (o) of the first paragraph, prepared in accordance with Article 11, must be submitted.

(4) In cases where the diagnosis and amounts of toxic compounds cannot be determined due to the dilutions in the finished product specified in subparagraph (n) of the first paragraph, full validation of the production and dilution process can be submitted in order to prove the quality of the finished product.

(5) If necessary, additional information and documents may be requested by the Authority for nosod and sarcods.

(6) It is obligatory to notify the Institution about the updated information in this article.

Expert reports

ARTICLE 11 – (1) When applying to the Agency, the license applicant submits the expert reports signed by the relevant experts regarding the quality and safety of the homeopathic medicinal product applied for.

(2) The duties of the experts who will prepare the reports, according to their qualifications, are as follows:

a) To perform tasks within their own disciplines, such as analysis, toxicology and similar experimental sciences, and objectively describe the qualitative and quantitative results obtained.

b) To prepare the observations in accordance with the Guidelines on the Application for Homeopathic Medicinal Products Registration, and in particular;

1) For analysts, whether the homeopathic medicinal product complies with the declared composition is determined by the control methods used by the manufacturer,

2) The homeopathic medicinal product is suitable in terms of toxicity,

to indicate.

(3) The resume of the expert, the statement of professional relationship with the applicant and, when necessary, the justification of the documents used for the application should be stated.

(4) The detailed reports of the experts form a part of the documents attached to the application submitted by the applicant to the Institute.

(5) The expert report showing that the product has been produced in accordance with the relevant legislation, including good manufacturing practices, is approved by the responsible technical staff.

Application

ARTICLE 12 - (1) Without prejudice to the provisions of the Industrial Property Law dated 22/12/2016 and numbered 6769, only the applications for products that meet the following conditions are evaluated by the Authority:

a) Oral or external use of the homeopathic medicinal product.

b) It is obtained from a single homeopathic stock.

c) The absence of an indication in all file information of the homeopathic medicinal product.

ç) The homeopathic medicinal product is diluted sufficiently to guarantee its safety; In particular, the finished product contains less than one in every 10,000 of the main tincture, or less than 1/100 of the lowest dose used in treatment according to the literature, of the active ingredients, without requiring a doctor's prescription.

(2) A separate application is made for each homeopathic medicinal product with different potency, route of administration and pharmaceutical form derived from the same homeopathic stock.

CHAPTER FOUR

Packaging Information and Terms of HUB

Information to be found on the outer packaging

ARTICLE 13 – (1) In the outer packaging of the homeopathic medicinal product or, if there is no outer packaging, in the inner packaging;

a) The wording “Homeopathic Medicinal Product” legibly and clearly,

b) Name, potency and pharmaceutical form of the homeopathic medicinal product,

c) The pharmacopoeial name and potency of the homeopathic stock,

ç) Excipients and carrier substances, which are known to have obvious effects and are included in the Guide on Packaging Information of Medicinal Products for Human Use and Excipients in the Instructions for Use; If the homeopathic medicinal product is topical, all excipients and carriers,

d) The method of application and, if necessary, the route of administration,

e) The amount of product contained in the package,

f) Warning that the homeopathic medicinal product should be kept out of sight and reach of children and in its package,

g) If necessary, special warnings regarding the homeopathic medicinal product,

ğ) A warning about consulting a doctor or pharmacist in case of an unexpected effect during use,

h) Warning not to buy cut or opened packages,

ı) The storage conditions of the product as well as special storage conditions, if any,

i) Production place and address,

j) The registration date and number of the product,

k) "Read the homeopathic medicinal product information before use." warning,

l) "Sold only in pharmacies." warning,

m) Name and address of the license holder,

n) Lot number,

o) expiration date,

ö) In order to ensure the traceability of the homeopathic medicinal product, the QR code and visually readable information about the content of the data matrix,

p) Special warnings regarding the disposal of unused products or wastes arising from products and, if necessary, an appropriate collection system,

takes place.

(2) Existing outer packaging of products without HÜB must contain the statements that should be included in the HÜB.

(3) The Braille requirement for a homeopathic medicinal product applies to the product's trade name. Where the product has several potencies, the potency of the product and the pharmaceutical form may be limited.

(4) In accordance with the Regulation on Control of Packaging Wastes published in the Official Gazette dated 26/6/2021 and numbered 31523, the recyclable packaging symbol and the abbreviation indicating the type of packaging and the number of the material type are placed on the packaging. The management of the outer packaging wastes of homeopathic medicinal products is carried out in accordance with the provisions of the relevant legislation.

(5) The outer packaging of the homeopathic medicinal product must be in Turkish.

Information to be found on the inner packaging

ARTICLE 14 – (1) The information required on the inner packaging is as follows. In the inner packages that do not have the features specified in subparagraphs (a) and (b), all of the information required to be found on the outer packaging is included, except for the points specified in subparagraphs (ğ), (h), (k) and (ö) of the first paragraph of Article 13.

a) In inner packagings in the form of blisters, as a minimum;

1) The wording “Homeopathic Medicinal Product” legibly and clearly,

2) The name of the homeopathic medicinal product,

3) The pharmacopoeial name and potency of the homeopathic stock,

4) The expiry date written in accordance with the date on the visually readable information next to the QR code,

5) Lot number,

6) The name or emblem or logo of the license holder,

takes place.

b) As a minimum, in inner packagings that are so small that the features and information determined in terms of packaging information cannot be included;

1) The name of the product, its potency, pharmaceutical form and, where necessary, the route of administration,

2) Application method,

3) The expiry date written in accordance with the date on the visually readable information next to the QR code,

4) The amount of product contained in the packaging,

5) Lot number,

6) If possible, the name or emblem or logo of the license holder,

takes place.

(2) The existing packages of the products that do not have an outer packaging contain the statements that should be included in the outer packaging specified in Article 13.

(3) The inner packaging of the homeopathic medicinal product must be in Turkish. However, in cases where the justification is approved by the Authority and the outer packaging is in Turkish, it may be accepted that the inner packaging is prepared using one of the official languages of the European Union member states.

Symbols and other information

ARTICLE 15 – (1) The outer packaging and the HÜB may contain symbols and pictorial diagrams explaining the information specified in the first paragraphs of Articles 13 and 14, and other information that is useful for users and compatible with the HÜB of the homeopathic medicinal product, provided that it is not encouraging and does not have a promotional nature. .

(2) Detailed issues regarding the symbols, pictorial diagrams and information specified in the first paragraph are arranged in the relevant guide on packaging, HÜB and tracking system.

Other requirements on packaging

ARTICLE 16 – (1) For homeopathic medicinal products that have a limited period of use after thawing, diluting or opening, the period of use and storage conditions are separately indicated on the package.

(2) In order to avoid the risk of confusion and error, color and size differences are clearly provided where necessary in the packages of homeopathic medicinal products that are similar in terms of name, pharmaceutical form and presentation but differ in potency.

(3) In case the homeopathic medicinal product is available for placing on the market, the information of the HÜB must be in Turkish. However, when necessary and desired, one of the official languages of the European Union member states can be used in addition to Turkish in the outer packaging, inner packaging and HÜB, provided that the same issues are included in all the languages used and with the approval of the Authority.

(4) The information specified in the first paragraphs of Articles 13 and 15 and the first and second paragraphs of Article 14 must be easily readable, clearly understandable and indelible.

Homeopathic Medicinal Product Information

ARTICLE 17 – (1) HUB is prepared in a way that the user can easily understand. HÜB is presented in a way that includes the following information and in accordance with the Guide on Packaging and Homeopathic Medicinal Product Information, Readability and Follow-up of Homeopathic Medicinal Products:

a) For identification of the homeopathic medicinal product;

1) Name of the homeopathic medicinal product, pharmaceutical form, scientific name and potency of the homeopathic stock,

2) The amount of product contained in the package,

3) The expression "Homeopathic Medicinal Product",

should take place.

b) Special warnings about the auxiliary/carrier substances that are important for the safe use of the homeopathic medicinal product and the necessary warnings specific to the homeopathic medicinal product, if any.

c) As general and necessary information for the correct use of the homeopathic medicinal product, instructions regarding the method of application and, if necessary, the route of administration are given.

ç) The shelf life of the homeopathic medicinal product depends on its structure.

d) “Sold only in pharmacies.” warning is included.

e) Along with the statement emphasizing that the expiry date is on the package;

1) Warning about not using after this date,

2) Storage conditions,

3) If necessary, warning against a visible deterioration/change in the product,

4) Pharmaceutical form and content in weight, volume or dosage unit for the presentation of each homeopathic medicinal product,

5) Production site name and address,

is found.

f) The date the HUB was last updated.

g) The name and address of the license holder are indicated.

ğ) HÜB can be prepared in accordance with the Guide on the Application for License for Homeopathic Medicinal Products for visually impaired people with complete or partial vision loss or impairment, and the Guide on the Package and Homeopathic Medicinal Product Information, Readability and Follow-up of Homeopathic Medicinal Products.

h) The HUB should be easily readable and clearly understandable.

ı) Special precautions regarding the disposal of a used homeopathic medicinal product or, if necessary, waste materials originating from such a product are indicated.

(2) The requirements regarding the packaging information in the Regulation on the Safety of Medicines published in the Official Gazette dated 15/4/2014 and numbered 28973 are included.

(3) In cases where animal source is used in homeopathic stock and auxiliary/carrier materials of homeopathic medicinal products, this source is included in the HÜB in accordance with the relevant guide.

Distribution

ARTICLE 18 – (1) In the distribution of homeopathic medicinal products, it is obligatory to comply with the provisions of the Guide on Packaging and Homeopathic Medicinal Product Information, Readability and Follow-up of Homeopathic Medicinal Products. However, in the purchases to be made by official health institutions and organizations, some additional information may be used in the packaging information, provided that it is not contrary to this Regulation.

(2) Licensees; When shipping more than one homeopathic medicinal product, it uses transport packaging to ensure the reliability of these products. Transport packages can be as packages, parcels, boxes or ties and can be placed inside each other. The quantities contained in the transport packages are determined at reasonable levels to carry them from opening to the last point during the sale.

(3) An identifier containing the information identifying the transport package or an identifier containing all the data matrix information of the homeopathic medicinal products in the transport package must be found on the transport packaging. The identifiers to be placed on the transport packaging are applied as determined in the relevant legislation. Stakeholders can use the Package Transfer System to transfer these identifiers between them.

(4) In cases where there is a problem in data coding due to the characteristics of the packages of homeopathic medicinal products, the transport packages of homeopathic medicinal products that can be sold together in more than one quantity are data-coded as a product.

CHAPTER FIVE

Evaluation, Licensing and Placing on the Market of the License Application

Preliminary examination of the application

ARTICLE 19 – (1) The issue whether the application file submitted to the Agency for obtaining a license for a homeopathic medicinal product is a complete application in terms of the documents to be submitted according to the nature of the application and the electronic license application requirements shall be evaluated by the Institution by subjecting it to preliminary examination. This evaluation is made in the order of application date. However, the applications that are deemed appropriate to be evaluated as priority or high priority in the licensing procedures by the Priority Evaluation Board are carried out with priority.

(2) Necessary evaluation is made within thirty days after the application file reaches the Institute and the result is notified to the applicant. If the application is found to be incomplete, the applicant completes the deficiencies within thirty days. The second preliminary examination to be made after the deficiencies are completed and submitted to the Authority shall be concluded within thirty days.

Evaluation of the application and licensing criteria

ARTICLE 20 – (1) In the application, documents proving the safety and quality of the homeopathic medicinal product are examined scientifically and administratively.

(2) The criteria to be taken into account by the Agency regarding the product when issuing a homeopathic medicinal product license are as follows:

a) The quality has been demonstrated by appropriate technological and pharmaceutical properties.

b) Proven safety under the anticipated conditions of use.

c) The control tests performed to determine whether there is viral contamination in blood products prove that the product is safe and the source of the plasma used in the preparation of these products is notified.

licensing period

ARTICLE 21 – (1) The Institute officially notifies the applicant that the application has been accepted or rejected as a result of the preliminary examination. The notification that the application has been accepted is accepted as the beginning of the licensing process. The licensing process is finalized within the next two hundred and ten days. However, the time taken for the evaluations of institutions outside the Agency, the time for public holidays excluding weekends and the time for extraordinary situations are not included in the licensing period.

(2) In cases where additional information and documents are requested from the applicant during the licensing process, the licensing period is suspended until the relevant information and documents are obtained.

Procedural rejection of the application

ARTICLE 22 – (1) In the evaluation of the license application made by the Authority within the scope of this Regulation, if the following situations are detected, the application is rejected due to the procedure and returned to the owner:

a) Failure to complete the deficiencies regarding the first preliminary examination and not make the second application within the time limit, or failure to complete the deficiencies regarding the first preliminary examination in the second preliminary examination application.

b) Failure to submit the information and documents requested by the Institution, other than the preliminary examination process, or the information and date to be submitted, together with the explanation that such information and documents could not be submitted, to the Institution within thirty days at the latest.

c) Failure to pay the license fee within sixty days after the official notification to the applicant that the licensing process has been completed.

Fundamental rejection of the application

ARTICLE 23 –(1) The homeopathic medicinal product for which a license application has been applied is subjected to analysis. In case of nonconformity in the analysis, the analysis is repeated with the improved samples. If non-compliance is found in the second analysis, an evaluation meeting is held with the company representatives about the analysis method, and the analysis method of the new sample is determined and analyzed. If non-compliance is found in the third analysis, a final evaluation meeting is held with the company representatives, the analysis non-compliance is described, and the analysis is made for the last time by determining the new analysis method. Although the specified analysis steps are completed, the application is rejected on the merits in cases where the qualitative and quantitative formula inconsistency and the declared specifications are outside the acceptable limits.

(2) As a result of the evaluation of the documents and information submitted after the applicant is given the right of maximum three written and two verbal answers for each of the following situations in the evaluation process of the application;

a) The qualitative and/or quantitative composition cannot be explained within the framework of homeopathic rules, including the level of potentiation,

b) It may be harmful under normal use conditions,

c) Its quality is not adequately documented,

In the event that at least one of the conditions is detected, the license application is rejected on the merits.

Notification of the fundamental refusal of the application and objection

ARTICLE 24 – (1) In case of rejection of the license application on the merits, the decision shall be notified to the applicant with justification, or if the notification cannot be made, it may be announced on the website of the Authority. The applicant has the right to object to the Institute within forty-five days from the date of notification or announcement against the decision. If no objection is made within forty-five days, the application documents are returned to the owner. In case the applicant does not receive the documents back; The provisions of the Regulation on State Archive Services published in the Official Gazette dated 18/10/2019 and numbered 30922 are applied.

(2) The objection is evaluated by the Institute within ninety days and the result is notified to the applicant. During the evaluation of the objection, if deemed necessary, the applicant is given the right of oral explanation and defense.

(3) The decision made as a result of the evaluation of the objection is final and no objection can be made to the Institute regarding the said decision.

(4) The rejection of the application on the merits shall not prevent the applicant from re-applying for a license.

Granting the license

ARTICLE 25 – (1) As a result of the examination and evaluation of the documents submitted to the Institute by the applicant, a license is issued for the homeopathic medicinal products that are found to be in compliance with the issues stipulated in this Regulation and the applicant is informed.

(2) A second license shall not be granted to the same natural or legal person, even with a different trade name, for a homeopathic medicinal product licensed by the Agency and a product in the same pharmaceutical form, having the same composition and potency in unit dose in terms of homeopathic stock.

(3) The same natural or legal person cannot use a different trade name for homeopathic medicinal products with the same homeopathic stock, for different potency or route of administration or pharmaceutical forms.

(4) A homeopathic medicinal product license cannot be issued with the same name as a medicinal product for human use, traditional herbal medicinal product, products that can be offered for sale with a health claim, cosmetic products or food supplements already licensed or authorized by the Authority.

(5) Licenses, certificates and other internationally valid documents may also be prepared as physical documents by the Authority.

(6) The list of homeopathic medicinal products licensed by the Authority is announced on the official website of the Authority and in the Official Gazette once a year.

Post-registration variations

ARTICLE 26 – (1) With the exception of the provision of Article 33, after the homeopathic medicinal product is licensed, an application is made to the Agency by the registration holder in accordance with the provisions of the relevant guideline for all changes regarding this product.

(2) For a homeopathic medicinal product for which a license application has been made, applications for variations are not accepted except for administrative changes and mandatory conditions, except for the change in the product name.

(3) If the information and documents requested by the Institute for the variation application made pursuant to the first paragraph or the necessary explanations regarding the failure to submit such information and documents together with the date of submission are not submitted to the Institute within thirty days at the latest, the variation application loses its validity. In cases where the failure to apply the variation creates quality and safety problems for the relevant homeopathic medicinal product, the provisions of Article 28 shall apply.

(4) In case of an application, the Institution may give scientific advice to the applicant after the homeopathic medicinal product is licensed, subject to a fee included in the price schedule.

The validity period of the license

ARTICLE 27 – (1) Licenses issued for homeopathic medicinal products licensed by the Agency are valid indefinitely, provided that the obligations set forth in Article 31 are fulfilled by the license holder.

Suspension of license

ARTICLE 28 – (1) Regarding a licensed homeopathic medicinal product;

a) It is produced with a different content than the content that is the basis of the license,

b) Making changes in the content, potency, pharmaceutical form and packaging without the knowledge and/or approval of the Authority,

c) The registration holder does not take into account scientific and technical advances in terms of production and control methods, and the necessary changes are not made in order to ensure that the homeopathic medicinal product is produced and controlled with generally accepted scientific methods, or if a change has been made, this change is not submitted to the approval of the Authority,

ç) Disregarding the warning made for products that are found to be faulty as a result of market controls and continuing faulty production,

d) Failure by the license holder to respond to the Authority's instructions regarding the product within the time specified by the Authority,

e) It is determined that there are errors in the documents submitted in the application made in accordance with the provisions of this Regulation, which will affect the quality or safety of the product, or the documents submitted lose their validity,

f) The reasons presented by the license holder are not found appropriate by the Authority,

g) Decision to suspend the license as a result of the evaluation by the Authority of the notifications received within the framework of pharmacovigilance practices,

ğ) Determining the situations that require the suspension of the license in accordance with the provisions of the Regulation on the Safety of Medicines,

h) If it is determined that the production method and control methods used by the producer in subparagraphs (ğ) and (ı) of the first paragraph of Article 10 are not applied as specified,

ı) Not making or notifying the necessary updates in HÜB,

i) Provided that it is approved by the Authority, at least one commercial batch of a homeopathic medicinal product has not been put on the market within the first thirty months from the date of registration, except for the cases where it is not produced for a single country market or cannot be offered to the market in our country due to the size of the commercial batch,

j) At least one commercial batch of a licensed homeopathic medicinal product manufactured in our country and previously put on the market within the scope of data matrix application is in the domestic or foreign markets for an uninterrupted thirty months; For the product imported to our country, it is determined that it is not in the domestic market or the official documents showing that it has been put on the market for homeopathic medicinal products outside the scope of the data matrix application are not submitted to the Agency,

k) Failure to fulfill the obligations set forth in Article 31,

l) Failure to comply with the provisions regarding packaging information and homeopathic medicinal product information specified in this Regulation,

m) Failure to fulfill the commitments in subparagraph (c) of the first paragraph of article 32 within the time specified in subparagraph (a) of the first paragraph of article 29,

If at least one of the conditions is detected, the license of the homeopathic medicinal product is suspended by the Authority.

(2) Production or importation of a homeopathic medicinal product, the license of which has been suspended, for placing on the market, shall be stopped. Homeopathic medicinal products that have already been imported or produced cannot be placed on the market unless the Agency decides otherwise. The decision on the homeopathic medicinal products available in the market is made by the Authority, taking into account the reason for the suspension of the license.

(3) The Institution may make an exception from the application of subparagraphs (i) and (j) of the first paragraph for homeopathic medicinal products that may cause serious public health problems if they are not ready for use or are not needed at all in our country's market but are exported.

(4) The list of homeopathic medicinal products whose licenses have been suspended is announced on the official website of the Institution.

(5) In case the products whose licenses have been suspended for the reasons specified in subparagraphs (i) or (j) of the first paragraph are desired to be placed on the market again, an application is made to the Authority for the suspension of the license, with a commitment to put the product on the market within six months at the latest, in accordance with the procedures determined by the Authority. If approved by the Authority, the product license is suspended. For products that are not placed on the market within the promised period, a transaction is established in accordance with Article 29.

Cancellation of license

ARTICLE 29 - (1) In the presence of one of the following conditions, the license granted for the product is revoked:

a) Except for those listed in subparagraphs (i) and (j) of the cases listed in the first paragraph of Article 28, the documents proving the opposite of the reason for suspension are not submitted by the marketing authorization holder within six months at the latest, regarding the products whose license is suspended due to one or more of them. or the documents explaining the situation are not approved by the Institution.

b) The license holder's request and the Authority's approval, provided that there is no attachment or injunction notified to the Authority on the license.

c) The products are not placed on the market within the promised period pursuant to the fifth paragraph of Article 28.

(2) Production or import of a homeopathic medicinal product whose license has been revoked shall be stopped. The decision on the products currently on the market is taken by the Authority, taking into account the reason for the cancellation of the license.

(3) Licenses that are deemed suitable for cancellation according to subparagraph (b) of the first paragraph are announced on the official website of the Authority for a period of six months. The licenses in this situation are transferred, upon request, to real or legal persons who make a commitment to put the product on the market and meet the conditions for applying for a license set forth in this Regulation, provided that the application conditions for the transfer of license are met, upon the request of these persons and the consent of the license holder. The process of canceling the licenses for which transfer application has been made will not continue.

(4) The list of homeopathic medicinal products whose licenses have been revoked by the Authority is announced on the official website of the Authority.

Loss of license or product files

ARTICLE 30 – (1) In case the license given by the Agency is lost, the license holder makes an application to the Agency for a lost license with an announcement in the national newspaper showing that the license is lost. In this case, a new license is issued.

(2) In case the registration file of the homeopathic medicinal product for which a registration application has been made is lost, the applicant or the registration holder makes an application to the Agency for a lost registration file. A copy of the file is given to the applicant for applications whose justification is approved by the Institution.

Liability of license holder

ARTICLE 31 – (1) The license holder is responsible to the Institution regarding the homeopathic medicinal product for which he is licensed:

a) Producing the homeopathic medicinal product in accordance with the specifications given in the application annex and accepted by the Institution.

b) Taking into account scientific and technical progress in terms of production and control methods and submitting it to the approval of the Institution in order to make any necessary changes in order to ensure that the homeopathic medicinal product is produced and controlled by generally accepted scientific methods.

c) When there is any change regarding the homeopathic medicinal product, notifying the Institution of the relevant change within the framework of the provisions of the relevant guideline.

ç) Updating the HUB when necessary to ensure the correct and safe use of the homeopathic medicinal product.

d) Responding to the issues requested by the Institution about the homeopathic medicinal product in a timely manner.

e) Fulfilling the obligations specified in the Regulation on the Safety of Medicines within the framework of pharmacovigilance practices.

f) Ensuring the market availability of the homeopathic medicinal product for which it is licensed.

g) Notifying the Institution immediately with all the details of any measures taken regarding the suspension of the registration or withdrawal of the homeopathic medicinal product from the market.

ğ) Payment of determined fees and charges related to homeopathic medicinal products.

h) The permanent presence of a qualified person responsible for product safety and his/her representative within the scope of pharmacovigilance practices.

ı) Taking the necessary measures to prevent the infections that can be transmitted in case the homeopathic medicinal product is a biological medicinal product.

i) If herbal drugs or preparations are used as a homeopathic stock, the plant from which this stock is obtained is correctly identified and, where applicable, grown in accordance with good agricultural practices.

j) Due to the quality and/or efficacy and/or safety of homeopathic medicinal products imported, exported or produced in our country under license; Notifying the Authority of the suspension or cancellation of the license, its withdrawal from the market or its recall in other countries where it is licensed.

k) Fulfilling the obligations regarding the Pharmaceutical Track and Trace System in the relevant guide.

(2) The Authority may request the license holder to provide the HÜB in a suitable format for fully and partially visually impaired persons.

(3) The license or the applicant is obliged to make an application in accordance with the principles set forth in this Regulation and to confirm the accuracy of the information and documents submitted to the Institute, and accepts all kinds of responsibility arising from the results of such information and documents.

(4) The license or the applicant is responsible for keeping the originals of all documents submitted to the Authority regarding the product and submitting them to the Authority when requested.

(5) The registration of the homeopathic medicinal product does not affect the legal and penal liability of the license holder.

license transfer

ARTICLE 32 – (1) The registration of a homeopathic medicinal product licensed by the Agency can be transferred. The following documents are submitted to the Authority for license transfer procedures:

a) A court decision stating that the license has been transferred by the court, or the decision of the enforcement office that the license has been sold through forced execution, or the contract drawn up in the presence of a notary public and containing the following matters:

1) The name, registration date and number of the homeopathic medicinal product subject to the license transfer process.

2) Names and addresses of real or legal persons who will transfer the license and take over the license.

3) A report stating that the current homeopathic medicinal product file approved by the Institution, complete and updated, has been delivered to the transferee in full.

b) The following documents showing that the person transferring the license can fulfill all the responsibilities expected from the license holder:

1) For those who can apply for a license in Article 7, the original or notarized copy of the diploma showing that they belong to one of the professions specified, or the graduation certificate obtained from the Higher Education Council.

2) In case of being a legal person, the Turkish Trade Registry newspaper stating the partners of the company and the duties and titles of the responsible persons.

3) Documents related to the pharmacovigilance officer within the scope of the Regulation on the Safety of Medicines.

4) The document defining the science service within the scope of the Regulation on Promotional Activities of Medicinal Products for Human Use and the address, telephone number and KEP address of this service.

c) The name, surname, address, telephone numbers and KEP address of the person who has taken over the license, together with the updated HÜB of the homeopathic medicinal product, a copy of the inner and outer packaging, and the original of the previous license for the product in question, in case of transfers made through a notary public; In cases where the updated HÜB cannot be submitted, a fully prepared undertaking by the transferee stating that all necessary changes and updates regarding the product's HÜB will be made in line with the relevant guidelines after the product's license transfer process is completed, and that no sales permit application will be made without obtaining approval.

ç) In the case of importation of a homeopathic medicinal product, a document issued by the licensing company showing that the real or legal person making the import is the only authorized representative for the import, licensing and sale of the said product in Turkey.

d) In case the homeopathic medicinal product is produced under license, a document issued by the licensing company showing that the real or legal person making the production is the only authorized representative for the licensing, production and sale of the said product in Turkey.

e) In case the applicant is not a manufacturer for homeopathic medicinal products to be manufactured in Turkey, the contract for contract manufacturing with a manufacturer that meets the conditions specified in the Regulation on Manufacturers of Medicinal Products for Human Use.

(2) In addition to the documents listed in the first paragraph, the following matters are valid for transfers made through a notary public:

a) A letter of undertaking prepared by the transferee company stating that no changes were made regarding the homeopathic medicinal product during the transfer application must be submitted.

b) In the event that a letter of undertaking prepared by the transferee company, stating that all necessary changes and updates will be made regarding the homeopathic medicinal product will be made after the transfer, is submitted in full, the necessary updates regarding the existing product file and the actions to eliminate the deficiencies, if any, are carried out after the registration transfer of the product. After that, it is done in accordance with the relevant guidelines and it is not possible to apply for a sales permit without obtaining approval.

c) In case of demand; With the condition of a written and notarized agreement of the companies that transfer and take over the license, the products with old barcodes are allowed to be produced and put on the market only by the transferee company for a period of six months after the new license is issued. Control processes regarding the production notifications of the products in this situation are carried out through the Pharmaceutical Tracking System. These products can be found in the market until their expiration date. The supply of the transferred products to the market is stopped by the transferor company. Products with old barcodes can be imported by the transferor company for a period of six months after the new license is issued, provided that the companies that transferred and took over the license have a written and notarized agreement.

(3) In case the licensor changes the real or legal person authorized by the licensing firm regarding the licensing/sale/production of the product in question in Turkey, in addition to the documents listed in the first paragraph, a letter stating that the current license holder has returned the original license is submitted; When a court decision is presented showing that the current license holder has no authority, all the requirements in this article must be fulfilled, together with the current Module 1 file of the homeopathic medicinal product, except for subparagraph (a) of the first paragraph.

(4) The Authority evaluates the license transfer application within thirty days.

Transfer of license application

ARTICLE 33 – (1) The real or legal person applying for a license may transfer the rights arising from the application to another real or legal person by fulfilling the relevant conditions specified in Article 32.

Obtaining a sales permit

ARTICLE 34 – (1) Pursuant to the provisions of this Regulation, it is obligatory to obtain a sales permit for the homeopathic medicinal product to be licensed by the Authority and put on the market for the first time.

(2) Licensee; In case of carrying out the storage activities in the facilities belonging to its own real or legal entity, the document issued by the Institution, in other cases the document issued by the Institution regarding the storage place, the document signed between the parties for the storage of the product, the registration certificate of the parties, together with the sales permit application, shall be submitted to the Institution.

(3) The Institution examines all printed materials regarding the homeopathic medicinal product applied for sales permit for necessary information.

(4) It is not necessary to obtain a resale permit for transactions that lead to changes in the packaging information and/or characteristics and/or HÜB of the homeopathic medicinal product. However, after the transfer of the production place from abroad to our country or from our country to abroad, packaging size change, after the license transfer process and before the products whose license is suspended in accordance with the fifth paragraph of the 28th article, are put on the market; A sales permit must be obtained by applying to the Authority together with the documents specified in the second paragraph.

Marketing authorization of homeopathic medicinal products containing blood products

ARTICLE 35 – (1) The license/permit holder for blood products with a sales permit, for which a license has been applied for or for which a license has been applied, applies to the Authority to obtain a marketing authorization for each batch of the product, in addition to the issues in Article 34, before placing the product on the market.

(2) Before the marketing authorization, the analyzes determined according to the product for each batch of blood products or homeopathic medicinal products containing blood products and for each plasma pool used in these series must have been performed in the Institution's laboratory or in a laboratory accepted by the Institution for this purpose. However, in cases where the blood product is not included as a homeopathic stock in the content of the homeopathic medicinal product and the reasons for not providing the plasma pool are approved by the Institution; The analyzes determined according to the product for each batch of the homeopathic medicinal product, without seeking a plasma pool analysis, must be performed in the Institution's laboratory or in a laboratory accepted by the Institution for this purpose.

(3) In order to obtain a marketing authorization for blood products or homeopathic medicinal products containing blood products, the relevant homeopathic medicinal products can be placed on the market if the amount requested to be offered for sale and the documents and information specified below are submitted to the Agency and the analyzes made in accordance with the second paragraph and the aforementioned documents are approved by the Agency. presentation is allowed.

a) Name and content of the homeopathic medicinal product.

b) Serial release certificate issued by an accredited national or international laboratory for each batch of bulk or finished product (approved by apostille/consulate if the document is obtained from abroad).

c) The original of the analysis certificate approved by the technical manager of the production center for each batch.

ç) A document showing the amount of products sold, issued by the license holder and, where applicable, by the licensor company, showing in which countries each batch is sold or, in cases where the whole batch is imported to our country, in which countries/countries the plasma pools used in the relevant series are used.

d) The rules based on plasma donation, the date of collection of plasma and the type of donor (volunteer, paid) and the list of donors when necessary.

e) A document issued by an accredited national or international laboratory stating that the HBsAg, HIV ½ and HCV RNA tests of the samples belonging to each plasma pool were applied and the results.

f) For each series, a document issued by the manufacturer stating that the donors are safe in terms of suspected diseases or diseases determined by the Institution (such as Creutzfeld-Jacob (CJ) disease) and that there are no donors with these diseases among the donors.

g) The current variation commitment for the product whose serial number is specified, issued by the licensee and, where applicable, the licensor.

(4) For the homeopathic medicinal products that are intended to be imported as bulk product and put on the market by producing the finished product in our country, the third paragraph (a), (b), (c), (d), (In addition to the issues in e), (f) subparagraphs, the original document issued by the license holder and, where applicable, the licensing company, showing the countries where other products using plasma pools used in bulk products are licensed/produced and in which countries they are sold, must be submitted to the Authority.For blood products imported in bulk and produced in our country and licensed and licensed accordingly, all documents are submitted within the scope of this paragraph and only the commitment expressed in subparagraph (g) of the third paragraph is submitted, provided that the analyzes made in accordance with the second paragraph and the relevant information and documents are approved. market release is allowed.

CHAPTER SIX
Miscellaneous and Final Provisions

Confidence

ARTICLE 36 – (1) In the evaluations within the scope of the provisions of this Regulation, the Institution may take into account the evaluations made by the official health authorities of the countries.

Promotion

ARTICLE 37 – (1) The promotion of products within the scope of this Regulation is subject to the Regulation on Promotional Activities of Medicinal Products for Human Use.

Guides

ARTICLE 38 – (1) Guidelines for the implementation of this Regulation are prepared by the Authority and published on the official website of the Authority.

security

ARTICLE 39 – (1) The information submitted to the Agency by the applicant to obtain a license for a homeopathic medicinal product is confidential. This confidentiality is protected by the Institution under the provisions of the relevant legislation.

Retraction

ARTICLE 40 – (1) The provisions of the Withdrawal Regulation published in the Official Gazette dated 19/11/2015 and numbered 29537 shall be applied for the recalls and withdrawals of the products that are subject to withdrawal from the products within the scope of this Regulation.

Administrative sanctions

ARTICLE 41 – (1) In case it is determined that homeopathic medicinal products are sold in channels other than pharmacies, action is taken in accordance with Article 18 of the Law.

Elimination of doubts

ARTICLE 42 – (1) The Institution is authorized to eliminate hesitations regarding the implementation of this Regulation, to regulate and direct the implementation.

Force

ARTICLE 43 – (1) This Regulation enters into force on the date of its publication.

Executive

ARTICLE 44 – (1) The provisions of this Regulation are executed by the President of the Turkish Medicines and Medical Devices Agency.