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REGULATION ON VETERINARY MEDICINAL PRODUCTS

CHAPTER ONE

Purpose, Scope, Legal Basis and Definitions

Purpose

ARTICLE 1 - (1) The purpose of this Regulation is to determine and to set out the practices for manufacturing, importation, exportation, use, packaging, labeling, promotion, transportation, storage and sales with or without prescriptions, marketing control and supply of veterinary medical products.

Scope

ARTICLE 2 –(1) This Regulation shall apply to veterinary products that are prepared industrially or employing industrial methods for placing on the market, veterinary medicated premixes produced for use in medicated feeding stuffs, active substance used as starting materials and substances having anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties.

(2) When identifying a product as a veterinary medical product, the provisions of this Regulation shall apply, if anything suspicious has occurred in respect of properties or this definition conflicts with another definition provided in any other legislation.

(3) This Regulation shall not cover the following products:

a) Medicated feeding stuffs prepared using veterinary medicated premixes,

b) Veterinary medical products based on radioactive isotopes,

c) Additives incorporated into animal feeding stuffs,

ç) Products prepared in a pharmacy according to the prescription of a veterinary, commonly known as a magistral formula, for a particular or group of animals or according to an official formula and criteria laid down in an applicable pharmacopoeia for direct delivery to the end user, notwithstanding the conditions applicable to availability, prescription and administration,

d) products intended for use in line with research and development objectives, provided that all regulations concerning human, animal and environmental health are exactly observed,

e)**(Abrogated:OJ-20/12/2014-29211)**

(4)**(Abrogated:OJ-20/12/2014-29211)**

Legal Basis

ARTICLE 3 –(1) This Regulation has been drawn up,

a) **(Amended:OJ-11/1/2013-28525)**[1] In reference to Sections 3, 4, 12, 13, 14, 31, 32, 34, 36, 37, 43 and 47 of the Law on Veterinary Services, Plant Health, Feed and Feeding Stuffs Law, numbered 5996, dated 11/6/2010; and the Clauses 6, 7, 27 and 28 of the Decree-Law Governing the Organization and Duties of the Ministry of Food, Agriculture and Livestock, numbered 639, dated 3/6/2011; and Section 5 of the Law on Professional Veterinary Conduct, Manner of Establishment and Authorized Duty-Frames of the Turkish Union of Veterinary Surgeons and their Chambers, numbered 6343, dated 9/3/1954; and Section 4 of the Law for the Preparation and Implementation of Technical Legislation governing Products, numbered 4703, dated 29/6/2001, and

b) By way of derogation from Directive 2001/82/EC of the European Parliament and of the Council on Veterinary Medical Products, Directive 2004/28/EC of the European Parliament and of the Council amending Directive 2001/82/EC on the Community code relating to veterinary medical products, Commission Directive 2009/9/EC amending Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to medical products for veterinary use, and the Commission Directive 91/412 laying down the principles and guidelines for good manufacturing practice for veterinary medical products.

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Definitions

ARTICLE 4 –(1) The following abbreviations and terms mentioned herein shall have the following meanings;

a) Ministry: shall mean the Ministry of Food, Agriculture and Livestock;

b) Starting materials: shall mean any substance or material used for the manufacture of a product, other than packaging materials;

c) **(Amended:OJ-20/12/2014-29211)** Bulk product: shall mean any liquid, semi-solid, solid powder or granular pharmaceutical products, which are carried inside the special carrying containers with large volume in order to be used at the further process steps or to be put into the primary packaging,

ç) Outer packaging: shall mean the packaging into which the immediate packaging is placed;

d) Institute Directorate: shall mean either, or, where used in plural form, all of the Veterinary Control Central Research Institute, other Veterinary Control Institute Directorates and the Food and Mouth Diseases Institute Directorate;

e) Off-label use: shall mean the use of a veterinary medical product that is not in accordance with the summary of the product characteristics as included in the packaging leaflet or label thereof;

f) Label/Labeling: shall mean any written information supplied in printed form on both the immediate and outer packaging of a product, as required by the related Ministry, about the product;

g) Active substance: shall mean any pharmaceutical active substance used for preventing animals from diseases, treating or modifying physiological functions of animals in a desired

way and/or fixing organic and functional disorders in animal organisms or diagnosing a disease;

ğ) Pharmacovigilance: shall mean efforts pursued for the determination, assessment, identification and prevention of adverse reactions and other potential problems associated with products or use thereof;

h) Directorate General: shall mean the Directorate General of Food and Control;

ı) Immediate packaging: shall mean the container coming in direct contact with the pharmaceutical form or containing the agents and excipients that collectively constitute the pharmaceutical form of a product;

i) Provincial Directorate: shall mean the Provincial Directorate of Food, Agriculture and Livestock;

j) District Directorate: shall mean the District Directorate of Food, Agriculture and Livestock;

k) **(Amended:OJ-20/12/2014-29211)** Adverse effect: shall mean the hazardous effects or adverse events that are observed in animals, humans or the environment, as a result of use of a product improperly and not in accordance with the product labeling and leaflets;

l) **(Abrogated:OJ-20/12/2014-29211)**

m) Generic medical product: shall mean a product that has the same qualitative and quantitative composition, in terms of agents, same pharmaceutical form with the reference product, the bio-equivalence of which is proven by bio-availability tests;

n) Withdrawal period: shall mean the period necessary between the last administration of the veterinary medical product to animals, under normal conditions of use and in accordance with the provisions of this Regulation, and the production of foodstuffs from such animals, in order to protect public health by ensuring that such foodstuffs do not contain residues in quantities in excess of the maximum residue limits for active substances laid down pursuant to applicable laws;

o) Law: shall mean the Law on Veterinary Services, Plant Health, Food and Feeding Stuffs, numbered 5996;

ö) Micro-organism culture: shall purport a population which is reproduced from a certain bacteria, mushroom, virus or protozoa species and consisted of these living organisms;

p) Auto-vaccine: shall mean any vaccine prepared from cultures of micro-organisms isolated from an animal to be administered to the same or other animals sharing the same environment with the animal from which it is isolated;

r) Marketing authorization holder: shall mean any natural person or legal entity, public agency or organization, that is in possession of authority to manufacture, import or export and place the products in the market;

s) Marketing authorization manager: shall mean any person designated and delegated by the marketing authorization holding natural persons or legal entities, public agencies and organizations in relation to their products;

ş) Marketing authorization: shall purport the certificate drawn by the Ministry for enabling the manufacture, importation, introduction to the market, storage and administration of a product according to the product requirements as adopted and imposed by the Ministry;

t) Periodical safety update reports: shall mean the set of reports that contain safety information obtained in the field as regards the product and have to be notified at regular time intervals designated by the Ministry;

u) Package leaflet: shall mean the leaflet containing information for the user that accompanies the medical product or is inserted into the packaging thereof;

ü) Prescription: shall mean the document, laid down in writing and properly dated and undersigned by a veterinarian to the attention of a pharmacist who is authorized to sell veterinary medical products or of another veterinarian, which includes the personal identification data and residence information as well as degree or diploma number of the issuing veterinarian, as well as information regarding the animal and its location, in addition to recommended areas of application and administrative dosages and methods of use;

v) Reference medical product: shall mean any product duly licensed for introduction to the market or authorized for marketing for the first time in the world, upon proofing of its scientific acceptability, efficacy, quality and safety at required levels, for the aspects of active substance(s);

y) Health-Care professional: shall mean any veterinarian, pharmacist or member of health-care staff in assistance thereof;

z) Sales authorization: shall mean a document, issued by the Ministry, to render a product for which marketing authorization has already been granted capable of being placed on the market after it is manufactured or imported;

aa) Batch: shall mean a defined quantity of starting material, packaging material or product processed in one process or series of processes so that it could be expected to be homogeneous;

bb) Branch: shall mean a workplace founded upon written authorization of the Ministry to pursue activities as a veterinary pharmaceutical warehouse, under the same trade name of the original Ministry-licensed veterinary pharmaceutical warehouse but subject to liability and instructions of another responsible manager;

cc)**(Amended:OJ-11/1/2013-28525)**[1] Representative pharmaceutical warehouse: shall mean any veterinary pharmaceutical warehouse established in order to to store veterinary medical products with marketing authorizations, and to perform such services as insertion of package leaflets, labels/labeling, price tags and other similar ancillary packaging services;

çç) Diagnostic kit: shall mean the reagents containing such immunologic agents that are used to diagnose or measure a disease or immunologic condition;

dd) Commercial name: shall mean the name given to the product;

ee) Manufacturing site: shall mean the location where the product is released for placing on the market as ready for use;

ff) Product: shall mean the veterinary medical product,

gg) Veterinary Biological Product Surveillance Center: shall mean the functional or departmental unit designated by the Ministry to carry out the surveillance checks and controls applicable to authorizations granted for veterinary biological products;

ğğ) Veterinary biological product: shall purport to products such as vaccines, serums and etc., prepared for creating active or passive immunity, measuring the state of immunity or diagnosing a disease or health disorder in animals;

hh) Veterinary pharmaceutical warehouse or warehouse: shall mean pharmaceutical warehouses which pursue activities related with wholesale dealing in veterinary medical products exclusively, under direct responsibility of a licensed pharmacist or veterinary surgeon;

ıı) Homoeopathic veterinary medical product: shall mean any veterinary medical product prepared from substances called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the country;

ii) Premix for medicated feeding stuffs: shall mean any veterinary medical product prepared in advance with a view to the subsequent manufacture of medicated feeding stuffs;

jj) Veterinary medical product surveillance center: shall mean the functional or departmental unit designated by the Ministry to carry out the surveillance checks and controls applicable to authorizations granted for veterinary biological products or within the framework of regular scheduled checks and controls;

kk) Veterinary medical product: shall mean the products and veterinary biological products which contain active substances made ready for use after passing through all production stages, for use in or administration to animals;

ll) Excipient: shall mean the substances used for preserving active substances in the desired pharmaceutical form and for desired periods, as well as enabling their safe and effective use and in creation of the product's pharmaceutical form;

nm) Assisting health-care services staff: shall mean any animal health-care technicians, veterinary health-care technicians or laboratory assistant whose main duty is to be of help to the veterinarian in time of, as well as carrying out sundries for accomplishment of procedures during the delivery of animal health service;

nn) **(Amended:OJ-20/12/2014-29211)** Competent pharmacovigilance service institution: shall mean the institution/organization, which has been authorized by the Ministry and which has been established in order to provide service for pharmacovigilance activities;

oo) **(Insertion:OJ-20/12/2014-29211)** Competent pharmacovigilance manager: shall mean the personnel, who carries out the pharmacovigilance works within the organization of the pharmacovigilance service institution which has been authorized by the Ministry.

CHAPTER TWO

Marketing Authorization

General requirements

ARTICLE 5 – (1) No veterinary medical product may be placed on the market, warehoused or administered in any form or manner whatsoever, unless a marketing authorization has been issued by competent authorities in accordance with the second paragraph of Section 12 of the Law and the provisions hereof.

(2) When a veterinary medical product has been granted an initial authorization in accordance with the first paragraph, any additional species, strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions, shall also be granted an authorization by the Ministry in accordance with the first paragraph or be included in the initial marketing authorization.

(3) The marketing authorization holder shall be responsible for the marketing of the medical product. The designation of a representative shall not relieve the marketing authorization holder of his legal responsibility.

(4) A veterinary medical product intended for use in food-producing animals may not conflict with applicable laws on residue limits of veterinary medical products in foodstuffs of animal origin. **(Insertion:OJ-11/1/2013-28525)** Authorizations of any products, which become on contrary due to any amendments/changes to the legislation, shall be subjected to a re-assessment within sixty days as of the date of any such amendment/change to the legislation.

(5) **(Amended:OJ-11/1/2013-28525)[(1)]** The Ministry may grant temporary authorizations for importation or manufacturing at the location, for which a manufacturing authorization has been granted by the Ministry, of the products or product starting materials which do not have any marketing authorization as described below. In such case, there shall be no product, for which a marketing authorization has been granted in Turkey, in replacement of the product for use. However, the requirement for non-availability of any product, for which a marketing authorization has been granted in Turkey, may not be sought for any products donated within the best knowledge of the Ministry. **(Amended sentence:OJ-20/12/2014-29211)** Such products, for which any temporary authorizations have been granted, may not be subject to trading.

a) Products or starting materials necessary for identification of efficacy, safety and pharmaceutical quality aspects of products pending an initial marketing authorization.

b) **(Amended:OJ-20/12/2014-29211)** Products or starting materials intended for use in research and development activities to be conducted at universities and such other public entities and organizations.

c) Products or starting materials intended for use on any animals at any protection areas or rehabilitation centers belonging to any public organizations and institutions, universities, foundations and associations carrying out activities in relation to any animal species in danger of extinction, or in relation to wildlife.

ç) Products or starting materials donated from abroad to be used at animal shelters and treatment and care locations belonging to municipalities, associations and foundations.

d) Products or starting materials intended for use in research and diagnostic activities to be conducted at laboratories or veterinary faculties approved by the Ministry.

e) Products or starting materials intended to be used on the animals, corresponding to the activities specified in the first paragraph of section 10 of the Law, or at any activities in relation to protection, recovery or development of any gene resources by any real or legal persons.

f) Products or starting materials intended to be used due to any of the reasons specified in the sixth paragraph of section 12 of the Law.

g) Products or starting materials intended to be used on any animals brought from abroad for any activities such as circus, fairs or racing purposes.

(6) **(Amended:OJ-11/1/2013-28525)[1]** In case of occurrence of any serious disease epidemic threating animal life, where there is no authorized medical product for that condition in existence or available to be used against such epidemic, or if the existing products are not capable of fulfilling the need, then the Ministry may grant temporary authorization for use of the below given products. **(Abrogated sentence:OJ-20/12/2014-29211) (…)**

a) Products authorized for use in another animal species or indication.

b) Products which can be manufactured at the manufacturing sites that are approved either by the Ministry, or the Ministry of Heath, and the products which are authorized at the other countries.

c) if there is no product as referred to in points (a) and (b), of a medical product authorized for use in human beings in accordance with the applicable legislative acts relating to medical products for human use.

(7) The provisions of paragraph six shall apply provided that the medical product, where administered to food-producing animals, should contain active substances meeting the requirements of legislative acts relating to residue limits of veterinary medical products in foodstuffs of animal origin. Unless the medical product used indicates a withdrawal period for the animal species concerned, the specified withdrawal period shall not be less than seven days for eggs and milk, twenty-eight days in meat from poultry and mammals including fat and offal, and five hundred degree-days in meat from fish. These periods may be increased by the Ministry, in case of requirement. **(Insertion:OJ-11/1/2013-28525)[1]** However, in respect of any homeopathic products and active substances, such period may be reduced to zero days, provided that such products and substances are in conformity to the legislation regarding the limits of residue at foodstuffs of animal origin.

(8) In the event that the products referred to in paragraph six above is used, then the Ministry may take special precautionary measures, or ask the related parties to comply with certain requirements with regard to importation, distribution, possession and use of the products.

(9) If an animal is being imported from, or exported to, a third country and is thereby subject to specific binding health rules, then the Ministry may permit the use, for the animal in question, of an immunological veterinary medical product that is not covered by a marketing authorization in the country in question but is authorized under the legislation of the third

country. Special permission of the Directorate General should be sought and obtained, for importation and use of immunologic medical products of the type concerned.

(10) **(Amended:OJ-11/1/2013-28525)**[1] The Ministry may, upon request, grant authorization for exportation of the products exclusively for exportation purposes. In respect of manufacturing and controlling of any products or bulk products manufactured for exportation purposes, the request of the concerned buyer shall be taken into account. Such products may not be used within the borders of the country. Controlling and responsibility for such products shall be incumbent on the manufacturing site, the authorization holder, the buyer and the country thereof.

(11) The Ministry may authorize importation or exportation of authorized products in bulk, provided to the extent that this would not have any adverse effects on the efficacy, safety or harmlessness of the product.

(12) **(Amended:OJ-20/12/2014-29211)** No additional marketing authorization shall be granted to a product that has the identical formula and identical pharmaceutical form with another product previously granted with marketing authorization in the name of the same marketing authorization holder.

(13) No marketing authorization can be granted to different persons for products which are proprietary to the same person staying on abroad and which contain identical active substance in identical quantities, and have the same pharmaceutical form.

(14) The owner of a product, the marketing authorization of which has been revoked for reasons specified under this Regulation, may not lodge any marketing authorization or takeover applications for another product containing same active substance in same quantities, and having same pharmaceutical form, unless after one year of such revocation.

(15) **(Insertion:OJ-11/1/2013-28525)**[1] **(Amended:OJ-20/12/2014-29211)** Inactivated auto-vaccines, which are manufactured from antigens or pathogens obtained from the animals from the same region for use in prevention or treatment at a farm at the same region, shall be excluded from the scope of the marketing authorization.

(16) **(Amended:OJ-20/12/2014-29211)** The decision as to whether marketing authorization would be obtained for any live auto-vaccines manufactured from antigens or pathogens obtained from the animals available at the farms or poultry-houses at the same region for use in treatment of a disease occurring in that region shall be made by the Directorate General.

Persons eligible for lodging marketing authorization applications

ARTICLE 6 – (1) The marketing authorization shall be granted to the natural and legal persons described in the third paragraph of section 12 of the Law.

(2) Legal persons or public entities and organizations may obtain marketing authorization by appointing one of the professionals specified in first paragraph of this Article as the marketing authorization manager. The natural persons described in the third paragraph of section 12 of the Law shall be deemed as marketing authorization managers.

(3) **(Amended:OJ-20/12/2014-29211)** In order for qualifying for pursuing activities in marketing authorization covered by this Regulation, natural or legal persons shall obtain

certificates of authorization for engagement with veterinary medical products, from the Ministry.

(4) The marketing authorization holders should obtain a sales authorization certificate, before placing their products on the market.

Certificate of Authorization for Engagement

ARTICLE 7 – (1) Both natural and legal persons shall lodge applications with the Directorate General, in order to obtain veterinary medical product engagement authorization certificates, accompanied by the following information and documents;

a) **(Amended:OJ-11/1/2013-28525)**[(1)] A petition covering the Republic of Turkey ID Number, and the declaration of residence, work telephone number and the fax number and the e-mail address of the marketing authorization manager.

b) Where the applicant is a legal person, original copy of the labor contract of the related professional, as approved by a notary public, which clearly states that he is employed as a marketing authorization manager and in such capacity, will be in charge of activities falling within the framework of related legislative acts,

c) In case of legal persons, a valid and up-to-date certificate obtained from related public agency, indicating that the marketing authorization managers appointed for duty therein are insured according to the effective laws, and currently working for such persons,

ç) **(Amended:OJ-11/1/2013-28525)**[(1)] An up-to-date and valid certificate of registration to the professional chamber given by the professional chamber, to which the marketing authorization manager is registered, and if there is no any such chamber for that profession, then the copy of the diploma or certificate of graduation of such person, two passport photographs and the circular of signature of the same,

d) If the applicant is a legal person, a commercial registry excerpt denoting the registered address of the company, founding objectives, partnership structure and people in charge of governance of the company, giving their respective duties, titles and signature authority frames,

e) Information on the applicant's product recall plan in order to recall products from the market and people responsible for implementing the same,

f) **(Amended:OJ-11/1/2013-28525)**[(1)] Photocopies of the valid and up-to-date certificates pertaining to the total quality management system, or the photocopy of the documents describing the intra-company quality assurance systems, all covering any other matters, deemed appropriate by the marketing authorization holder, as well as the documentation regarding increase of customer and employee satisfaction, decrease of costs, creation of a hight competitive power, prevention of errors, and establishment of the documentation, records and archive as required by the relevant legislation, in respect of the activities of the marketing authorization holder in relation to the veterinary medical products.

(2) If one of the owners or partners of the applicant in the form of a legal person has appropriate degree of major and professional title in the area of concern, and is further appointed to be the marketing authorization manager, then the labor contract as approved by a notary public shall not be required.

(3) **(Amended:OJ-11/1/2013-28525)[1]** Holders of certificates shall be obliged to notify the Ministry of any potential change in the information based on which, the engagement authorization certificates are drawn, in no later than thirty days of such effect. Any finding or determination of failure by the certificate holders to notify such changes within the specified period of time or of any attempted or actual falsification or fraud will lead to immediate suspension of the engagement authorization certificates of the holders, along with subsequent discontinuation of their activities covered by the scope of this Regulation.

(4) The marketing authorization manager will have to notify the Ministry, of his resignation, all in one month of his quitting office. If he fails to do so and this fact is ascertained, the marketing authorization manager in default will not be permitted by the Ministry to assume office as a manager in charge of veterinary medical products for two years to advance upon his resignation or departure from office.

(5) Legal person certificate holders will have to lodge with the Directorate General, a valid and up-to-date letter of the Social Security Institution, which demonstrates that their respective marketing authorization managers continue to hold this position in January of each year. Those certificate holders failing to make this notification shall be warned and given a period of one month to comply. Those, who fail to make the notification sought within the aforementioned time allowance, will have their certificates suspended, and their activities covered by the scope of this Regulation shall be ceased.

Marketing authorization procedures

ARTICLE 8 – (1) **(Amended paragraph:OJ-11/1/2013-28525)[1]** The application shall be submitted to the Directorate General, with a file covering the below given details and documents. The application file shall be drawn up and prepared in accordance with the applicable guidelines.

a) A valid copy of certificate of authorization for engagement,

b) name or business name and permanent address or registered place of business of the person responsible for placing the veterinary medical product on the market and, if different, of the manufacturer or manufacturers involved, and of the sites of manufacture,

c) name of the veterinary medical product,

ç) qualitative and quantitative particulars of all the constituents of the veterinary medical product, using the usual terminology, and giving the international non-proprietary name recommended by the World Health Organization, where such a name exists,

d) description of the method of manufacture,

e) therapeutic indications, contra-indications and adverse reactions,

f) dosage for the various species of animal for which the veterinary medical product is intended to be used, its pharmaceutical form, method and route of administration and proposed shelf life, and any pharmacovigilance details and precautions, if any,

g) explanations of the precautionary and safety measures to be taken when the product is stored, when it is administered to animals and when waste therefrom is disposed of, together

with an indication of any potential risks the medical product might pose to the environment and the health of humans, animals or plants,

h) indication of the withdrawal period and a tolerance level for residues which may be accepted in foodstuffs without risk for the consumer, together with routine analysis methods which could be used by the Directorate General to trace residues, to be proposed and justified by the applicant,

ı) description of the control testing methods employed by the manufacturer,

i) results of following tests, as undersigned by people the technical and professional qualifications of which are proven in data supplied on resumes and further proven scientifically:

1) physico-chemical, biological or microbiological tests,

2) Safety and residues tests,

3) pre-clinical and clinical trials,

4) tests for assessment of environmental impacts.

j) a summary of the product characteristics, one or more specimens of the sales presentation of the veterinary product together with the package insert,

k) **(Amended:OJ-20/12/2014-29211)** Certificate of Good Manufacturing Practice (GMP) issued or accepted by the Ministry, for the manufacturing sites of the products,

l) **(Amended:OJ-20/12/2014-29211)** If the products are authorized abroad, a summary of the product characteristics and/or proposed texts of package inserts/ product labeling, certificates of free sale issued concerning the product, justification of reasons if the product is authorized but not yet placed on the market and details of any decision to refuse authorization, in any jurisdiction and the reasons for that decision,

m) **(Amended:OJ-20/12/2014-29211)** If substances of animal origin are employed for the manufacture of a certain product, a certificate drawn to the effect that such ingredients are totally appropriate in terms of any pathogens specified by the Ministry,

n) **(Amended:OJ-20/12/2014-29211)** If the products are authorized abroad, the list of countries in which the product is placed on the market and letter of authorization issued by the proprietor of the product seated on abroad, to demonstrate that the applicant is the sole authorized agent for the product within the territory of Turkey, duly devised with exclusive rights concerning importation of the product to Turkey, obtaining of marketing authorization and placing the product on the market.

o) **(Insertion:OJ-20/12/2014-29211)** In case of contract manufacturing, the agreements executed by and between the parties.

(2) **(Amended:OJ-20/12/2014-29211)** If the products are authorized abroad, certificates specified in points (ç), (k) and (l) above should be approved by the competent authorities of the relevant country responsible for marketing authorization and control of the products, with signatures and seals affixed further verified by a Turkish consulate or diplomatic mission operating in that country. If the aforementioned documents are approved by another person or

organization authorized by the competent authorities, then an official letter will be required from such competent authorities, for verification of capacities of the approving person or organization to do so. These documents shall be submitted along with their certified Turkish translations.

(3) The Ministry may either bring new standards to or require observance of internationally recognized standards in studies concerning the products or laboratories to host the same.

Studies concerning the Product

ARTICLE 9 – (1) **(Amended:OJ-20/12/2014-29211)** Provided that provisions of the Decree/Law No. 551 of 24/6/1995 on Protection of Patented Rights are reserved, the applicant shall not be required to provide the results of the safety and residue tests or of the pre-clinical and clinical trials if he can demonstrate that the medical product is a generic of a reference medical product. A generic veterinary medical product authorized pursuant to this provision shall not be placed on the market until six years have elapsed from the initial authorization of the reference product. However, the six-year period provided above shall be extended to nine years in the case of veterinary medical products for fish or bees or other minor species. In the case of veterinary medical products intended for one or more food-producing species, the six-year period provided above shall be extended by one year for each extension of the marketing authorization to another food-producing species, if it is authorized within the five years following the granting of the initial marketing authorization. This period shall not, however, exceed a total of nine years, for a marketing authorization for four or more food-producing species.

(2) The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information intended to provide proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorized active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bio-availability studies need not be required of the applicant if he can demonstrate that the generic medical product meets the relevant criteria as defined in the appropriate detailed guidelines.

(3) In cases where the veterinary medical product does not fall under the definition of a generic medical product, or, where bio-equivalence cannot be demonstrated through bio-availability studies or in the case of changes to the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration vis-à-vis the reference medical product, the results of the appropriate safety and residue tests and pre-clinical tests or clinical trials shall be provided.

(4) Where a biological veterinary medical product which is similar to a reference biological veterinary medical product does not meet the conditions in the definition of generic medical products, owing to, in particular, differences relating to raw materials or in manufacturing processes of the biological veterinary medical product and the reference biological veterinary medical product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The type of supplementary data on and file for the veterinary medical product to be provided must comply with the relevant criteria stated in the respective

guidelines and the related notes of detailed guidelines. The results of other tests and trials from the reference medical product's dossier shall not be provided.

(5) **(Amended:OJ-11/1/2013-28525)[(1)]** With the exception of point (i) of the first paragraph of Article 8 of this Regulation, results of safety and residue tests or of pre-clinical tests or clinical trials may not be sought, if it is demonstrated that the active substance has been in well-established veterinary use for ten years, with recognized efficacy and an acceptable level of safety, as per the requirements specified in the product file, and by being supported by appropriate scientific literature.

(6) If an applicant makes use of scientific literature to obtain authorization for a food-producing species, and submits, in respect of the same medical product and with a view to obtaining authorization for another food-producing species, new residue studies, together with further clinical trials, it shall not be permissible for a third party to use such studies or such trials, for a period of three years from the grant of the authorization for which they were carried out.

(7) In the case of veterinary medical products containing active substances used in the composition of authorized veterinary medical products but not hitherto used in combination for therapeutic purposes, the results of safety and residue tests, if necessary, and new pre-clinical tests or new clinical trials relating to that combination shall be provided. However, it shall not be necessary to provide scientific references relating to each individual active substance.

(8) After the marketing authorization has been granted, the marketing authorization holder may allow use to be made of the pharmaceutical, safety and residues, pre-clinical and clinical documentation contained in the file for the veterinary medical product with a view to examining a subsequent application for a veterinary medical product having the same qualitative and quantitative composition in active substances and the same pharmaceutical form.

(9) By way of derogation from point (i) of the first sub-paragraph of Article 8, and in exceptional circumstances with respect to immunological veterinary medical products, the Ministry may not require the applicant to provide the results of certain field trials on the target species if these trials cannot be carried out for duly substantiated reasons.

(10) **(Amended:OJ-11/1/2013-28525)[(1)]** The Ministry may not request some of the requirements, information and documents, which are demanded for the other products, during granting of a marketing authorization for the products to be used for aquarium fish, cage birds, homing pigeons, terrarium animals, small rodents, and ferrets and rabbits kept exclusively as pets.

(11) **(Insertion:OJ-11/1/2013-28525)[(1)]** Provided that the other provisions of this Regulation, and the provisions of the regulations regarding the residue limits of foodstuff of animal origin are reserved; the Ministry may implement a dedicated and simplified authorization process only for the homeopatchic veterinary medical products which meet all of the below listed requirements;

a) The administration method of which is available in the European Pharmacopeia or in any other official pharmacopeia used at any other country,

b) Any products which do not have any therapeutic indication specified on its veterinary medical product label or at any other information source,

c) Any products, for which a dilution degree sufficient for guaranteeing safety of the product, in particular those which are not denser than 1/10.000 as per the main tenture.

(12) **(Insertion:OJ-11/1/2013-28525)[(1)]** In respect of any homeopathic products, for which it is claimed that there is a therapeutic indication, or which do not correspond to the products described in the eleventh paragraph; the ordinary authorization procedure shall be applied. The Ministry may not seek some of the information, documents and studies, demanded for the other products, for any homeopathic products, which could not be included to the dedicated simplified authorization procedure, or which will be used for pets or exotic species, and may bring out some special requirements thereto. Dedicated simplified authorization procedure may be implemented for various homeopathic veterinary products derived from the same homeopathic stock or stocks. The below listed details shall be provided regarding the product with the purpose of ensuring the pharmaceutical quality of the products, and ensuring that each batch has the same homogeneity;

a) Names of the homeopathic stock or stocks, either scientific or specified in the pharmacopeia; details about any probable administration routes of the same; and the pharmaceutical form and dilution rate of the same.

b) Detailed information about how the homeopathic stock or stocks is/are obtained and controlled, evidence about the homeopathic nature, and how it is ensured that there is no pathogens in the homeopathic products containing biologicals.

c) Manufacturing and controlling protocol and dilution and potantiation description for each pharmaceutical form.

ç) Manufacturing authorization for the relevant medical product.

d) The certified copies of any licenses or authorizations granted by any other country for the same medical product.

e) One or more samples of immediate and/or outer package, mock-ups of the product.

f) Data regarding the stability of the product.

g) The suggested/proposed withdrawal period along with all necessary verification.

Summary of product characteristics

ARTICLE 10 – (1) The summary of the product characteristics shall contain, in the order indicated below, the following information;

a) name of the veterinary medical product followed by the strength and the pharmaceutical form;

b) qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the medical product. The usual common name or chemical description shall be used;

c) pharmaceutical form;

ç) clinical particulars;

1) target species,

2) indications for use, specifying the target species,

3) contra-indications,

4) special warnings for each target species,

5) special precautions for use, including special precautions to be taken by the person administering the medical product to the animals;

6) adverse reactions (frequency and seriousness),

7) use during pregnancy, lactation or lay,

8) interaction with other medical products and other forms of interaction,

9) amounts to be administered (dosages) and administration route,

10) overdose (symptoms, emergency procedures, antidotes), if necessary,

11) withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero;

d) pharmacological properties:

1) pharmacodynamic properties,

2) pharmacokinetic particulars;

e) pharmaceutical particulars:

1) list of composition,

2) major/important incompatibilities,

3) shelf life, when necessary after reconstitution of the medical product or when the immediate packaging is opened for the first time,

4) special precautions for storage,

5) nature and composition of immediate packaging,

6) special precautions for the disposal of unused veterinary medical products or waste materials derived from the use of such products, if appropriate;

f) Names and addresses of the marketing authorization holder and the manufacturer,

g) first, subsequent revision and renewal dates of marketing authorization,

ğ) Restrictions on sale/release/use of the medical product to be added.

(2) Applicants shall ensure that the detailed and critical summaries referred to in the (i) sub-paragraph of Article 8(1) are drafted and signed by persons with the requisite technical or professional qualifications, set out in a brief curriculum vitae, before being submitted to the competent authorities. Persons with the technical or professional qualifications referred to

above shall justify any use made of the scientific literature in accordance with the file relating to the veterinary medical product. A detailed curriculum vitae of the persons referred to above shall be appended to the detailed critical summaries.

Label/Labeling and Package Leaflets

ARTICLE 11 – (1) **(Amended:OJ-20/12/2014-29211)** All veterinary medical products granted with a marketing authorization should be presented to the market together with a Ministry approved package leaflet and label. However, this requirement may be ignored by the Ministry for products with each package of which package leaflet may not physically be provided.

(2) **(Amended:OJ-20/12/2014-29211)** No modifications can be made in any approved package leaflet and labeling, unless with consent of the Ministry.

(3) Products not complying with the requirements covered in this Article shall be deemed as faulty.

(4) The immediate packaging and outer packaging of veterinary medical products shall bear the following information, which shall conform with the summary of product characteristics, and shall appear in legible characters:

a) the words "For Animal Treatment Only",

b) the name of the medical product, followed by its strength and pharmaceutical form,

c) qualitative and quantitative composition of the veterinary medical product, expressed in active ingredients per dose-unit or as a percentage, according to the pharmaceutical form,

ç) If required, statement of names and quantities of excipients,

d) Purpose of Use in brief or treatment class,

e) the species of animal for which the veterinary medical product is intended, the method and, if necessary, the route of administration,

f) if necessary, symptoms of intoxication and antidote,

g) brief warning on times needed to elapse for veterinary medical products that are authorized for use in foodstuffs, to lower down to maximum permissible residue levels depending on the types of foodstuffs,

ğ) warnings, "Read the leaflet before use" and "Keep out of reach of children",

h) Storage conditions and if desired, symptoms of deformation,

ı) If required, information on how to dispose the packaging or leftovers thereof, at the end of use,

i) form of commercial presentation,

j) Location and terms of sale,

k) Marketing authorization date and number,

l) Name and address of marketing authorization holder,

m) name and address of the manufacturing site,

n) If required, the license owner,

o) If required, symbol or figure relating to the animal species,

ö) Batch number,

p) **(Amended:OJ-20/12/2014-29211)** Expiry date and/or date of manufacture,

(5) If the above mentioned information cannot fit in the space provided for their placement as a whole or it becomes necessary to use typeface in too small points that makes reading difficult, certain paragraphs/sections that are deemed ignorable for health may be removed from labeling, provided that such removal is authorized by the Ministry.

(6) For such small packages as ampoules or small containers on which it is impossible to give the particulars above, inclusion of the following information shall be deemed sufficient, save, however, that the immediate packaging is presented within an outer packaging and the product is delivered with a leaflet:

a) Name and strength of the veterinary medical product,

b) Active ingredients expressed quantitatively,

c) Route of administration,

ç) Batch number,

d) Expiry date,

e) the words “For Animal Treatment Only”

(7) **(Amended:OJ-20/12/2014-29211)** All information shall be presented in Turkish. Upon request, the Ministry may authorize sales of products with multilingual leaflets or labeling, containing text in Turkish. Any technical details available in the multilingual labeling are required to be consistent the Turkish labeling details. For products authorized abroad, veterinary medical products may be placed on the market with Turkish versions of their labeling juxtaposed over those prepared in the original language of the exporting country and with leaflets authorized abroad and prepared in Turkish. In the event that the practice of Turkish interior labeling will have negative impacts on the product, then the Ministry may authorize that details of interior labeling are not in Turkish, provided that the product is provided along with a Turkish outer packaging and/or leaflet.

(8) Where no outer packaging is provided, all information contained in the leaflet should be shown on the container (i.e. bottle) and if this is not practically possible, appropriate measures be taken to ensure that a package insert is delivered with every shipment of a veterinary medical product.

(9) The leaflets shall at least include the following information, in accordance with the file relating to and characteristics of authorized veterinary medical product:

a) the words “For Animal Treatment Only”,

b) name of the veterinary medical product and its strength, and a term describing the animal species in which it is intended for use or the word “veterinary”,

c) Pharmaceutical form,

ç) Therapeutic effect,

d) Composition

e) pharmaceutical particulars:

f) Area of application, indications of use, time, interval, dosing rates and target animal species,

g) Specific technical data and special precautions for target species,

ğ) Undesirable effects,

h) Interaction with other medicaments and other forms of interaction (i.e. compatibility and incompatibility etc.)

ı) Overdose (symptoms, emergency procedures, antidotes),

i) times needed to elapse and other precautions to be taken for veterinary medical products that are authorized for use in foodstuffs, to lower down to maximum permissible residue levels depending on the types of foodstuffs,

j) contra-indications,

k) common warnings such as “Consult a veterinarian before use”, “Keep out of reach of children” , and “Consult a veterinarian upon an unexpected effect.”

l) Special precautions to be taken by the person administering the medical product,

m) Special precautions for storage and shelf life,

n) Special precautions for the disposal of unused medical product or waste material and on non-target species,

o) Sales presentation form showing the packaging qualitatively and quantitatively,

ö) Location and terms of sale,

p) Date on which the leaflet is approved,

r) Marketing authorization date and number,

s) Name and address of the marketing authorization holder

ş) Manufacturer’s name and address.

(10) The leaflets and labeling of homeopathic veterinary medical products may only include the following information:

a) the words “homeopathic medical product for veterinary use”, in clearly legible form,

b) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the pharmacopoeia taken as reference in manufacture of the medical product,

c) name and address of the marketing authorization holder and, where appropriate, of the manufacturer,

ç) method of administration and, if necessary, route,

d) Expiry date,

e) Pharmaceutical form,

f) contents of the sales presentation,

g) special storage precautions, if any,

ğ) target species,

h) a special warning if necessary for the medical product.

ı) Batch number,

i) Marketing authorization date and registration number,

(11) The Ministry may require that information which are essential and based on data obtained at a later time and symbols for the tracking system be included in package leaflets and labeling, in addition to the information described above. This also applies to previously approved package leaflets and labeling.

(12) No photographic imagery or pictures may be included in labeling and leaflets. However, medical products for veterinary use in non-food-producing animals and with special methods of administration may be excluded. Besides the corporate emblem or logo, labeling may include animal figures indicating the species in which the medical product can be used. The Ministry may render inclusion of certain symbols or figures in the leaflet or labeling, mandatory.

Prescriptions

ARTICLE 12 – (1) For the purpose of enforcement of this Regulation, veterinary medical products are divided into to categories as those available with and without prescription.

(2) Those products that bear the following characteristics will be available with prescription:

a) those products subject to official restrictions on supply or use,

b) those products which have narrow safety ranges and may pose threats against human, animal and environmental health, even if used in accordance with the information supplied on labels,

c) those products which are used in or administered to food-producing animals and particularly cause residues,

ç) Those products the preparation of which is ordered by veterinarians from pharmacists,

d) Those products which are suitable for use beyond their intended use, due to their properties,

e) Those products which require or cause major modifications that may effect the diagnosis or treatment,

f) Those products, the active substances of which are placed on the market for a period less than five years.

(3) Save provisions of the second paragraph above are reserved, the Ministry may grant authorization for the sales without prescription of veterinary medical products that are appraised to be free of any potential health-related risks, eligible for routine use and not abusable, after a thorough assessment of the various aspects of the product such as the quantities of active substances in each unit, route of administration and toxicological effects.

Naming for purposes of Trade

ARTICLE 13 – (1) The following requirements shall duly be taken into consideration, when assigning names to veterinary medical products, for trading purposes:

a) Names may not contain misleading statements about product characteristics.

b) **(Amended:OJ-20/12/2014-29211)** Disease names, pathogens and symptoms thereof may not be used in place or as part of trade names. For the biological products; strain, serotype or disease names as well as abbreviations thereof may be used.

c) Active substances contained in the product may not be used as a stand-alone trade name. However, the names of active substances may be assigned as the trade name of the products containing them, accompanied by the trade name or business title of the marketing authorization holder.

ç) **(Amended:OJ-20/12/2014-29211)** A trade name originally given to an already authorized medical product or to a product the marketing authorization of which has been revoked may not be used in any other medical product, except those of the marketing authorization holder which bear the same name but have different pharmaceutical form and priorly granted with an authorization. However, those medical products the marketing authorizations of which have been revoked on consent or request of the authorization holders, and which have not yet been placed on the market are excluded.

d) The proposed trade name of the medical product for veterinary use shall be assessed by the Ministry. The Ministry may require a change in the names as proposed, in cases of necessity.

e) Provided that compliance with the provisions hereof is sustained, trade names proposed by the marketing authorization holder may be accepted. However, the registered intellectual property rights attached to names obtained from competent authorities and Ministry's right to action for avoidance of doubt between the names of other products are hereby reserved.

(2) The Ministry may require the modification or replacement of a particular or group of names or expressions indicative of the strengths of authorized veterinary medical products, which are not consistent with the requirements laid down herein. No charges or fees shall be applicable to procedures relating to modifications and replacements of names as required by the Ministry.

Pre-investigation of application files

ARTICLE 14 – (1) The files submitted by applicants for obtaining marketing authorization for their medical products for veterinary use shall first be assessed by the Directorate General for order and integrity of their administrative content, through a pre-investigation.

(2) The pre-investigation shall be concluded in no later than thirty days of first receipt of the application dossier by the Ministry. Those dossiers found qualifying and eligible at the end of this pre-investigation will further be submitted to the Committee for evaluation.

(3) In the event of defects or inconsistencies found in an application dossier, the applicant shall immediately be informed on the situation through a notice in writing given to the same in no later than fifteen days of completion of pre-investigation. The applicant will then supply the missing information and/or make good inconsistencies so discovered, all within ninety days. If he fails to make up and complete the information and documents he is expected to furnish within such period of time, the applicant will have his application dossier returned.

(4) Once the defects and inconsistencies found during the pre-investigation stage are totally eliminated and the files submitted to the Directorate General as complete, the pre-investigation will be finalised in thirty days. Those dossiers found qualifying and eligible will be submitted to the Committee for evaluation. In case of defects or inconsistencies found in an application dossier at this stage, it will be returned to its original owner, without further process.

Examination of Application Dossiers

ARTICLE 15 – (1) The application dossiers verified and approved for integrity and order of administrative content as a result of the pre-investigations held at the Directorate General shall be further processed and finalised all within two hundred and ten days upon written notification of the applicants of the fact that they are being submitted to the committee. This period is exclusive of the extra time granted to the applicant during the pre-investigation stage, time consumed to performance of analyses on products and time required for obtaining opinions from other entities and organizations.

(2) During the procedure for marketing authorization, the Ministry:-

a) shall check that the documentation submitted in support of the application complies with the requirements laid down in above and, on the basis of the reports drawn up by the experts, ascertain whether the conditions for the issue of the marketing authorization have been fulfilled;

b) may submit the medical product, its raw materials and if necessary intermediate products or other constituent materials for testing by a State laboratory or by a laboratory designated for that purpose, in order to ensure that the testing methods employed by the manufacturer and described in the application documents, in accordance with point (i) of the first paragraph of Article 8, are satisfactory.

c) shall check appropriateness of analytical detection method proposed by the applicant for establishment of residues by entering in a comprehensive exchange of information with related organizations.

(3) The Ministry may, where appropriate, require further information. In this case, the time-limit of two hundred and ten days shall be suspended. Likewise, if the applicant is required to provide verbal or written clarifications, this time-limit shall be suspended until the further data required have been provided.

(4) The Ministry may perform audits at premises where the testing and controls have been performed, with a view to ensure that exported veterinary medical products are manufactured and/or their control testing is performed in compliance with this Regulation.

(5) At the end of the audits mentioned above, the application for marketing authorization shall be refused and the fact, immediately informed in writing to the affected applicant with appropriate justification, if:-

a) It becomes apparent that the veterinary medical products, led particularly by products mainly intended for use in animal husbandry, for which a market authorization is being sought would alter the balance between risks and benefits against favor of the animal health and welfare and consumer safety,

b) the veterinary medical product for which marketing authorization is sought is found to be either ineffective or less than capable of delivering the immunity it is intended to confer,

c) it is ascertained that the formulation would not be appropriate and in approved quality for pharmaceutical aspects,

ç) no benefit is assessed in the product's offering for public use,

d) it is ascertained that the length of the withdrawal period would be insufficient to successfully eliminate any risks directed against the health of the animal to be treated and of the public consuming the food produced from that animal or any situation to the otherwise cannot be proven,

e) The dossier is found as not having been compiled in accordance with the relevant guidelines,

f) The medical product for veterinary use is meant for a prohibited area of use,

g) legal preparations are in progress for providing coverage for the protection of public health, consumer and animal health.

(6) The Directorate General shall grant the marketing authorizations to applicants whose applications were evaluated successful, along with delivery of approved forms of leaflets and/or package labels. The Directorate General shall publish a brief summary of characteristics of the product for which it has granted a marketing authorization, as well as the product itself, at its official website.

(7) The Directorate General may, in exceptional cases and in consultation with the applicant, render the grant of marketing authorization conditional upon fulfillment by the applicant of a requirement concerning the safety of the product and immediate notification of any adverse event occurring with its use and indication of necessary measures in response thereto. Recourse may be made to such procedures for granting of marketing authorizations for objective and demonstrable reasons.

Committee for evaluation of veterinary medical products

ARTICLE 16 – (1) The Ministry will set up and implement a committee from among people having specialized knowledge on medical products for veterinary use, to evaluate, assess and direct marketing authorization applications made in respect thereof. **(Abrogated sentence:OJ-20/12/2014-29211)** (…)

(2) The Committee will carry out the following duties:

a) Establish its own working and decision-making rules,

b) Evaluate and assess and draw and submit proposals for refusal, revocation and/or suspension of and/or changes in other relevant matters concerning applications associated with veterinary medical products,

c) Make out and communicate opinions about products used or usable in veterinary medicine,

ç) Actively participate in joint efforts for drawing legislative acts to govern and regulate medical products and instruments for veterinary use,

d) Where appropriate, desirable or necessary, evaluate modifications or changes relating to veterinary medical products,

e) Fulfill such other similar duties as may from time to time or at any time be assigned to it by the Ministry.

(3) **(Amended:OJ-20/12/2014-29211)** The Committee shall convene at least six times a year.

(4) Decisions as regards the marketing authorization applications will be taken by and among those members of the committee having reviewed the application dossiers based on simple majority of votes. Dissenting opinions, if any, will be put on record in the minutes of each respective meeting.

(5) On consent or request of the Ministry, the market authorization holder or applicant or his qualified representative may join the committee to submit opinions in relation to the medical product being under evaluation.

(6) The Committee may seek information, documents or opinion, in courtesy, from competent authorities of the states in which the medical products for veterinary use, for which marketing authorizations have been granted or are in progress have been manufactured or hold a valid and legitimate marketing authorization, as well as international organizations, universities and research institutions known to conduct studies or activities in the domain. The Committee may send invitations to people to be assigned by such entities and organizations as aforementioned to join it in any of its meetings.

(7) The Committee will render its decisions, so as to confer upon whether acceptance and granting of marketing authorization to application files or acceptance and granting of marketing authorization, after any imperfections or inconsistencies found in application dossiers are made good and without the need for re- or further consideration thereof or refusal of applications.

(8) Decisions thus made will immediately be notified in writing to the applicant by the Directorate General all within ten days following the relevant session of the committee meeting. The applicants shall be obliged to follow up the status of their applications, throughout the entire process. In the event that no objections are brought against a decision rendered by the Committee within a period of two months advancing upon the date of award or the committee decision is not enforced properly and promptly or any notice or notification given in confirmation of this fact in writing within the same period, the application dossiers not physically retained by the Directorate General shall be returned to their owners. Costs of

consignment service for return delivery of the aforesaid documents shall be borne by the respective applicants.

(9) The Committee will grant the necessary amount of time extension to the applicant as needed to allow it fulfill and enforce the decision taken. In case of failure of the applicant to fulfill and enforce the decision taken by the Committee within such extended time or, within original time, as the case may be, without any request moved for an extension, the applications will be returned back to the applicants Application files remaining outside the Directorate General shall be returned to their owners. Costs of consignment service for return delivery of the aforesaid documents shall be borne by the respective applicants.

Sales authorization, pharmacovigilance manager and competent pharmacovigilance service institution

ARTICLE 17 – (Amended along with the heading:OJ-20/12/2014-29211)

(1) The marketing authorization holders will assign and appoint a veterinarian, who serves on full time basis within its organization, to be their respective pharmacovigilance manager to carry out and finalize pharmacovigilance studies and related efforts concerning their products, with a view to obtain sales authorizations, or will have the pharmacovigilance service institution, authorized by the Ministry, carry out such studies. In the event that such pharmacovigilance services are ensured to be carried out by any competent service institution, then the following principles shall be applicable.

a) In case of procurement of the service from any competent authority, the marketing authorization holders will assign and appoint a veterinarian, who serves within its organization, to be their respective pharmacovigilance manager.

b) The labor contract for procurement of services, as approved by a notary public, will be submitted to the Ministry.

c) Procurement of services shall not relieve the marketing authorization holder of her/his respective liability.

ç) Competent pharmacovigilance service institutions shall notify the Ministry of the termination of the labor contract, within a period of thirty days. Pharmacovigilance service institutions, which have failed to make the notification as aforementioned within the permitted time frame, shall be first warned about the matter, and in case of repetition thereof, the authorizations of the service institution shall be canceled.

d) In case of termination of the service procured from any competent pharmacovigilance service institution, the marketing authorization holders shall notify the Ministry of the matter, within thirty days following termination of the service. The sales authorizations granted to all veterinary medical products of the marketing authorization holders, which have failed to make the notification as aforementioned within the permitted time frame, and which do not assign and appoint a new pharmacovigilance manager, shall be suspended, and market release authorization shall not be granted for the veterinary medical products until a new manager is duly elected and appointed to fill the position.

(2) Competent pharmacovigilance service institutions shall carry out the following matters in respect of their activities.

a) Competent pharmacovigilance service institutions shall assign and appoint a veterinarian, who serves on full time basis within its organization, to be their respective pharmacovigilance manager to carry out pharmacovigilance studies on behalf of the marketing authorization holders.

b) The procedures and principles of operation of the competent pharmacovigilance service institutions and the matters regarding their audits are required to comply with the guidance drawn up by the Ministry.

c) Pharmacovigilance service institutions, whose activities are suspended, or whose authorizations are canceled, shall be announced by the Ministry.

(3) The marketing authorization holders and the competent pharmacovigilance service institutions shall apply to the Directorate General with such information and documents as hereinafter delineated, in relation to their pharmacovigilance managers, who will serve within their organization:

a) A petition covering the Republic of Turkey ID Number, residence declaration, work telephone and fax numbers and e-mail addresses of the pharmacovigilance manager/competent pharmacovigilance manager,

b) Where the applicant is a legal person, original copy of the labor contract of the related professional, as approved by a notary public, which clearly states that he is employed as a pharmacovigilance manager/competent pharmacovigilance manager and in such capacity, will be in charge of activities falling within the framework of related legislative acts,

c) In case of legal persons, a valid and up-to-date certificate obtained from related public agency, indicating that the pharmacovigilance managers/competent pharmacovigilance managers appointed for duty therein are insured according to the effective laws, and currently working for such persons,

ç) The up-to-date and valid certificate of registration to the professional chamber, to which the pharmacovigilance manager/competent pharmacovigilance manager is registered, and two passport photographs and the circular of signature of the same.

(4) If one of the owners or partners of the applicant in the form of a legal person has been appointed to be the pharmacovigilance manager/competent pharmacovigilance manager, then the labor contract as approved by a notary public shall not be required.

(5) Pharmacovigilance managers should be selected from among the individuals other than the responsible manager and the people assuming responsibilities for production and quality control at manufacturing sites as well as the marketing authorization manager. The pharmacovigilance and marketing authorization manager of the products, which are used in case of procurement of service from any competent pharmacovigilance service institution, or for the animals that are non-food producing, may be the same person. If the marketing authorization holder for veterinary medical products is also the owner of the manufacturing site where the product is being manufactured, then permission can be granted for the same person to fulfill the positions of both pharmacovigilance and marketing authorization manager of the same manufacturing site, having due regard to the number of marketing authorizations held and volumes of sale realized. The marketing authorization holder may appoint different persons for assuming responsibilities for different medical products. The Ministry may

require, by mandate, the appointment of more-than-one persons to assume responsibilities depending on the number of authorized medical products for which a sales authorization is sought.

(6) If the information and documents supplied on the pharmacovigilance manager/competent pharmacovigilance manager are found in compliance with the requirements laid down herein, the Directorate General shall issue a certificate in the name of the marketing authorization holder/pharmacovigilance service institution and manager. Such certificates may replace the documents sought under second paragraph hereof, in time of subsequent applications.

(7) The pharmacovigilance manager/competent pharmacovigilance manager will notify the Ministry, of his resignation, all in one month of his quitting office. If he fails to do so and this fact is ascertained, the pharmacovigilance manager in default will not be permitted by the Ministry to assume office as manager in charge of veterinary medical products for two years following his resignation or departure from office.

(8) If the pharmacovigilance manager/competent pharmacovigilance manager resigns from office, the marketing authorization holders will have to inform the Ministry in later than one month of his departure from office, in addition to elect and appoint another person to replace his position. Otherwise, the sales authorizations granted to all veterinary medical products of the marketing authorization holder shall be suspended; and market release authorization will not be granted for the veterinary medical products until a new manager is duly elected and appointed to fill the position; and operating authorizations of the service institution shall be suspended until a new manager is duly elected and appointed to fill the position.

(9) Legal person authorization holders will lodge with the Directorate General, a valid and up-to-date letter of the Social Security Institution, which demonstrates that their respective pharmacovigilance managers/competent pharmacovigilance managers continue to hold this position in January of each year. Those authorization holders failing to make this notification shall be warned and given a one month period to comply. New sales authorizations for products of those marketing authorization holders, who have failed to make the notification as aforementioned within the permitted time frame, shall be retained; and placement on the market of the veterinary medical products for which sales authorizations have been granted shall be ceased, if and when required; and the operating authorizations of service institution shall be suspended.

Issues of Sales Authorizations for veterinary biological products

ARTICLE 18 – (1) **(Amended sentence:OJ-20/12/2014-29211)** The marketing authorization holders will file separate applications with the provincial directorate, for each batch of biological veterinary medical products, which are manufactured in Turkey, or import quantities of each batch of biological veterinary medical product manufactured abroad, for use during checks and inspections for the granting of sales authorizations prior to placement of the products on the market, along with:

a) an application letter wherein the product packaging and dosage amounts for administration, the batch number and expiry date of the product are specified,

b) photocopy of the document issued by the Directorate General for the pharmacovigilance manager,

c) the certificate of analysis belonging to the medical product from which prepared samples are to be taken in pursuance with the instructions of the Ministry.

(2) As a result of examination of application files, the officials of the provincial directorate will take samples from the medical products in question, acting in line with the guidelines to be provided by the Ministry.

(3) The officials of the provincial directorate shall then send the samples they have taken to the Biological Veterinary Medical Product Surveillance Center, along with applicable certificate of analysis and other forms specified in the guidelines. Costs of consignment service for return delivery of the aforesaid documents shall be borne by the respective applicants.

(4) Following examination of the certificates of analysis issued to and testing of samples from the medical product having been sent, at the Biological Veterinary Medical Product Surveillance Center upon completion of other necessary assessments, those medical products which are found eligible will receive issues of sales authorizations by the institute directorate with which the aforesaid Center is affiliated.

(5) Medical products of the type described herein, the samples of which have not been subjected to tests and controls at the Biological Veterinary Medical Product Surveillance Center shall be tested and verified for compliance by another institute directorate to be appointed by the Ministry. The Institute Directorate performing the tests and controls shall draw up a report that shows product compliance and submit the same to the Biological Veterinary Medical Product Surveillance Center. The sales authorizations for products included in such report as aforementioned will be granted by the institute directorate with which the foregoing Center of Surveillance is affiliated.

(6) Also, the report showing the tests conducted on the product(s) for granting of sales authorization and their respective results and findings shall be sent to the applicant, together with the sales authorization. Information on products for which a sales authorization has been granted will be communicated to the Directorate General.

(7) As regards the sales authorizations of products not being subjected to tests and controls for the granting of sales authorization at the Biological Veterinary Medical Product Surveillance Center or another Institute Directorate, the tests and controls to be performed at testing and control laboratory premises of the manufacturer will be attended physically by a veterinarian appointed by the Biological Veterinary Medical Product Surveillance Center, as an observer. The sales authorizations for products validated at this stage will be granted by the institute directorate with which the foregoing Center of Surveillance is affiliated.

(8) **(Amended:OJ-11/1/2013-28525)[(1)]** The reports on products found non-compliant at the end of quality controls performed for the granting of the sales authorization shall be sent to the marketing authorization holder. If the marketing authorization holder raises an objection within seven days following the date of service of notification of the report, then the product may be subjected to a second control. The results of a second control to be performed consequent to such objection shall be deemed final and binding. Products found non-compliant shall be disposed of under supervision of personnel of the provincial directorate. If the product has been imported, and upon request of the marketing authorization holder, any non-conforming products may be returned to the country where they have been sent from. A

duly signed and approved photocopy of the record on the disposal procedure shall be communicated to the Institute Directorate to which it is affiliated.

Issues of sales authorizations for other veterinary medical products

ARTICLE 19 – (1) **(Amended:OJ-20/12/2014-29211)** The sales authorizations to be granted for medical products other than biological veterinary medical products in respect of each different commercial presentation form before initial placement on the market shall be issued by the Directorate General.

(2) Market authorization holders will apply to the Directorate General with ready-made samples of the product, if required, once the quality control results become available for manufactured or imported medical products. The Directorate General shall examine the application and instruct the provincial directorate of the place where the products are found to conduct sampling for testing for validation and control, from supplied product batches. **(Insertion:OJ-20/12/2014-29211)** The products, a different commercial presentation form of which has been analyzed previously, may not be re-analyzed if it is deemed appropriate by the Ministry.

(3) The Directorate General will issue sales authorizations for products found to be compliant at the end of these controls.

(4) Results concerning those products found to be non-compliant shall be notified to the authorization holder. Any objections to be raised against the results shall be subjected to an assessment in accordance with Article 85 of this Regulation. The ownership of the medical products which have been found non-compliant at the end of tests and analyses shall pass to the State for their due disposal. The Ministry shall grant a second opportunity for marketing authorization holders to obtain sales authorizations for their medical products for veterinary use. If the resultant findings of the secondary tests and controls performed on the said products yield negative, then the marketing authorizations readily granted for the same products shall be revoked, and the title of existing batches will pass to the State for their due disposal. The charges of tests and controls conducted for the granting of sales authorizations shall be borne solely by the marketing authorization holders, at their own risk and account.

(5) Following the initial sales authorization, the sales authorizations for each batch of products either manufactured or imported from other countries shall be issued by the marketing authorization manager. The marketing authorization manager will perform the whole set of checks and controls as necessary before placement of the product on the market, guaranteeing that the product meets all the requisites for authorization and has undergone all administrative and technical processes specified in relation to it. The marketing authorization manager should keep the sales authorizations granted for each batch for a period of at least five years and make information relating to each batch available for inspection by the Ministry, on request.

(6) **(Insertion:OJ-20/12/2014-29211)** The Ministry will have each batch of the products, to which the certificates of Good Manufacturing Practice have not been granted by the Ministry, or which have been manufactured at the facilities situated at the countries that have not executed a mutual-recognition agreement, analyzed as in the first batch, before placement of each batch of such products on the market, if and when so required.

Liabilities of the marketing authorization holder

ARTICLE 20 – (1) In addition to strictly observing the provisions of all applicable laws and regulations in effect, the marketing authorization holder will particularly be liable for:

a) informing the Ministry in writing at a suitably prior time, on each and every change it plans to cause in the information and documents originally submitted for the granting of marketing authorization,

b) providing response to the Ministry within periods allowed for the purpose, whenever information is requested on the product by the latter,

c) Informing the Ministry of any updates in the world concerning the use, restriction or revocation of the veterinary medical products and starting materials,

ç) Retaining in safe custody and permanently up-to-date, in such a way that allows tracking and inspections for five years of any and all records required by the Ministry and furnish the same with any and all kinds of information and documents requested, in a timely manner,

d) ensuring that samples are taken by the Ministry as desired for testing and controls,

e) manufacturing or having manufactured in accordance with the information supplied in time of the granting for marketing authorizations for veterinary medical products, carrying out or letting others carry out the quality checks and controls of each manufactured batch and keeping a close track of all contemporaneous scientific and technical progress related with these matters and adapting to them, when necessary,

f) Affording the supply of necessary materials as required by the Ministry for identification of residues and for the performance of quality controls on veterinary medical products,

g) Once after the placement of the veterinary medical product on the market, carrying out any and all activities concerning efficient and safe use of the product, especially tracking the adverse effects of the products, putting on record the resultant findings and complaints and reviewing and evaluating reports and their findings with a view to communicate the results to the Ministry and owners of the complaints, if applicable,

ğ) Paying the charges and fees as ascertained by the Ministry for application to grants of authorizations, amendments caused therein, certificate renewals, reviews and controls,

h) Ensuring that the products retain anticipated quality and are dispensed in appropriate conditions,

ı) If required, providing specialized technical support in relation to analytic methods applicable for testing and analyses of the products and their residues,

i) **(Amended:OJ-11/1/2013-28525)[(1)]** Ensuring that samples, at the quantity determined by the Ministry, from each batch manufactured or imported, are retained,

j) Ensuring that any products, which are unusable or which have become deprived of being usable, are disposed of in accordance with the relevant regulations.

(2) The granting of a marketing authorization for a particular veterinary medical product by the Ministry shall not release or relieve the marketing authorization holder from any liabilities

or obligations. The liabilities and obligations referred shall continue to be in effect also after placement of the product on the market.

(3) The responsibility for authenticity and validity of all information and documents submitted to the Ministry shall rest with the applicant.

(4) **(Amended:OJ-20/12/2014-29211)** Any change or modification in the products authorized abroad shall be immediately notified to the Ministry.

CHAPTER THREE

Manufacturing Sites of Veterinary Medical Products

Authorization requirement

ARTICLE 21 – (Amended:OJ-20/12/2014-29211)

(1) The manufacturing processes of veterinary medical products shall be carried out in compliance with the marketing authorizations at manufacturing sites authorized pursuant to the provisions of this Regulation. However, at manufacturing sites holding valid licenses issued by the Ministry of Health, veterinary medical products can be manufactured, with the exception of biological ones, within the framework of the marketing authorization granted, provided that the Ministry is informed about the activity. The veterinary medical products available in the categorization of the external ectoparasites, may be manufactured at the facilities, which have obtained authorizations for manufacturing the plant protection products, provided that the requirements specified under the good manufacturing practices guidance are satisfied.

(2) At manufacturing sites authorized by the Ministry, no other goods than veterinary medical products can be manufactured.

(3) The manufacturing authorization may be granted to any manufacturing sites, where all activities for the pharmaceutical ingredients and finished products are carried out, as well as to any facilities, where one or several of the manufacturing processes such as manufacturing of bulk products, filling, partition, auxiliary packaging activities, quality control and batch release is/are conducted.

(4) The requirements of good manufacturing practices shall be sought upon the stage of pre-clinical development within the life cycle of any veterinary medical product. However, the authorization for site works of any veterinary medical product, which is at the stage of research and development, will be obtained from the Ministry. The Ministry may grant authorization to the manufacturing sites in respect of importation of veterinary medical products, active substances, packaging materials, microorganism culture, in order to be used during the research and development activities.

(5) The areas covered by the manufacturing authorization may not be used for the activities such as veterinary pharmaceutical warehouse and retail sales points.

(6) The facilities, where the products for which a marketing authorization has been granted in Turkey are manufactured, including the ones for exporting purposes, as well as the personnel and activities of such facilities should comply with the good manufacturing practices guidance for veterinary medical products.

Responsible manager

ARTICLE 22 – (1) Manufacturers intending to obtain manufacturing authorizations for their manufacturing sites or premises should appoint and ensure employment, on a full-time regular basis, of a responsible manager having received satisfactory formative training and field experience in one of the professional categories specified in Section 12 of the Law. The responsible manager should provide documentary proof of the facts that he has worked for at least two years in a manufacturing site or premise that produces medical products for human or veterinary use under a valid and effective authorization and that he actually possesses experience and knowledge in areas relating to quality testing of products and quantitative analyses and controls of starting materials.

(2) The manufacturing site authorization holder may fulfill the tasks and responsibilities defined for the position of responsible manager himself, if he meets or exceeds the above mentioned requisites.

(3) The responsible manager shall mainly be liable for:

a) ensuring the conduct of all activities within the site or premise in compliance with the applicable laws,

b) ensuring the due and complete keeping of records led by dates of production, names of products, quantities supplied and names of recipients and manufacturer's batch numbers,

c) ensuring that all products manufactured possess the required levels of quality and characteristics as specified in the marketing authorization file and for the purpose, guaranteeing that all tests and analyses are performed.

Granting of Authorization

ARTICLE 23 – (1) Whoever intends to obtain a manufacturing authorization for medical products for veterinary use shall apply to the Ministry, together with the following information and documents:

a) Full address,

b) Site location on the city or town plan, if available,

c) Building and floor plans,

ç) Commercial Registry papers indicating the registered domicile of the corporate applicant, its founding objectives, partnership structure and responsible people together with description of their respective duties, positions, titles and signatory capacities,

d) Sketches illustrating production flow charts (the class of ventilation provided will be marked on the sketches)

e) information on activities performed at the manufacturing facility,

f) detailed information on production and pharmaceutical forms being manufactured,

g) listings of machinery, equipment and instrumentation employed for such activities as production, quality control and etc.,

ğ) particulars of the plumbing and ventilation system, together with a sketch layout.

(2) Applications qualified at the end of the examination will receive preliminary manufacturing site authorization, while, for those not qualified, the applicants will be informed of the non-conformities and defects found.

(3) Those applicants who have managed to obtain a preliminary manufacturing authorization will complete and submit to the Ministry, in the attachment of their applications covering their representations that they will carry out their manufacturing procedures in strict compliance with good manufacturing practices, to obtain a manufacturing authorization for their veterinary medical products:

a) **(Amended sub-paragraph:OJ-11/1/2013-28525)**[(1)] With regards to the responsible manager, quality control manager and quality assurance manager:

1) An up-to-date and valid certificate of registration to the professional chamber given by the professional chamber, to which such person is registered, and if there is no any such chamber for that profession, then the copy of the diploma or certificate of graduation of such person, two passport photographs and the circular of signature of the same,

(2) A petition covering the Republic of Turkey ID Number, residence declaration, work telephone and fax numbers and e-mail addresses of such person,

3) letter undertaking that they agree and acknowledge their respective roles and responsibilities,

4) other documents showing experience in the relevant area or domain,

5) original copy of the labor contract of the related professional, as approved by a notary public, which clearly states that the professional in question is employed as a responsible manager and in such capacity, will be in charge of activities falling within the framework of related legislative acts, and that such person is insured as per the legislation.

b) As regards the manufacturing site and manufacturer:

1) Products that should be manufactured in reserved/isolated areas,

2) Products manufactured, analyzed or etc., under contracts, by assigned third parties,

3) Activities like production, analysis etc., performed by assigned third parties under contract,

4) Original or notary certified duplicate copy of the Non-Sanitary Enterprise License,

5) **(Amended:OJ-20/12/2014-29211)** The positive Environmental Impact Assessment Decision for manufacturing site of the active substance of the veterinary medical products, the positive Environmental Impact Assessment Decision for manufacturing site of the veterinary medical products other than veterinary biological products, or the decision prescribing that environmental impact assessment is not required,

6) Cashier receipts confirming full remittance of related duties and charges.

c) Where managers fulfill their roles and duties as part of a team, information on personal identities, experiences and levels of education of team members.

(4) **(Amended:OJ-20/12/2014-29211)** Application documents shall be assessed within a period of ninety days following submission of the same to the Ministry, and the compliance of any information and documents submitted during the application process shall be reviewed. In case of detection any deficiencies, the applicant shall be provided with feedback, and shall be requested to eliminate such deficiencies. In respect of the applications deemed appropriate, the applicant shall be notified of the fact that s/he is required to apply for the certificate of good manufacturing practices. The actions to be taken in order to obtain the certificate of good manufacturing practices shall be determined by the Ministry. Both manufacturing authorization and the certificate of good manufacturing practices shall be granted to the facilities deemed appropriate as a consequence of the on-site inspection.

(5) Those applicants who intend to obtain a manufacturing site authorization for veterinary medical products without first receiving a preliminary authorization, should provide all the documents specified in first and third paragraphs of this article.

(6) **(Amended:OJ-20/12/2014-29211)** The health protection strip applicable at the sites, where biological veterinary medical products are manufactured and controlled, shall be applied taking into account the micro-organisms to be employed and bio-safety measures taken at the manufacturing site. The manufacture and control of the microorganisms and the necessary characteristics of the areas, where experimental animals to be used for such activities are kept, and the bio-safety requirements and categories shall be determined by the Ministry.

(7) The manufacturing site authorization shall be granted for the manufacturing site and pharmaceutical forms actually mentioned in the application, only. The manufacturing sites are obliged to fulfill the requirements of new arrangements as may subsequently be made by the Ministry after the granting of authorization. The Ministry shall provide the authorization holders with appropriate time to carry out this extra procedure for compliance with the new arrangements

(8) Manufacturing sites which have to use experimental animals in their production or testing and control cycles must have obtained in advance the necessary set of authorizations from the Ministry, as foreseen by the applicable laws, regarding the experimental animals in question, before applying for a manufacturing authorization.

(9) The approval of the Ministry should be sought for any and all changes to be made at the manufacturing site. The Ministry will conclude its review and assessment on each request of change reaching at it, all within thirty days of its first receipt thereof. This period may be extended to ninety days, when circumstances would so require. For initial applications and change requests, the time consumed to consummation of defects by the applicant as required shall not be included in the time count for the above set period of ninety days.

(10) **(Amended:OJ-20/12/2014-29211)** The inspection and certification of the manufacturing sites situated in Turkey and abroad in respect of the good manufacturing practices will be performed at cost of the respective applicants.

(11) **(Amended:OJ-11/1/2013-28525)**[(1)] Manufacturing site authorization holders may request registration of conformance of their manufacturing sites and the products they manufacture in them, with good manufacturing practices.

Obligations of the Manufacturing Site Owners

ARTICLE 24– (1) The obligations of the manufacturing site owners shall be, as follows:

a) to hire labor in necessary quantities and with required qualifications to ensure conduct of manufacturing, control, storage and dispensing of veterinary medical products in accordance with the applicable law provisions,

b) to inform and get permission from the Ministry with respect to all administrative and technical changes involving the manufacturing site.

c) to inform the Ministry immediately, of the responsible manager's inability or unavailability to perform his roles and duties or his resignation from office.

ç) to provide all reasonable access and assistance to auditors appointed by the Ministry in time of conduct of their audits and inspections on the premises.

d) to make all arrangements and take all reasonable measures as necessary for rendering the responsible manager able to fulfill his role and duties arising out of or in connection with his position.

e) to strictly abide by and follow principles on good manufacturing practices of veterinary medical products and at all times select, prefer and use exclusively such active substances that completely accord with good manufacturing practices as starting materials.

f) To fulfill the requirements of instructions and guidelines to be enacted in pursuance of the provisions of this Regulation.

g) to pay in full all duties and charges stipulated in the applicable law, on matters that require authorization or approval of the Ministry, such as manufacturing site authorizations, changes and etc.

Quality management

ARTICLE 25 – (1) The manufacturer shall establish and implement an effective pharmaceutical quality assurance system, involving the active participation of the management and personnel of the different services involved.

Personnel

ARTICLE 26 – (1) **(Amended:OJ-20/12/2014-29211)** It shall employ the persons assuming responsibilities for production and quality control at manufacturing sites other than the responsible manager, as well as any other personnel. In respect of the personnel, the following matters should be satisfied.

(2) **(Amended:OJ-20/12/2014-29211)** The responsible manager, production, quality assurance and quality control managers are obliged to attend physically at the manufacturing site during the activities and fulfill such responsibilities as laid down in this Regulation. In cases where the responsible manager, production, quality assurance and quality control manager may not attend work, the manufacturer shall appoint people with identical or similar qualifications to hold office temporarily in proxy and document this fact. Should the entire duration of such temporary replacement exceed a total of ten days, he will inform the

Directorate General. In cases of duty vacations for more than two months, a new manager should be appointed to positions to be vacated, on consent of the Ministry.

(3) If any of the aforementioned managers are found not attending work personally during conduct of auditory inspections, the missing persons shall be warned. Any official receiving warnings for not attending work for more than twice in any given year shall be suspended from office indefinitely. The person whose duty and position as responsible manager have been terminated for reasons described above will be banned by the Ministry from holding office in peering positions involving or concerned with veterinary medical products, for at least a period of two years from the date of his departure from office.

(4) If the responsible manager resigns from office, the manufacturer will have to inform the Ministry immediately of his departure from office, in addition to electing and appointing another person in his place. The manufacturing authorizations of manufacturers who fail to inform resignation of responsible managers and elect and appoint another person to takeover the duty in their place will be suspended.

(5) The responsible managers will have to notify the Ministry his resignation, all in five days of their quitting office. If they fail to do so and this fact is ascertained by evidence, the responsible managers in default will not be permitted by the Ministry to assume office as such, in charge of veterinary medical products for two years to elapse following their resignation or departure from office.

(6) For changes in manager positions, the newly appointed manager will be made known to the Ministry, with submission of documents specified in article 23 hereof and its consent sought and obtained in return.

(7) As all stages of the manufacturing process need to be implemented under supervision and directions of managers, if either one of them does not attend his duty for any reason whatsoever, no production can take place, except with reservation of provisions of the paragraph relating to delegation by way of proxy.

(8) **(Amended:OJ-20/12/2014-29211)** The manufacturing site will have to lodge with the Directorate General, a valid and up-to-date letter of the Social Security Institution, which demonstrates that their respective managers continue to hold this position in January of each year. Those manufacturing sites failing to make this notification shall be warned and granted an additional one month period. The manufacturing authorization of the facility failing to make this notification as aforementioned within the permitted time frame shall be suspended.

Premises and equipment

ARTICLE 27 – (1) As regards premises and equipment;

a) Premises and manufacturing equipment shall be located, designed, constructed, adapted and maintained to suit the intended operations,

b) Layout, design and operation must aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid contamination, cross contamination and, in general, any adverse effect on the quality of the product,

c) Premises and equipment intended to be used for manufacturing operations which are critical for the quality of the products shall be subjected to appropriate qualification.

Documentation

ARTICLE 28 – (1) As regards documentation, the following rules shall apply:

a) The manufacturers shall establish a system of documentation covering the different manufacturing operations that they perform. Documents shall be retained clear, free from errors and kept up to-date. Pre-established procedures for general manufacturing operations and conditions shall be available, together with specific documents for the manufacture of each batch. This set of documents shall make it possible to trace the history of the manufacture of each batch. The batch documentation shall be retained for at least one year after the expiry date of the batches to which it relates, or at least five years after the date of expiry of the batch, whichever is the longer. Documents submitted to the Ministry in support of application for a product authorization and updated initially and subsequently shall be retained until the authorization is revoked.

b) When electronic, photographic or other data processing systems are used instead of written documents, the manufacturer shall have validated the system by proving that the data will be appropriately stored during the anticipated period of storage. Data stored by these systems shall be made readily available in legible form. The electronically stored data shall be protected against loss or damage of data (e.g. by duplication or back-up and transfer onto another storage system) for further submission to the Ministry in writing, upon request.

Production

ARTICLE 29 – (1) The different production operations shall be carried out according to pre-established instructions and procedures and in accordance with good manufacturing practice. Adequate and sufficient resources shall be made available for the in-process controls. Appropriate technical and/or organizational measures shall be taken to avoid cross contamination and mix-ups. Any new manufacture or important modification of a manufacturing process shall be validated. Critical phases of manufacturing process shall be regularly revalidated.

(2) For purposes intended in this Regulation, all aspects relating to production of active substances subject to use as starting materials and all processes before the product enters in composition including whole or partial production of active substances, exportation, separation, packaging and labeling procedures.

Quality control

ARTICLE 30 – (1) The quality control will be carried out within the framework of the following requirements:

a) **(Amended:OJ-20/12/2014-29211)** The manufacturing site shall establish and maintain a quality control department. This department shall be placed under the authority of a person having the required qualifications and shall be independent of the other departments. The quality control manager should possess experience for at least two years in a manufacturing site or premise that produces medical products for human or veterinary use under a valid and effective authorization in respect of areas relating to quality testing of products and quantitative analyses and controls of starting materials.

b) The quality control department shall have at its disposal one or more quality control laboratories appropriately staffed and equipped to carry out the necessary examination and testing of starting materials, packaging materials and intermediate and finished products testing. Resorting to outside laboratories is authorized, provided that a contract manufacturing agreement is entered by and between manufacturers and exporters for arranging the conduct of certain tests and controls of production at laboratories outside the manufacturing site, where responsibilities of both parties mutually against each other and against the Ministry are explicitly defined.

c) During the final control of finished products before their release for the sale or distribution, in addition to analytical results, the quality control department shall take into account essential information such as the production conditions, the results of in-process controls, the examination of the manufacturing documents and the conformity of the products to their specifications (including the final finished pack).

ç) **(Amended:OJ-20/12/2014-29211)** The finished product sample, starting materials used for the production of the batch and packaging material should be kept for a period of time and in quantities specified under the good manufacturing practices guidance for each batch product placed on the market.

Work contracted out

ARTICLE 31 – (1) Work contracted out shall be carried out according to the following provisions:

a) Any manufacturing operation or operation linked with the manufacture which is carried out under contract, shall be the subject of a written contract between the contract giver and the contract acceptor.

b) The contract shall clearly define the responsibilities of each party and in particular the observance of good manufacturing practice by the contract acceptor and the manner in which the qualified person responsible for releasing each batch shall undertake his full responsibilities.

c) The contract acceptor shall not further sub-contract any of the work entrusted to him by the contract giver without the written authorization of the contract giver.

ç) The contract acceptor shall respect the principles and guidelines of good manufacturing practice and shall submit to inspections carried out by the competent authorities.

Complaints and product recall

ARTICLE 32–(1) The manufacturer shall implement a system for recording and reviewing complaints together with an effective system for recalling promptly and at any time the veterinary medical products in the distribution network. Any complaint concerning a quality defect shall be recorded and investigated by the manufacturer. The Ministry shall be informed by the manufacturer of any quality defect that could result in a recall or abnormal restriction on the supply. Any recall taking place in the foregoing manner shall be informed by the Ministry to other countries where the product has been exported.

Self-inspection

ARTICLE 33 – (1) The manufacturer shall conduct repeated self-inspections as part of the quality assurance system in order to monitor the implementation and respect of good manufacturing practice and to propose any necessary corrective measures. Records of such self-inspections and any further corrective action shall be maintained.

CHAPTER FOUR

Whole and Retail Sale of Veterinary Medical Products

General Requirements on Sales

ARTICLE 34 – (1) **(Amended:OJ-11/1/2013-28525)[1]** The wholesale of veterinary medical products, excluding any veterinary biological products, may be carried out Ministry licensed veterinary pharmaceutical warehouses, pharmaceutical warehouses operating under license issued by the Ministry of Health, and retail sales of the same may be carried out at pharmaceutical warehouses and clinics and animal hospitals that have obtained retail sales license for veterinary medical products from the Ministry as per the provisions of this Regulation. No veterinary medical product sales can take place at locations other than those specified, including the Internet. Clinics, polyclinics and hospitals must seek and obtain a retail sales authorization also for veterinary medical products intended for use in animals served by them even for purposes other than resale.

(2) **(Amended:OJ-20/12/2014-29211)** At the workplaces where ornamental birds, aquarium fish and exotic decoration animals are put on sale under authorization, only the veterinary medical products, other than veterinary biological medical products, that are specific to these animal species can be sold However, such places should possess and meet the requirements given under Article 35. Such places shall not be allowed to perform product sales until they possess and meet the prescribed requirements. Such places are required to keep records, and to act in compliance with the instructions and guidance materials published by the Ministry.

(3) The Ministry may impose special extensions on the conditions of sale and use of certain veterinary medical products, which may potentially affect human, animal and environmental health adversely.

(4) **(Amended:OJ-11/1/2013-28525)[1]** Product authorization holders may not assign to any third parties, use for any purposes other than intended, or carry out the trading of the starting materials they have supplied for the purpose of manufacturing their products.

(5) No products or compounds may be prepared at any sales points, and the products may only be sold in their final sale presentation forms as submitted for the granting of marketing authorization and not in such a manner that deteriorates the integrity of their immediate packaging.

(6) All sales points will have to monitor whether or not the products they put on sale have marketing and sales authorizations. No sales or distribution of batches that reportedly contain unauthorized, fake, imitated or already expired veterinary medical products or products with opened packages or decomposed or decaying products will be allowed at the sales points. If any violation is detected, such products will be removed outside the sales point, and the situation shall be notified immediately to the provincial directorate, and action shall be taken according to the instructions given. In case of detection of products not reported on sales, the Ministry will start required set of action against the sales points.

(7) **(Amended:OJ-20/12/2014-29211)** The marketing authorization holders of veterinary medical products, excluding any veterinary biological products, may distribute their products only to the veterinary pharmaceutical warehouses and pharmaceutical warehouses operating under the license issued by the Ministry of Health. The marketing authorization holders shall keep the products only at the manufacturing site where they have been manufactured or representative veterinary pharmaceutical warehouses.

(8) The Ministry may block any intended or actual sale or transfer of products to wholesalers and retailers which fail to fulfill the requirements of this Regulation.

(9) Marketing authorization holders, sales points or persons authorized to purchase veterinary medical products for their own use may not give away or donate or otherwise dispense, free of charge, any veterinary medical products to ranches, animal owners and livestock breeders and other undertakings lacking sales authorizations, for such reasons as provision of benefits in benevolence to, promotion or supporting of a community or business.

(10) Pharmaceutical warehouses and pharmacies selling veterinary medical products under license provided by the Ministry of Health shall be obliged to fulfill the provisions of this Regulation.

(11) **(Insertion:OJ-11/1/2013-28525)**[(1)] Excluding any veterinary products for human use, and any plant protection products, any persons who possess and keep, import, export or carry out trading of any substances efficient in terms of anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic substances, and which are used at manufacturing of any starting materials to be used at manufacturing of any veterinary medical product or product, shall be accountable to the Ministry, and shall be obliged to keep any and all records regarding the trading of their products in details, and to retain such records for a period of at least three years, in order to submit the same to the Ministry, when and if required.

(12) **(Insertion:OJ-11/1/2013-28525)**[(1)] The marketing authorization holders, manufacturing sites, veterinary pharmaceutical warehouses, locations authorized to carry out retail sales, and any livestock enterprises authorized by the Ministry for wholesale of veterinary medical product supply shall be obliged to comply with the written and electronic monitoring systems determined by the Ministry, and to establish the required infrastructure for such purpose. The marketing, manufacturing site, retail sales point or wholesale supply authorizations or veterinary pharmaceutical warehouse licenses of any persons, who have not fulfilled to perform the required actions with respect to the monitoring systems within the period granted by the Ministry, shall be suspended until the necessary requirements are met and satisfied. In respect of any and all applications for authorizations and licenses to be submitted as of the date of effect of the monitoring system, the requirements of the monitoring system shall be sought in addition to the application requirements.

(13) **(Insertion:OJ-20/12/2014-29211)** The sites authorized in accordance with the provisions of this Regulation may operate under the scope of the authorization only. The sites other than the aforementioned sites and any organizations such as associations, unions and foundations may not purchase, sell, store and distribute any veterinary medical products.

Characteristics of Sales Points

ARTICLE 35 – (1) Every holder of the authorization for distribution of veterinary medical products shall have at his disposal proper and sufficient equipment and physical structuring in order to be able to pursue activities in compliance with the applicable law provisions.

(2) Principles that sales points are required to enforce and observe will be set out in a guideline published by the Ministry through their official website. However, such isolated sections as examination rooms, operation rooms and etc., may possess only such veterinary medical products that are necessary for interventions.

(3) Marketing authorization holders and warehouses must abide themselves by and strictly observe the instructions of the Ministry, and take all measures that may not adversely affect the product characteristics in time of distribution. The distributor will be held ultimately responsible, for this matter.

Activity scope of the veterinary pharmaceutical warehouses and the products availability of which is compulsory

ARTICLE 36 – (Amended along with the heading:OJ-20/12/2014-29211)

(1) Any veterinary pharmaceutical warehouse shall determine its activity scope for at least one of the following sub-paragraphs, and shall keep available the types of the veterinary medical products under its scope, in minimum quantities determined by the Ministry. The products, availability of which is compulsory, and quantities thereof shall be announced on the web page of the Ministry.

a) Cattle, sheep and goat, water buffalo, equidae and bee.

b) Avian, fish and any other aquatic animals, and bee.

c) Cat and dog, and any other pets and decoration animals.

(2) Any veterinary pharmaceutical warehouse may keep available the veterinary medical products in quantities, which it will determine, for any other species other than the ones under its scope.

(3) The Ministry may compel the veterinary pharmaceutical warehouses to hold in stock certain veterinary medical products that might pose importance in animal health in quantities and for periods to be specified, either at national or regional.

(4) Any veterinary pharmaceutical warehouses shall take any required measures in order to response the requests for veterinary medical products, which are received from the pharmacies and from any places authorized to perform retail sales and from any other warehouses, to the extent of their stocks, and in order to deliver the veterinary medical products to the places requested as soon as possible and under the most favorable conditions.

(5) Any veterinary medical product manufacturing sites, any representative veterinary pharmaceutical warehouses and any representative veterinary pharmaceutical warehouses operating under the license issued by the Ministry of Health, and the marketing authorization holders for veterinary biological products, additionally, shall take any required measures in order to response the requests for veterinary medical products, which are received from the veterinary pharmaceutical warehouses and from the pharmaceutical warehouses operating

under the license issued by the Ministry of Health, to the extent of their stocks, and in order to deliver the veterinary medical products to the places requested as soon as possible and under the most favorable conditions.

(6) The actions shall be taken for those who have demonstrably failed to comply with the requirements of the fourth and fifth paragraphs of this article, in accordance with the subparagraph (i) of the first paragraph of Article 37 of the Law.

Promotion

ARTICLE 37 – (1) Sales points should act upon the arrangements governing promotion of veterinary medical products. Sales points may not use any expression purporting or divulge, advertise, disclose or otherwise carry out campaigns or promotions to raise awareness among the public on the fact that they sell veterinary medical products by making use of signboards, posters, handouts, flyers, websites, electronic mail groups and electronic media like social networks or tools like promotional materials. The right to promote the product rests exclusively with the holder of marketing authorization. However, warehouses may advertise themselves and their services provided that they only include their names and contact information in relevant media.

(2) **(Abrogated:OJ-11/1/2013-28525)**[1]

Modifications and Inspection

ARTICLE 38 – (1) A holder of license/authorization intending to make major modifications at sales points should seek for and obtain, through an application in writing supported with documents justifying or describing such modifications, authorization from the provincial directorate. On application, the provincial directorate will review the documents submitted to it and grant the preliminary authorization. Right after the modification, the provincial directorate will carry out an inspection on site and if it approves the modifications so far made, draw up a report, according to which it shall approve the modification and inform the applicant on results.

(2) All sales transactions will be ceased if the sales point gets damaged in great deal threatening the safety of veterinary medical products, for such reasons as fire, earthquakes, floods and etc. The products will be entrusted to a trustee, if the circumstances so require, until such time when repairs / renovations are finished or legitimately put for sale, if deemed appropriate or desirable.

Veterinary pharmaceutical warehouse opening conditions

ARTICLE 39 – (Amended:OJ-11/1/2013-28525)[1]

(1) Veterinary pharmaceutical warehouse license may be granted only to any natural persons who are veterinary surgeons or pharmaceutists, or to the persons who employ such persons as the responsible manager. If a warehouses is engaged in trading of veterinary biological products, then the license may be granted to the persons, who employ a veterinary surgeon as the responsible manager, or to the persons who are veterinary surgeons.

(2) Any logistics companies, which conduct storage and maintenance and handling and transportation activities for veterinary medical products, shall also be obliged to obtain a veterinary pharmaceutical warehouse license.

(3) The responsible manager at the veterinary pharmaceutical warehouses belonging to any natural persons is the veterinary surgeon or pharmaceutist owning such warehouse. Such natural person may employ another veterinary surgeon or pharmaceutist as the responsible manager. Certificate of the responsible manager shall be issued and granted by the Directorate General.

(4) Duties and responsibilities of the responsible manager shall be as follows;

a) To ensure that the activities and operations of the warehouse are carried out in accordance with the regulations,

b) To ensure that the products are accepted, stored and shipped at the appropriate conditions,

c) To ensure that any records requested by the Ministry are kept ready for any audits/inspections,

ç) To participate in any audits and controls/inspections to be carried out by the Ministry,

d) To provide any details and information timely as requested by the Ministry,

e) To participate in any trainings and meetings to be held by the Ministry, or the relevant chamber of profession or any other professional association, when and if required.

f) **(Insertion:OJ-20/12/2014-29211)** To ensure performance of recall procedures.

(5) The responsible manager shall be obliged to be present at the veterinary pharmaceutical warehouse during the period of its activities and operations. Before obtaining the authorization for the responsible manager, another veterinary surgeon or pharmaceutist shall be designated and notified to the provincial directorate, as the deputy. If the authorization exceeds two months within a year, then a certificate of responsible manager shall be obtained from the Directorate General for another veterinary surgeon or pharmaceutist.

(6) If the responsible managers is found not attending work personally during conduct of auditory inspections, he shall be warned. In case of repetition of such situation, then the certificate of responsible manager of the concerned person shall be revoked. Any warehouses, the certificate of responsible manager of which is revoked, shall be obliged to employ a new responsible manager within one month at the latest. The license holder shall designate the deputy responsible manager within five business days, and shall inform the provincial directorate about the situation. The license of any warehouse, which do not employ a responsible manager within the period prescribed, or which do not notify the deputy, or for which it is detected that its deputy is not present at the workplace, shall be suspended, and the activities and operations of such warehouse shall be ceased. Any persons, whose certificate of responsible manager has been revoked, may not be liable for any matter in relation to veterinary medical products for a period of one year as of the date of such revocation.

(7) **(Amended:OJ-20/12/2014-29211)** If the responsible manager quits office, then the owner of the warehouse and the responsible manager shall inform the provincial directorate about such case by submitting a petition for such purposes within a period of five business days. The owner of the warehouse shall inform the provincial directorate about a new responsible manager within a period of fifteen business days. The licenses of warehouses failing to comply with such periods shall be suspended until a new responsible manager is designated. Any responsible manager, who has not submit such notice of information duly, may not

assume any responsibilities in relation to veterinary medical products for a period of one year as of the date of her/his quitting office.

(8) Any license holders, employing responsible managers, shall be obliged to deliver the document, stating that the responsible manager continues to hold her/his position, to the provincial directorate, within January of each year. The licenses of any warehouses, which fail to provide such notice, shall be suspended.

(9) **(Insertion:OJ-20/12/2014-29211)** The owner of the warehouse shall establish the necessary infrastructure to ensure that the responsible manager can fulfill her/his duties and responsibilities.

(10) **(Insertion:OJ-20/12/2014-29211)** There will be an administrative department, and the product acceptance, quarantine, storage, product shipment and product rejection departments at the veterinary pharmaceutical warehouse as separated from each other.

(11) **(Insertion:OJ-20/12/2014-29211)** The veterinary pharmaceutical warehouse shall protect the veterinary medical products under the conditions specified in their labels and leaflets.

(12) **(Insertion:OJ-20/12/2014-29211)** The temperature and humidity values of the storage, quarantine and rejection departments of the veterinary pharmaceutical warehouse shall be measured from the points determined through the validation studies on real time and non-stop basis, and shall be monitored and recorded.

Issue of operating licenses for veterinary pharmaceutical warehouses

ARTICLE 40 – (Amended:OJ-11/1/2013-28525)[(1)]

(1) License applications shall be filed with the provincial directorate of the location where the warehouse is situated, together with the following documents:

a) The petition containing the full address of the warehouse, and the telephone and fax numbers and e-mail addresses of the responsible manager and the warehouse,

b) The Republic of Turkey ID Number of the responsible manager, and her/his residence declaration, list of signatures and 4 passport photographs,

c) A valid and up-to-date certificate of registration obtained from the professional chamber to which the responsible manager is registered,

ç) The layout plan showing the equipment and various sections of the veterinary pharmaceutical warehouse,

d) development plan of the veterinary pharmaceutical warehouse,

e) Certificate of compliance in terms of safety against any fire and explosions,

f) detailed information on the other activities to be performed at the warehouse, for representative pharmaceutical warehouses,

g) Details about the vehicles and equipment to be used by the veterinary pharmaceutical warehouse,

ğ) If the applicant is a legal person, a commercial registry excerpt denoting the registered address of the company, founding objectives, partnership structure and people in charge of governance of the company, giving their respective duties, titles and signature authority frames; and a copy of the articles of association of the company, and the labor contract stating that the company employs the relevant professional as the responsible manager, and that such person is responsible for the activities and operations corresponding to the scope of the relevant legislation, and a declaration in relation to assignment of the responsible manager if the same is a partner of the company,

h) If the applicant is a natural person, then the Republic of Turkey ID Number and residence declaration, list of signatures of such person, and the declaration of such person if s/he wishes to act as the responsible manager on her/his own, or if such natural person will designate another person as the responsible manager, then the document and the labor contract indicating that such person is being employed by the responsible manager and that s/he will be responsible for the activities and operations corresponding to the scope of the relevant regulations,

(2) Following it is seen that the application documents are in full and complete, the provincial directorate shall inspect the veterinary pharmaceutical warehouse on its site within fifteen business days. Such inspection shall be performed by at least two staff members serving at the provincial directorate.

(3) The provincial directorate shall send the documents and the inspection report pertaining to the veterinary pharmaceutical warehouse, deemed appropriate upon the inspection, to the Directorate General for issuance of the license.

(4) The provincial directorate shall provide information by means of a letter, explaining the situation, within fifteen business days, to the location which is not deemed appropriate upon performance of such inspection, or which is detected to have insufficiencies. If such insufficiencies are not perfected within a period of one month following the date of service of notice of such letter, then the application shall be returned to the applicant.

(5) The Directorate General shall issue a license in two copies for any applications that are detected to have been deemed appropriate. A copy of the license shall be sent to the applicant, and the other copy shall be sent to the provincial directorate.

(6) If it detects any insufficiency or non-conformance in respect of any application, then the Directorate General shall inform the provincial directorate about the situation, in order to enable the same to notify the case to the applicant. If such insufficiencies are not perfected within a period of one month following the date of service of notice to the applicant, then the application shall be returned to the applicant by the provincial directorate.

Warehouse activities

ARTICLE 41 – (1) Warehouses shall not be permitted to make direct sales to end users, whether as wholesalers or as retailers.

(2) Warehouses may distribute the products excluding veterinary biological products only to the following locations:

a) Pharmacies,

b) veterinary clinics, polyclinics and hospitals holding retail sale authorizations,

c) Other pharmaceutical warehouses,

ç) **(Abrogated:OJ-11/1/2013-28525)**[1]

(3) The Ministry may allow for the supply of veterinary medical products from warehouses through procurement contracts settled through public tendering procedures, by public agencies and organizations providing animal health services, raising animals or somehow related with livestock breeding, based on reports drawn up by veterinarians. **(Insertion:OJ-20/12/2014-29211)** The products provided/supplied under this article may not be subject to trading.

(4) **(Amended:OJ-11/1/2013-28525)**[1] **(Amended sentence:OJ-20/12/2014-29211)** Livestock enterprises providing animal health services through the veterinarians, they employ on full-time basis within their organizations, including those publicly owned, may obtain products from the warehouses, provided that the approval of the Ministry has been obtained. However, such medical products may only be administered to the livestock owned by such enterprises. These enterprises may not sell or distribute these products to any third persons for whatsoever reasons. Matters relating to this paragraph will be ascertained by the Ministry, who will disclose the same through its official website.

(5) In time of procurements mentioned in the third and fourth paragraphs of this Article, the entire responsibility for the retention of the products shall rest with the buyers of such products.

(6) Warehouses may not sell or distribute the products covered by this Regulation to any natural or legal persons, lacking possession of a license/authorization for selling or distributing the same.

(7) **(Insertion:OJ-11/1/2013-28525)**[1] The following principles shall be complied with in respect of sales, storage/retention and shipment of veterinary biological products.

a) **(Amended:OJ-20/12/2014-29211)** The marketing authorization holder and the veterinary pharmaceutical warehouse may distribute any veterinary biological products only to the veterinary pharmaceutical warehouses, animal hospitals holding retail sales authorization, veterinary surgeon polyclinics and clinics, the public institutions authorized as per the third paragraph and to the livestock enterprises authorized as per the fourth paragraph.

b) In order for being able to import its products, and to store and to distribute the same either before and after the sales authorization, the holder of marketing authorization of the veterinary biological product, imported or manufactured on subcontracting basis, should be a veterinary or a representative pharmaceutical warehouse, or should have executed an agreement with another veterinary or representative pharmaceutical warehouse for the storage and shipment of the product.

c) The holder of the marketing authorization, the manufacturing site, the veterinary pharmaceutical warehouse, sales point authorized for retail sales, and the livestock enterprises authorized by the Ministry for supply of products, shall be obliged to ensure appropriate storage and shipment temperatures, to monitor, to keep the records, and to provide any such

details when requested by the buyers, as per their responsibilities regarding importation of the product, or storage, shipment from the manufacture and administration of the product.

ç) If the veterinary biological product is peculiar to use for diagnosis purposes, then the holder of the marketing authorization or the veterinary pharmaceutical warehouse may distribute such products to the diagnosis and analysis laboratories authorized by the Ministry, and to the public organizations carrying out research and diagnosis activities in relation to animal diseases.

d) At the livestock enterprises authorized by the Ministry, the veterinary biological products may be administered only to the animals owned by that enterprise. The administration may be implemented by the veterinary surgeons or assistant health-care personnel employed within the organization of the enterprise.

e) Any integrated livestock enterprises, which have livestock and poultry at different addresses, and which are authorized as per the fourth paragraph, shall obtain vehicles and equipment appropriate for shipment of veterinary biological products. Such kind of livestock enterprises shall employ veterinary surgeons and assistant health-care personnel at a number sufficient to administration of the products, or shall have such administration performed at a veterinary surgeon polyclinic, clinic or animal hospital situated at the location where the farm or poultry house is situated. The products may not be stored at any places other than the ones, for which an authorization is applied, and may not be delivered to farms, poultry houses and the owners. The veterinary surgeon or the assistant health-care personnel, who has performed such administration, shall issue an administration document, and shall deliver one copy of such document to the owner of the farm or poultry house.

f) Any places authorized to perform retail sales may not sell and deliver any biological products such as vaccines and serums and invivo test antigens to any livestock enterprises, animal owners or breeders, and may not issue prescriptions for such products. The products may be administered only by the veterinary surgeons or assistant health-care personnel at the places that are authorized for retail sales. After the veterinary biological product is administered, a document provided from the provincial directorate shall be issued, and a copy of the relevant page shall be delivered to the owner of that animal.

g) Holders of marketing authorization, manufacturing sites, veterinary pharmaceutical warehouses, places authorized to perform retail sales and the livestock enterprises authorized as per the fourth paragraph shall add liquid nitrogen on the basis of regular time intervals to the container of the products stored and kept in liquid nitrogen. Such places shall keep and retain regularly the documents proving purchase of the liquid nitrogen they use, as well as the records in relation to adding liquid nitrogen.

ğ) **(Amended:OJ-20/12/2014-29211)** In respect of the responsibility for monitoring of the storage and shipment temperature and keeping the records thereof, of the marketing authorization holders, manufacturing sites and veterinary pharmaceutical warehouses; such responsibility shall cease upon delivery of the product to the other veterinary pharmaceutical warehouses, retail sales points, the public institutions authorized as per the third paragraph or the livestock enterprises authorized as per the fourth paragraph. The responsibility of the retail sales points and the public institutions or livestock enterprises authorized for provision/supply of products, shall start as of the time of delivery, and last to the administration of the product.

h) In the event that any livestock enterprise authorized as per the fourth paragraph fails to fulfill the requirements and conditions regarding storage, shipment, administration and the records of the veterinary biological products, or if such enterprise becomes deprived of the same, or if such enterprise fails to monitor temperature during storage or shipment, then provision/supply of such product shall be suspended until the situation is recovered. Such case shall be notified to the veterinary pharmaceutical warehouses, that have performed the sales to such enterprises, by the provincial directorate. In the event that either the entire or some portion of the product, provided by the livestock enterprise, is administered by any other persons than the veterinary surgeons or assistant health-care personnel, or if the records and documents of the administration is not available, or is lacking, then the persons who have carried out such administration shall be subjected to legal proceedings as per the sub-paragraph (ç) of the first paragraph of Section 37 of the Law. If any livestock enterprise distributes the product outside its organization, then such enterprise shall be subjected to legal proceedings as per the sub-paragraph (g) of the first paragraph of Section 37 of the Law.

(8) **(Insertion:OJ-20/12/2014-29211)** The veterinary medical product manufacturing sites and the research institutions and organizations may obtain products from the veterinary pharmaceutical warehouses in respect of the research and development activities upon the permission of the Ministry of Health.

Warehouse records

ARTICLE 42 – (1) Warehouses are obliged to keep all records of procurements, sales and stocks of veterinary medical products, in such a manner that allows for traceability of these products on the basis of production date, name, quantity, batch number, names and addresses of persons or organizations from which products have been purchased or to which products are distributed and for recall procedures when necessary, maintain all records and documents up to-date and as ready for inspections for at least a period of five years, to submit the same to the Ministry on demand and to make them available for reviews and inspections of inspectors.

(2) The warehouses should keep a Book of Supervisory Audits, to allow for putting on record of various matters found during inspections.

(3) **(Amended:OJ-20/12/2014-29211)** Procedures and rules applicable to the records to be kept and keeping of these records shall be ascertained through the instruction published by the Ministry. The records shall be kept in respect of the psychotropic / narcotic products pursuant to the legislation in relation to such products.

(4) **(Amended:OJ-20/12/2014-29211)** The veterinary pharmaceutical warehouse shall carry out an internal audit at least once a year. Any non-conformities identified as a consequence of the internal audit, and the reasons thereof, and any corrective and preventive actions taken against such matter shall be recorded in detail, and such records shall be kept available for audit for a period of five years.

(5) Delegated pharmaceutical warehouses should keep the entirety of records concerning the products for which they carry out storage or secondary packaging services, according to the provisions of this Article.

Branches and delegated pharmaceutical warehouses

ARTICLE 43 – (Amended:OJ-20/12/2014-29211)

(1) The veterinary pharmaceutical warehouses or branches/offices of the representative veterinary pharmaceutical warehouses shall be obliged to obtain license.

(2) Any veterinary medical product manufacturing sites and any representative veterinary pharmaceutical warehouses operating under the license issued by the Ministry of Health may not perform distribution to the places other than the veterinary pharmaceutical warehouses and the pharmaceutical warehouses operating under the license issued by the Ministry of Health.

(3) The representative veterinary pharmaceutical warehouses may conduct the activities for raw material, primary packaging, labeling, printed materials, storage, protection of reference samples and auxiliary packaging, in respect of the manufacturing sites or the marketing authorization holders, provided that they will satisfy the requirements of the good manufacturing practices, and through an agreement executed by and between the parties. In respect of the protection of products, the requirement of the veterinary pharmaceutical warehouse shall be carried out.

Any changes in trade names and addresses of the representative veterinary pharmaceutical warehouses and veterinary pharmaceutical warehouses, and transfers thereof

ARTICLE 44 –(Amended along with the heading:OJ-20/12/2014-29211)

(1) If the warehouse changes its address to another location, the responsible manager shall apply to the provincial directorate with an application letter, to which attached will be:

a) the approved development plan or occupancy permit of the address of relocation,

b) letter or other documentary form of consent of the board of directors of the legal person, concerning relocation,

c) commercial registry paper indicating the new address after relocation,

ç) The layout plan drawn to a scale of 1/50, showing the equipment and various sections of the new warehouse,

d) A certified document obtained from competent authorities to the effect that the location reserved for use as a warehouse is suitable for the counts of fire safety.

e) receipt showing full payment of applicable fees and duties,

f) License and certification of responsible manager drawn for the former address,

(2) In case of any change in the address details of the warehouse, the owner of warehouse or the responsible manager shall apply to the provincial directorate together with the new address and the license to be revised, and the certificate of responsible manager.

(3) In case of any change in the trade name, the owner of the warehouse shall apply to the provincial directorate together with the license to be revised and the certificate of responsible manager, as well as with the Trade Registry Gazette stating the change of the trade name in respect of the legal persons.

(4) If the warehouse is to be transferred, the transferee of the property shall apply for registration with the provincial directorate together with the notary certified deed of transfer

entered by and between the transferor and the transferee and documents belonging to the transferee as required for initial applications, the license to be revised, and the certificate of responsible manager.

(5) In respect of change of place; in the event that application documents are found out to be appropriate, the provincial directorate shall carry out on-site inspection, as in the first application for license.

(6) In respect of transfer processes, the transfer of psychotropic/narcotic products shall be carried out under the supervision of the authorities from the Ministry.

(7) The provincial directorate shall forward the applications that it deems appropriate, to the Directorate General together with a copy of the application documents in order for issuance of a new license.

Retail outlets and retail sales authorization

ARTICLE 45 – (Amended:OJ-11/1/2013-28525)[1]

(1) Retail sales authorization for veterinary medical products shall be issued in the name of Ministry licensed clinics, polyclinics and the animal hospitals.

(2) Retail sales authorization for veterinary medical product shall be issued in the name of the licensed veterinarian at clinics and polyclinics, or in the name of the practitioner of veterinary medicine who will be designated as the person responsible for the sales of veterinary medical products at clinics, polyclinics and animal hospitals opened up in the form of simple partnerships.

(3) Applications will be filed with the provincial directorate, together with the following documents:

a) The petition covering the Republic of Turkey ID Number and residence declaration and telephone and fax numbers and the electronic mail address of the veterinary surgeon for whose name a retail sales authorization will be issued.

b) A valid and up-to-date certificate of registration granted by the professional chamber, to which the veterinary surgeon is registered, and list of signatures, and 4 passport photographs.

c) If the applicant is a legal person, the original or copy of the commercial registry excerpt denoting the registered address of the company, its founding objectives, partnership structure and people in charge of governance of the company, giving their respective duties, titles and signature authority frames; and a copy of the articles of association of the company; and a letter stating that a sales manager has been assigned.

ç) The receipt showing full payment of applicable fees and duties.

d) In respect of hospitals and any clinics and polyclinics, established by a veterinary surgeon, if the sales manager is employed from outside of those places, then the labor contract stating that such person is responsible for the activities and operations covered by the relevant regulations; and the valid and up-to-date document stating that such person is insured and working in accordance with the applicable legislation, obtained from the relevant public entity.

e) The details pertaining to the vehicles used during shipment of veterinary medical products to the farms or poultry houses for use of such products at the clinic services offered outside the retail sales points, and the equipment used for transportation of the same.

(4) Provided that the consent of the clinic, polyclinic and the hospital is obtained, the responsible persons may delegate a power of attorney to another veterinary surgeon, with whom a service contract has been executed, in order for fulfillment of their duties in relation to sales of the products. If the person, responsible for sales of the product, has delegates an attorney at the workplace, then the documents pertaining to such attorney and regarding the responsible manager as described within the third paragraph, and the deed of consent of the attorney, shall be added to the application.

(5) The provincial directorate shall issue a report stating that all items, including facilities, have been deemed appropriate upon completion of the on-site inspection, carried out on the documents, within a period of fifteen business days. Such inspections shall be carried out by two staff members. In respect of the sales points situated within the borders of the district, a staff member serving at the district directorate shall attend the committee, and a copy of the file shall be sent to the district directorate.

(6) ıf the sales point is not deemed appropriate upon completion of such inspection, then information with the relevant grounds shall be delivered to the applicant within a period of fifteen days. Should the applicant fails to remedy the defects and imperfections reported to it within a period of one month after its receipt of notice on non-conformities, then the application file shall be returned to the applicant.

(7) If the sales point is deemed appropriate, then a retail sales authorization for veterinary medical product shall be issued within a period of fifteen days. Such document shall be issued in two copies. One copy of the document shall be delivered to the concerned person. One copy of the same shall be retained at the provincial directorate. If the sales point is situated within the borders of the district, then a copy of the file shall also be delivered to the district directorate.

(8) The retail sales authorization shall be arranged in the name of a veterinarian. No further authorizations can be granted to this person.

(9) If the sales manager resigns active office for any reason whatsoever, then the clinic, polyclinic or hospital shall be obliged to designate a new sales manager within five business days, at the latest; and to submit an application to the provincial directorate with the previous sales authorization. Within this period, the veterinarian reported as substitute will carry out such procedures and transactions concerning sales. If no sales manager is appointed on time, then the authorization shall be revoked, and sales activity shall be ceased; and the products shall be seized until a new manager is appointed.

Relocation, transfer and closure procedures

ARTICLE 46 – (Amended along with the heading:OJ-20/12/2014-29211)

(1) The holder of retail sales authorization shall apply to the provincial directorate together with a properly arranged letter of application and the previously granted authorization as well as full set of documents sought for obtaining of the authorization, for the new address he plans to relocate his business and assets. As in the case for initial applications, the new

authorization shall be granted if the application is found eligible, at the end of inspections duly performed. If the relocation process is to be carried out within the borders of different provinces, then the letter of transfer of the provincial directorate granting the previous retail sale authorization and the details for the stock products during the transfer process shall be attached to the application documents.

(2) If the ownership and control of the clinic, polyclinic or animal hospital is transferred to a third party, the retail sales authorization will immediately become null and void. The persons taking over the property of the sales point as transferee shall apply to the provincial directorate for obtaining a new retail sales authorization on their behalf, through an application letter and the previously granted authorization provided in the attachment thereof.

(3) In case of transfer or closure of the workplace, the retail sales authorization holder or his/her legal successors in case of his death, shall apply to the provincial directorate granting the authorization together with an application letter. The provincial directorate shall carry out on-site inspection in relation to the application within a period of 15 days. Book of Supervisory Audits, Book of Narcotics and Psychotropic Product Inventory and Consumables and any other books shall be received by the provincial directorate through the an official report in order to be retained, and shall be delivered to its authorization holder in order to be retained for the period of other records.

(4) The products available in the stock shall be identified through the official report, and shall be delivered to the authorization holder in order to be transferred to any other retail sales point, or to the point from which it has been purchased. Upon the request or in case of expiration of their shelf lives, such products shall be disposed of. Such processes shall be carried out within the permission and knowledge of the provincial directorate. Any products, which are not transferred or returned within a period of six months, shall be disposed of at the cost of its owner.

(5) The authorization holder shall provide any records for the retention conditions of the products to be transferred or returned.

(6) In respect of the transfer and closure processes, no retail sales authorization shall be issued to the retail sales authorization holder, which fails to carry put his/her responsibility prescribed under this Regulation, for a period of two years.

Records of retail outlets

ARTICLE 47 – (1) Retail outlets possessing valid sales authorizations should keep and maintain the following books:

a) a Book of Supervisory Audits in which facts and matters established in time of audits will be entered,

b) A Veterinary Medical Product Register, where each incoming veterinary medical product shall be entered, upon arrival at the retail outlet,

c) **(Abrogated:OJ-11/1/2013-28525)**[1]

ç) Book of Narcotics and Psychotropic Product Inventory and Consumables,

d) A Returned/Reassigned Goods Registry, in which veterinary medical products that have been rejected or transferred, for which a decision of recall was taken.

(2) **(Amended:OJ-11/1/2013-28525)[(1)]** At the retail outlets, prescription sales may be performed as described below:

a) In respect of any sales as performed by relying on the prescription of the veterinary surgeon outside the retail outlet, the incoming prescription shall be kept at a separate file basing on the date of incoming.

b) The veterinary surgeons of the retail outlets shall issue a prescription for the veterinary medical products they use for treatment and the examination they performed. The details regarding such prescriptions shall be recorded on to the recording book of the outlet; and the prescription shall be kept at a separate file basing on the date of the prescription.

c) The veterinary surgeons of the outlet may issue prescriptions, without performing any examinations, for recommendation purposes, to the owners of the animals, at the cases other than the situations described in the sub-paragraphs (a) and (b). If the recommended veterinary medical products are delivered to the owners of the animals by the outlet, then such prescriptions shall be kept at a file separate from the other prescriptions, basing on the date order.

(3) **(Amended:OJ-11/1/2013-28525)[(1)]** In respect of all prescriptions, the retention period shall be at least five years, unless otherwise is not indicated by the Ministry. The prescription groups indicated in the second paragraph shall be retained separate from each other. Prescriptions are deemed as the record of the products exited from the outlet.

(4) The commercial documents relevant to purchase, sale, transfer and return procedures shall be kept in separate files for at least a period of two years, in order of chronology.

(5) Prescriptions of Narcotics and Psychotropic Drugs and all commercial documents shall be retained in separate folders from those containing the files of other veterinary medical products, for at least a period of five years.

(6) Registry and record entries should be easily readable and conceivable, facilitating for easy and fast access and kept in such a way to allow backward tracking of all related activities and stages, for at least a period of five years.

(7) All books and registers except Book of Supervisory Audits and Book of Narcotics and Psychotropic Product Inventory and Consumables may be kept on electronic storages in such form as designated by the people responsible for the same, save that they contain all the required information. This will not affect the retention times of records, the ultimate responsibility of which rests with the sales authorization holder.

(8) At least once a year a detailed audit shall be carried out to compare incoming and outgoing medical supplies with supplies currently held in stock, any discrepancies being recorded. These records shall be available for inspection by the competent authorities for a period of at least five years.

(9) Procedures and rules applicable to the records to be kept and keeping of these records will be ascertained by the Ministry, who will disclose the same through its official website.

(10) **(Insertion:OJ-11/1/2013-28525)[(1)]** In case of promulgation of a monitoring system, the Ministry may perform changes in respect of the records and books to be kept by the retail outlets.

(11) **(Insertion:OJ-11/1/2013-28525)[(1)]** The pharmacies may sell any products subject to prescription in accordance with the sub-paragraph (a) of the second paragraph.

Rules Pertaining to Prescriptions

ARTICLE 48 – (1) The veterinarian who administers or recommends administration of any given veterinary medical product to an animal should arrange a prescription for the purpose of documenting the situation, when required, and hand such prescription to the person taking care of the animal, putting it on record, if necessary.

(2) The veterinarian's prescription should at least contain a date, personal identity particulars of the veterinarians (i.e. name and surname, signature, address, reference number of diploma or other certificate of formal qualification held etc.), identification information of the animal and information on the veterinary medical product or preparation prescribed (name, strength and pharmaceutical form, indications of use, commercial presentation form, route of administration, doses and treatment period).

(3) The Ministry may introduce special arrangements in the informative content of prescriptions and use thereof for a particular situation, enterprise, class or category of veterinary medical products or group of animals and render the application thereof mandatory or may categorize prescriptions. The products' status of being subject to prescription will be ascertained by the Ministry, who will disclose the same through its official website.

(4) The veterinarian may use authorized veterinary medical products other than biological veterinary medical products off-label or recommend such practice, if there is not any preferable or advisable authorized veterinary medical product available for use in a particular case of treatment. In such case, the veterinarian will be obliged to give all necessary information to the breeder or ranch owner concerning any and all potential effects and consequences of the off-label use and indicate it in appropriate records and on the prescription clearly. In case of off-label use, if not a specific withdrawal period has been ascertained for the veterinary medical product in use depending on relevant animal species, the Ministry may introduce a minimum time-limit and/or set of rules. The responsibility associated with off-label use shall rest with the administrator and acceptor of the administration of the veterinary medical product.

(5) No further entries of another veterinary medical product can be made on the prescriptions containing information about psychotropic and narcotic products.

(6) Prescriptions shall be drawn in at least three copies. One copy shall be retained by the prescribing veterinarian. The remaining two copies will be entrusted to the animal owner for with one original to be finally delivery at the retail outlet of the veterinary medical product. If the prescribed veterinary medical product is a medicated veterinary premix, then prescription shall be arranged in four originals and the fourth copy will be retained at the premise to prepare the medicated feeding stuff.

(7) **(Insertion:OJ-11/1/2013-28525)[(1)]** The animal owners shall retain any invoices, prescriptions and records in relation to any medical products administered to their animals,

including those administered previously before the purchasing, even if the animals have been sacrificed, the animal or the product of the same has been consumed as a foodstuff, at least for a period of five years. Such records shall be kept so as to cover the details such as the name of the product, its pharmaceutical form, administration route, date and amount, any off-label administration, if any, and any details thereto, the date of provision/supply of the product, and the address of such provision/supply, and so as to avoid any doubt in terms of the animals treated. The animal owners shall be obliged to present such records to the Ministry, when and if requested. The Ministry shall determine the principles in relation to the records, which are required to be kept by the animal owners or the livestock enterprises; and shall announce such principles on its official website.

Rules Pertaining to Retail Trades

ARTICLE 49 – (1) Below set are the rules and principles that must be followed in time of retail trading of veterinary medical products::

a) Trading transactions may not be carried out by such means as explicitly not permitted by the Ministry.

b) Sale transactions will be performed under responsibility and supervision of the veterinarian to whom a retail sales authorization has been granted or his duly authorized assign. No one but these people may finalise the sale.

c) Veterinary medical products sold on prescriptions may not be sold without the same.

ç) Prescriptions not arranged properly according to established produce or having lost the quality of being an official document and prescriptions sent via the Internet, facsimile or phone communications, couriers, brokers or other similar means shall not be acceptable. The provisions of this paragraph shall not apply to electronically made prescriptions (e-prescriptions) obtaining physical form and effect immediately after being prepared on electronic environment and digitally signed in a secure way by the prescribing veterinarian.

d) Psychotropic and narcotic products may be sold and delivered only to the veterinarian who has made the prescription. They may not be sold or delivered to any other person. **(Amended last sentence:OJ-11/1/2013-28525)**[(1)] The details shall be recorded into the product registry logbook, as well as the Book of Narcotics and Psychotropic Product Inventory and Consumables.

e) Separate billing shall be made for psychotropic and narcotic medical preparations, a copy of which shall be retained for at least a period of five years.

f) Peddling on portable benches or booths and sale of veterinary medical products in circuits are hereby prohibited. The delivery of veterinary medical products in use to the owner or caregiver of the treated animal in time of examination or intervention shall be an exception to this rule.

g) Retail outlets may neither trade veterinary medical products among themselves inter alia, nor sell the same to warehouses. However, in cases of emergency, where the sale or use of veterinary medical products are restricted by a revocation of sales authorization or the activities of the manufacturer or distributor thereof are to be suspended for a long period of time, due to a medical or legal urgency, sales can be performed with a view to ensure transfer

and assignment of the veterinary medical products, under direct supervision of officials from the provincial or district directorate, when this becomes necessary. The outlets may return excess veterinary medical products back to the warehouses from which they purchased the same in the first place.

ğ) The retail outlets may, in no way, perform wholesale dealings or sign up for and participate in procurement sessions to be staged for the purpose.

h) The veterinary medical products that have to be administered only by a veterinarian or assistant health personnel may be sold only to the same.

CHAPTER FIVE

Promotion of Veterinary Medical Products

Scope of Promotions

ARTICLE 50 – (1) The promotion of veterinary medical products for which a marketing authorization has been granted may be carried out by marketing authorization holders or people to whom the latter has delegated their powers in such capacity. No entity, organization, association, society, foundation, union or other similar body or undertaking but the marketing authorization holder may promote, recommend or encourage the use of veterinary medical products, even through the veterinarian. No veterinary medical product can be promoted publicly, in the absence of a valid marketing authorization.

(2) **(Amended:OJ-11/1/2013-28525)[(1)]** Promotional activities cover the promotion of the products, covered by this Regulation, to the veterinary surgeons and pharmacists, and providing information about administration and side/adverse effects of those products to the other health-care professionals. The promotion oriented at health-care professionals shall be carried out by means of professional media, supporting of or arranging scientific activities, or organizing visits to such professionals by the promotion representatives.

(3) **(Amended:OJ-11/1/2013-28525)[(1)]** Only the products, allowed to be sold to such workplaces, may be promoted to the workplaces selling homing pigeons and aquarium fish and exotic decoration animals under license issued by the Ministry.

(4) **(Amended first sentence:OJ-11/1/2013-28525)[(1)]** The products cannot be advertised or promoted through mass communication means and media such as radio, television, newspapers, magazines, and the Internet and etc. However, with the exception of veterinary medical products with recognized narcotic and psychotropic effects, disclosures can be made with respect to a veterinary medical product on newspapers and magazines, which reports that the veterinary medical product in question has been placed on the market under the heading "To the attention of veterinarians and pharmacists" and communicates the name or title or distinguishing emblem or other insignia of the authorization holder, the commercial name of the product, strength and pharmaceutical form, the generic names of its active ingredients, the brief indication of pharmacotherapeutic use, date and number of authorization granted and whether or not it is available on prescription. The contract address of the marketing authorization holder may as well be included, if deemed necessary or desirable. These disclosures will not contain any pictures other than those of the veterinary medical product. The approval of the Ministry must be sought and obtained for disclosures of this type, wherefore, the final texts to be disclosed should be sent to the Ministry at a suitably prior

time. Press releases can be published only for once. Press releases to be published on newspapers may not exceed 1/8 of the full page size, in dimensions.

(5) **(Amended:OJ-11/1/2013-28525)**[1] Only the publications delivered or sold to the veterinary surgeons and pharmacists, and the publications containing scientific and medical texts shall be accepted as professional media. The press and media delivering news targeted at breeders shall not be deemed as professional media.

(6) The wholesalers and retail outlets of veterinary medical products may not disclose or announce that they are engaged in the sales thereof, neither can they carry out any promotional efforts concerning the products. No such materials as posters, notices and etc. that promote the veterinary medical products may be hung or juxtaposed in sales premises except those bearing the phrase "please consult a veterinarian for name of the product".

(7) Veterinary medical products with recognized narcotic and psychotropic effects may not be promoted through informative or reminding efforts, by means of means of mass communication or diluted samples or prototypes of them may not be prepared and distributed. These products may only be promoted in the professional media.

(8) Promotional arguments employing comparative approaches and methods should coincide with scientific facts and professional ethics and be demonstrable. Promotional arguments should not target a specific competitive product.

(9) **(Amended:OJ-20/12/2014-29211)** No promotional or advertising material may be included in product labeling or leaflet, excluding the special uses thereof.

(10) **(Amended:OJ-11/1/2013-28525)**[1] The marketing authorization holders may issue summary of product characteristics or leaflets on their websites. As an exception to the fourth paragraph, the marketing authorization holders, which wish to carry out advertisement and promotion in relation to their products through the Internet, shall establish domains that can be accessed only by means of personal passwords, etc., and that are prepared as oriented to the veterinarians and pharmacists.

(11) **(Insertion:OJ-20/12/2014-29211)** The promotional works for the veterinary medical products shall be conducted in line with the provisions of the guidance published according to this Regulation.

General characteristics of promotional information

ARTICLE 51 – (1) All information supplied in promotional materials of a veterinary medical product should absolutely be true, realistic, provable, valid and reliable. These information may not and shall not be arranged or handed out in such a manner that would cause unnecessary or excessive use or detrimental effects of the veterinary product. The information provided should be consistent with those provided in the package insert or leaflet.

(2) Since no particular medicament is safe in an absolute sense, use of the term "safe" should be avoided in a promotional material, unless and until the relevant criteria and class are given.

(3) Citations to be made in promotional materials shall be incorporated into the context thereof, with full reference made to their bibliographical sources.

(4) Information should be covered on potentially hazardous or detrimental impacts to human, animal and environmental health of the veterinary medical products.

Representative

ARTICLE 52 – (1) The promoting representative should have full knowledge of scientific data and facts, as and to the extent required for the successful promotion of the veterinary medical product. The qualifications of the representatives shall be at responsibility of the product authorization holders. For such purpose, the product authorization holders should give the necessary training to representatives.

(2) The representative should report any adverse information concerning the veterinary medical products he is promoting, to the product authorization holder.

(3) The product authorization holder shall be responsible for all promotional activities to be conducted by the representatives, as well as all matters regarded with the promotion.

(4) **(Insertion:OJ-20/12/2014-29211)** The qualifications of the promotion representatives, working procedures and principles thereof, and all practices in relation to such matter shall be determined in line with the instruction published by the Directorate General.

Representative Samples

ARTICLE 53 – (1) The veterinary medical product samples to be used for promotional purposes shall meet the following requirements:

a) No price statements should be included.

b) Samples should be presented in reduced quantities from the smallest commercial presentation form of product placed on the market. However, the promotional samples of veterinary medical products the quantities of which may not be reduced due to their pharmaceutical form may be used as is.

c) The wording “specimen for veterinary use only, not for sale” should be placed on both immediate and outer packaging labels in an appealing manner.

ç) The sample may not be differ from the original product except for characteristics specified in this paragraph.

(2) Samples of veterinary medical products available on prescription can only be given to veterinarians.

(3) Authorization holders will set up a satisfactory recording and control system for the manufacturing, importation and dispensing of free representative product samples, identifying persons to assume responsibilities thereof. These records shall be reported to the authorized representatives of the Ministry whether by electronic means or in printed hard copies in such form and content to be designated by the Ministry, upon request.

(4) The annual distribution quantities of free representative samples may not exceed 5% of the volume of sales realized in the preceding year, with the product they relate. The sample distribution activities shall be limited to two years from the date on which the veterinary medical product is placed on the market.

(5) Promotional samples may not be used as research material in clinical studies.

Promotional materials and promotions

ARTICLE 54 – (1) The promotional materials should at least meet the following characteristic requirements:

a) Promotional materials shall be dispensable only to veterinarians and pharmacists. However, the Ministry may exclude the promotional materials intended for use as product reminders so as to include the commercial names and names and logos of authorization holders of veterinary medical products that do not leave residues in food-producing animals or require specialized knowledge and experience for being used, from operation of this clause.

b) The materials should not go beyond their intended purpose as product reminders both qualitatively and quantitatively, but remain within modest limits in material value. The Ministry shall set the maximum material value of the promotional materials, when necessary.

c) The entire information provided on package inserts or leaflets of veterinary medical product should be used in such materials as books, booklets, brochures, slides, films and etc., which contain more than information supplied on the name, strength, pharmaceutical form and authorization holder of the veterinary medical product.

(2) **(Amended:OJ-11/1/2013-28525)[(1)]** No gifts, promotional distributions, lotteries or draws, special offers and campaigns other than price discounts will be permitted for encouraging use and boost up sales of the veterinary medical products; and no direct or indirect material gains shall be allowed begotten from people who intend to use or prescribe for the same. However, professional materials may be handed over to veterinarians or pharmacists, provided that other requirements are successfully met..

(3) Product or sample donations made in courtesy to public entities and organizations and other persons, bodies and establishments approved by the Ministry for supporting scientific research and education shall be excluded from coverage.

(4) Marketing authorization holders may distribute posters or promotional materials containing informative and awareness-raising statements on concerns of human, animal and environmental health, in addition to corporate logos to all societal segments, save on condition that they mark a target community group in the first place and avoid advertising the veterinary medical products.

Activities and liability

ARTICLE 55 – (1) The veterinarian, holders of the marketing authorization for a medical product for veterinary use or any authorized agents or permitted assigns thereof may organize and hold or sponsor and/or support such events as meetings, seminars, symposium, educational gatherings and etc. or take part in such events as expositions, concerning the veterinary medical products in their possession. The Ministry may appoint observers to these events.

(2) Hospitalization of guests during these activities should always be kept at a reasonable level and assigned to second degree in priority of concern, given the main intentions with the gathering and should be delivered only to veterinary surgeons and pharmacists, excluding VIP guests.

(3) No activity other than those clearly specified under this Article shall be permitted conducted for the purpose of promoting a particular veterinary medical product.

(4) The holders of authorization shall be liable for:

a) ensuring that the promotional activity with regard to a veterinary medical product for which an authorization has been granted is conducted in strict compliance with the requirements of this Regulation.

b) providing any and all information and documents concerning the promotional activities, if required by the Ministry.

c) saving and keeping one each copy of all promotional materials to be used for a period of two years, for resubmission to the Ministry, if and when requested.

ç) ensuring, mediating and being instrumental to implementation of all decisions taken by the Ministry on promotions of veterinary medical products.

d) conveying all such documents as relevant to the promotional activities whether already conducted or to be conducted in future and arranging for and ensuring the training of representatives on legal and scientific subjects, upon request.

CHAPTER SIX

Pharmacovigilance

Pharmacovigilance activities

ARTICLE 56 – (1) The pharmacovigilance activities shall be conducted by all related parties using such information as derived or obtained from the following references:

a) reports and manifests of veterinarians or pharmacists,

b) Post-authorisation safety studies, including pharmaco-epidemiological studies,

c) decisions adopted by competent authorities of other countries on efficacy and safety of products,

ç) national and international scholarly articles on efficacy and reliability,

d) other information that may affect assessment of benefits or risks of the veterinary medical product such as non-conforming use or misuse of the product,

e) data that may provide additional information on efficacy and reliability of any given product and on other signals of risk,

f) Computerized health databases,

g) Feedbacks and complaints from breeders and administrators,

ğ) results obtained from supervisory audits or tests performed on field samples.

Obligations of the authorization holders

ARTICLE 57 – (1) Since guaranteeing the efficacy and safety of veterinary medical product is the first and foremost responsibility of him, the authorization holder shall be obliged to take

all precautionary and other measures as necessary for ensuring continuous monitoring with efficiency of pharmacovigilance efforts, establishment and subsequently, sustenance of the necessary system of pharmacovigilance, including but not limited to training his own in-house staff.

(2) The authorization holder will secure continued participation of the person who he has appointed to be his pharmacovigilance manager in training courses on pharmacovigilance either organised or approved by the Ministry.

(3) The authorization holder has to recruit and employ a pharmacovigilance manager on a perpetual basis, within his organisation, even if he carries out pharmacovigilance activities through any other commercial, academic or scientific enterprise.

(4) The holder of authorization shall be liable, with regard to information reaching at their hands, for:

a) comprehensive record-keeping and archiving on all suspected adverse reactions taking place in Turkey or any other country in which the veterinary medical product in question is being marketed.

b) recording and reporting all suspected serious adverse reactions and human adverse reactions related to the use of veterinary medical products, of which he can reasonably be expected to have knowledge, or which are brought to his attention, immediately to the Ministry, and in no case later than fifteen days following the receipt of the information.

c) recording and immediately reporting all other suspected serious adverse reactions, which meet all reporting criteria pursuant to the guidelines on pharmacovigilance and of which he can reasonably be expected to have knowledge, or which are brought to his attention, immediately to the Ministry, and in any case, no later than fifteen days following the receipt of the information.

ç) ensuring that incidents of suspected adverse reactions and human adverse reactions, altering the known risk-benefit balance of the product and anyhow occurring in the territory of another country, which are brought to his attention are reported collectively and without delay, so that they are available to the Ministry and in no case later than fifteen days following the receipt of the information.

d) reporting all undesirable effects or adverse reactions not of a serious or unexpected nature, only inside the periodic safety update report and at such times as mentioned in paragraph (e) of this article or in a collated batch to the Ministry, on its request.

e) submitting records of all adverse reactions to the Ministry in the form of a periodic safety update report, either immediately upon request or periodically as follows: six monthly for the first two years after authorization, annually for the subsequent two years, and at the same time of the first renewal. Thereafter, the periodic safety update reports shall be submitted at five-yearly intervals together with the application for renewal of the authorization. The periodic safety update report shall include a scientific evaluation of the benefits and risks afforded by the veterinary medical product.

Pharmacovigilance manager and competent pharmacovigilance service institution

ARTICLE 58 – (Amended along with the heading:OJ-20/12/2014-29211)

(1) The pharmacovigilance manager shall be responsible for the following;

a) the establishment and maintenance of a system which ensures that information about all suspected adverse reactions which are reported to the personnel of the company, including its representatives, is collected and collated in order to be accessible at least at one point within the country;

b) collection, recording, archiving and evaluation of information concerning risks and reliability afforded by veterinary medical products and in this context, ensuring full availability of up-to-date information in marketing authorization files of the products;

c) ensuring that any request from the competent authorities for the provision of additional information necessary for the evaluation of the benefits and risks afforded by a veterinary medical product is answered fully and promptly, including the provision of information about the volume of sales or prescriptions of the veterinary medical product concerned;

ç) ensuring cooperation and coordination with the Ministry at necessary levels;

d) the provision to the Ministry in a timely and prompt manner, of any other information relevant to the evaluation of the benefits and risks afforded by a veterinary medical product, including appropriate information on post-marketing surveillance studies;

e) monitoring, checking and auditing the activities of the competent pharmacovigilance institution in case of procurement of pharmacovigilance service, and reporting any nonconformities to the Ministry.

(2) That qualified person responsible for pharmacovigilance and the competent pharmacovigilance service institution shall conduct all his activities in line with the guidance published according to this Regulation.

(3) The responsibilities of the pharmacovigilance service institution are as follows;

a) To establish and operate a system which will enable to provide pharmacovigilance service,

b) To monitor and assess all suspected adverse effects which are reported directly or indirectly to the institution by the Ministry, marketing authorization holders or representatives, health care professionals or owners of animals, provided that such effects are related to the products in respect of which pharmacovigilance service is provided,

c) To collect, record, archive and evaluate any information concerning risks and reliability of the products, pharmacovigilance studies of which are monitored by it, and to submit such information to the marketing authorization holder,

ç) To submit any information and documents in relation to the periodical reliability updating report and reliability studies upon granting of authorization of the products, pharmacovigilance studies of which are monitored by it, to the Ministry,

d) To carry out the obligations of the marketing authorization holder against the Ministry,

e) To ensure the collaboration and coordination between the marketing authorization holder and the Ministry.

Obligations of healt-hcare professionals

ARTICLE 59 – (1) The health-care professionals will professionally be obliged to report any adverse reactions occurring in relation to the use of veterinary medical product in patients, which they personally witness, to the Ministry.

(2) The health-care professionals shall report the serious and unexpected adverse reactions which occur in relation to the use of veterinary medical product in their clinical attendance and which may reasonably be linked to the product, to the Ministry either directly or through the provincial/district directorates at which they assume roles and in no case later than fifteen days following the receipt of the information.

Confidentiality

ARTICLE 60 – (1) The identities and resident addresses of the animal owners and reporting health-care professionals shall be kept confidential in reporting made to the Ministry, by the Ministry. Such information may never be divulged to any persons other than the resident personnel of the Ministry without express consents of the people to which they appertain. The authorization holders, health-care institutions and organizations and health-care professionals shall be abided by and strictly follow the same confidentiality requirements.

(2) **(Insertion:OJ-20/12/2014-29211)** The competent pharmacovigilance service institution may not disclose any information on the source and content of the notification served to it in respect of the product, the studies of which are conducted by the same, in any manner whatsoever, to any institutions or persons other than the marketing authorization holder and the Ministry.

Report forms

ARTICLE 61 – (1) The adverse reaction reporting form shall be used for reporting of adverse reactions of authorized veterinary medical products to the Ministry. In cases where no such form is available, reporting shall be done in freestyle writing. Details regarding the reports shall be provided in the guidance published according to this Regulation.

Ministry's Obligation To Report

ARTICLE 62 – (1) The ministry shall report any suspected serious adverse reactions of a veterinary medical product, occurring within the territory of Turkey, which are brought to its attention through statutory reporting, to the related marketing authorization holder in no later than fifteen days following the receipt of the information. The Ministry may share and exchange information with international organizations having continued interest in the area, with which it has established contacts.

Assessment by the Ministry

ARTICLE 63 – (1) The feedback, information and reports reaching at the Ministry concerning pharmacovigilance activities, including the post-authorization reliability studies, will be assessed and evaluated by the Committee for Medical Products for Veterinary Use. The Ministry shall carry out the communications it is expected to carry out in relation to matters it considers as needing change in the safety information of veterinary medical products and other necessary notifications as regards its decisions for or against recalls, suspensions or revocations within fifteen calendar days following the committee's completing its assessment. In case of urgency, the Ministry may suspend the marketing authorization of a

veterinary medical product, provided the marketing authorization holder is informed at the latest on the following working day.

Products without marketing authorization

ARTICLE 64 – (Amended along with the heading:OJ-11/1/2013-28525)[(1)]

(1) Monitoring of any feedback received from health-care professionals in relation to the adverse effects of the autovaccines and the products, which are not authorized in Turkey, but which are authorized to be imported, manufactured or used, shall be carried out in accordance with the provisions of this Regulation.

Reconsideration

ARTICLE 65 – (Amended:OJ-11/1/2013-28525)[(1)]

(1) The Ministry may request a reconsideration of the products for which a marketing authorization has been granted, and for that purpose, it may demand additional information and documents. At the end of the reconsideration, it may revoke or suspend the marketing authorization granted for product, or alter or amend the terms applicable to manufacturing, importation, sales, supply and use thereof, and grant any extra time as reasonably needed for the alternations or amendments to be made and gain effect.

(2) With reservation of the provisions of fourth paragraph, the time for expiry of marketing authorizations shall be five years. The marketing authorizations may be renewed at the end of this five-years period, based on an assessment of the risks against benefits analysis. The marketing authorization holder shall submit his application to the Directorate General incorporating his claim for extension, accompanied by the list of documentation on quality, safety and efficacy and the original copy of the authorization, until six months prior to formal expiry of his marketing authorization. The Directorate General will be entitled to inquire this information from the authorization holder, at any time. **(Amended sentence:OJ-20/12/2014-29211)** For the renewal of marketing authorizations granted for products authorized abroad, the administrative documents specified in Article 8 hereof should also be provided in the attachment of the application.

(3) Once renewed, a marketing authorization will gain validity for an unlimited period of time, if not a further request for its renewal is moved at the end of the next five-years period, within the framework of pharmacovigilance efforts pursued by the Directorate General. **(Amended sentence:OJ-20/12/2014-29211)** Renewal of marketing authorizations, granted for any product, for an indefinite period of time shall not relieve the authorization holder from any liabilities or obligations.

(4) The authorizations granted for veterinary medical products which are not placed on the market within three years after the receipt of marketing authorization or following latest placement of the veterinary medical product on the market shall be revoked.

(5) The Directorate General may bring exceptions to the fourth paragraph, in cases of requirement and provided that it has fully justifiable reasons, for protecting the health of animals or human beings.

(6) **(Amended:OJ-20/12/2014-29211)** The authorization of the products, application of which has not been submitted upon expiration of its validity period, or deficiencies of which

have not been eliminated, shall be deemed to have been suspended as of the mentioned date. The authorizations originally granted for the products, for which not any claims are raised for a renewal through applications or raised but with defects and imperfections, which are not remedied within a period six months following expiry of validities, shall be revoked. However, the Ministry may grant an additional extension of three months, after considering the period of delay in submission of documents required in respect of the products authorized abroad.

CHAPTER SEVEN

Product recall

Preamble with recalls

ARTICLE 66 – (1) Product recalls are implemented with a view to prevent effective distribution and/or use of a veterinary medical product reported to be defective, in order to ensure availability of defect-free, high quality products in the market, while protecting the health and safety of the consumer.

(2) Recall shall be initiated either on request of the Ministry or manufacturer's resolve. The recall procedure will be carried out by the company responsible for the veterinary medical products, under supervision of the Ministry. The company responsible for the veterinary medical products is liable for acting in good faith and upon principles of accountability, taking all measures as may reasonably be found necessary by the Ministry in relation to the recall operation.

(3) **(Insertion:OJ-20/12/2014-29211)** Any defective products, in respect of which the person responsible for the defect cannot be identified, shall be recalled by the Ministry. The decision on the products recalled shall be made by the Ministry. In case of identification of it, any expenses incurred for such recall shall be collected from the person responsible for it.

Obligations of the marketing authorization holders with regard to product recalls

ARTICLE 67 – (1) Regarding the recall operation**(Amended expression:OJ-11/1/2013-28525)[(1)]** the marketing authorization holders will be obliged to fulfill the following requirements;

a) Distribution records should be arranged so as to ensure recognition of every batch and every customer and product recall within the shortest possible time, when required.

b) A product recovery plan shall be drawn allowing fast and effective product recall, which may be put under implementation immediately, at any time. This plan will describe the various roles and responsibilities, paths to be followed, places where notifications are to be made and information given, manner of notifications and procedures for the record-keeping in relation to the returning veterinary medical products, as separate for each recovery operation.

c) A system will be established, which will be capable of transferring the required information and instruction in a short time to the depths of the levels that the product recall will penetrate.

ç) In circumstances where lives are threatened, the responsible company shall inform the Ministry immediately and without having regard to the day of the week or time of the day.

d) Modifications and attachments made to the recall plan shall also be notified to the Ministry.

e) The responsible company will be liable for indemnifying those affected by the recall to the level and extent the procedure reaches at. The path to be followed on this matter shall be established and indicated by the responsible company in the notification. The responsible company will be obliged to fulfill this procedure in such a period of time as needed to not put people and entities from which products were recalled, at unease. However, such period may not be greater than two months.

f) **(Insertion:OJ-20/12/2014-29211)** In the event that the marketing authorization holder fails to carry out her/his responsibility for recalling process, then such process shall be carried out by the Ministry. All expenses incurred for such process shall be collected from the marketing authorization holder.

Classification of Recalls

ARTICLE 68 – (1) This Regulation categorizes all recalls into one of three classes, according to the level of hazard involved, as follows:

a) Class I: Dangerous or defective products that predictably could cause serious health problems or death,

b) Class II: Products that might cause a temporary and curable health problem, or pose only a slight threat of a serious nature, **(Amended expression:OJ-20/12/2014-29211)** and ineffectiveness and effectiveness decreases,

c) Class III: Products that are unlikely to cause any adverse health reaction.

(2) Recalls fall within either one of the following type designations, depending on how deep they need to extend, in the distribution chain.

a) A type A recall is designed to reach individual customers or patients through media release (radio, television, regional and national press), and Class I recalls generally fall within this type designation.

b) A type B recall is designed to reach wholesalers throughout the country, directors of hospital services (private as well as state hospitals), Ministry approved retail outlets, doctors, nurses, pharmacists, authorized prescribers and dispensers. Class II recalls generally fall within this type designation.

c) A type C recall is designed to reach wholesale level and other distribution points (e.g. pharmacies, doctors, hospitals). Class III recalls generally fall within this type designation.

Reasons of Recalls

ARTICLE 69 – (1) Defects associated with the quality of the products, lacks or omissions in good manufacturing practices and labeling errors are among the main reasons for product recalls. A recall will be implemented, when the requirement arises, due to:

a) Defects related with product packaging, such as leaks, damage, material deformation, manufacturing fault, use of non-compliant packaging etc.

b) Labeling and printing errors such as mislabeling - wrong or missing text or figures, Missing or incorrect information - leaflets or inserts and etc.

c) Defects relating to content, such as Contamination, for example, microbial spoilage, dirt or detritus, particulate matter, Chemical/physical contamination (significant impurities, cross-contamination, particulates), presence of pyrogens, chemical decomposition, deformation in aesthetics, form and taste, collapses, turbidity, ambiguous substances, deviations from specified standards and etc.

ç) Defects relating to efficacy of the product such as ineffective product, serious adverse reactions and toxicity etc.

d) Such other reasons as unauthorized production, unauthorized changes in formulation, packaging and manufacturing site of products, expired products, non-compliance with good manufacturing practices and etc.

Recall procedures

ARTICLE 70 – (1) If anything comes up rendering a product recall necessary, the Ministry will inform the responsible company, asking it to start with recall procedure. The Ministry shall state the level of depth and class of the recall in their notification.

(2) Having commenced with the recall procedure, the company will furnish the Ministry with such information as referred to under third paragraph of this Article concerning the product being recalled. It will be incumbent upon the responsible company to provide the Ministry with any additional information as the latter may find necessary or desirable.

(3) A company conferring upon a recall in respect of a product shall immediately commence with recall procedures and submit the following information to the Ministry:

a) Product name, pharmaceutical form and dosage,

b) batch number, date of manufacture of the product to be recalled,

c) the rationale underlying its decision for a recall and incidents where defects or potential defects have been discovered,

ç) an assessment of the risk associated with the defect and consumer groups at risk,

d) Number of defective batches and total number of batches,

e) product quantities dispensed,

f) the names of places receiving product deliveries and quantities of product delivered at each of them,

g) class and type of recall,

ğ) means of communication to be used in time of recall (i.e. mail etc.), a copy of the notification thereof, if available or description on how communication will be assured,

h) names, work and home phone numbers of persons responsible for recall procedure.

(4) The Ministry shall review the information submitted to it by the responsible company and, if it so opts, alter the class and depth of recall.

Notification

ARTICLE 71 – (1) In Class I Recalls, the Ministry will warn the public using all mass communication means, asking them to avoid use of defective product. Within twenty-four hours after the delivery of notification, measures shall be taken as necessary for bringing defective products existing in the market, under control.

(2) When a decision is made for a product recall, the situation will be informed to all such entities and people which may have in possession the product depending on the level of depth the recall extends, via appropriate communication channels, in the shortest possible time, by the responsible company. Regardless of the form or manner of notification, a written notice should definitely be given. Following this notification, the products to be recalled shall be brought under control within three days in case of Class II recalls or within six days in case of Class III recalls.

(3) The notification of product recall made by the Company should be free of any advertising elements and should just deliver the message to the best knowledge of the target community groups. This notification should at least contain the following information:

a) Product name,

b) Pharmaceutical form and dosage,

c) batch number and date of manufacture,

ç) reason of recall,

d) the manner in which the product shall be recalled,

e) manner of compensation for the product recalled,

(4) The Directorate General will issue a notification through its official website on decisions taken by it for product recalls.

Measures

ARTICLE 72 – (1) Following the notification of recall, those possessing defective products will cease distribution and/or sales thereof. These people shall be obliged to take the necessary measures until the recall procedure ends.

(2)**(Amended:OJ-20/12/2014-29211)** In case of adoption of any recall decision, then the marketing authorization holder shall cease the manufacturing process of the product for a period specified by the Ministry. The importation of the products manufactured abroad shall be ceased without granting any time. The Ministry shall inform the manufacturing site and the marketing authorization holder about its decision on continuity of the manufacturing or importation of the product, upon submission of any information and documents in relation to the reason of the relevant defect/failure and to any corrective and preventive measures taken in order to prevent the re-occurrence of such defect/failure, in compliance with the good manufacturing practices guidance.

Report arrangement

ARTICLE 73 – (1) After making sure that all defective medical products available in the market have been retrieved, down to the level to which the recall extends, the marketing authorization holder shall draw up and submit a report to the Ministry, which includes:

a) distribution records of defective product batch or batches (name and quantity),

b) locations, dates and manner of notification of recall,

c) number of customers observing the recall notification and quantities of medical product in their possession,

ç) customers disregarding the warning,

d) total quantity of returning medical product (to be put on record under supervision of the provincial / district directorate),

e) action to be taken in respect of returning medical product.

(2) The Ministry shall be informed daily about Class I recalls.

Termination of Recalls

ARTICLE 74 – (1) The Ministry will decide for terminating a product recall. The information supplied by the responsible company shall be collated with the results of supervisory audits conducted across the organization of the Ministry and feedback from other sources to allow for an overall assessment of the conjuncture, at the end of which the Ministry shall decide whether or not the recall has been completed. If the Ministry concludes that the recall is yet at insufficient levels, it will require the responsible company to continue with it.

(2) Action proposed to be taken by the responsible company about the recalled product shall be submitted to the Ministry for its approval. If it is approved by the Ministry, the action is put under implementation. The Ministry is liable for giving the detailed information about the action in progress, to the responsible company.

(3) Following Ministry's decision for termination of the procedure of recall of products, the information given by the responsible company shall be evaluated by the Ministry. When it makes sure that the recall has fully been completed, the recalled products have been either destroyed or restored and measures have been taken to prevent a recurrence of the same defect, the Ministry will close the recall file.

Liaison

ARTICLE 75 – (1) **(Amended:OJ-11/1/2013-28525)[(1)]** Marketing authorization holders and warehouses shall be obliged to set up a system for establishing liaison with the destinations where deliveries of their products are made in the shortest period of time.

(2) Retail outlets have to keep records concerning medical products subject to sale on prescription, as specified in the related Article, for tracking the recall operation.

CHAPTER EIGHT

Autovaccines

Production, distribution, use, recording and reporting of autovaccines

ARTICLE 76 – (Amended:OJ-11/1/2013-28525)[(1)]

(1) Manufacturing of the autovaccines shall be carried out in accordance with the below given procedures and principles;

a) **(Amended:OJ-20/12/2014-29211)** Autovaccines shall be manufactured at the areas allocated for autovaccines at the facilities, to which the manufacturing authorization has been granted based on the veterinarian's report.

b) **(Amended:OJ-20/12/2014-29211)** In respect of manufacturing of autovaccines; the micro-organism cultures, the pure culture of which is derived from the veterinary diagnosis, analysis laboratories authorized by the Ministry, the Institute Directorates or universities, shall be used.

c) Autovaccines may be prepared from the cultures of the micro-organisms derived from the organs or tissue pieces of any flocks or animals at the livestock enterprise, which are infected with disease, or which have died because of a disease, or which are suspicious of carrying disease, and their body fluids or such other substances having a role at contagion.

ç) The flock and the animals from which the pure culture has been derived shall be identified. Such identification shall be done by the number of that animal in respect of individually identified ones, and by the number of the hutch in respect of the avians, and the number of the enterprise in respect of fish and the other animals.

d) The micro-organism culture may be used for a period of fifteen months as of the date, on which the pure culture has been derived, or within twelf months following the manufacture of the first batch of the autovaccine in which they are used, in respect of manufacturing of autovaccines. However, excluding flock use, the micro-organism culture may be used for a period of twenty four months for individual use purposes, in respect of manufacturing of autovaccines.

e) Each batch product, manufactured from the micro-organism cultures until the age of twenty four months at the manufacturing site, and which is peculiar to the flock use, shall be checked/controlled in terms of the quantity of residual formaldehyde if it is administered to any animals producing food and if it is used at the manufacturing, in addition to the control/checking of sterility, purity, inactivation. The manufacturing site may perform additional control/checks if it deems required.

f) The manufacturing site shall obtain permission from the Ministry, by submitting the efficiency tests for use by flocks, in respect of the autovaccines, which it manufactures by derivation from the micro-organisms, for which a period of twenty four months has elapsed as of the date on which it has derived the pure culture. Samples, at sufficient number, of each batch, for which permission has been obtained, shall be retained in order for controls/checks to be performed by the Ministry, when and if so required.

g) Labeling of the autovaccine shall bear the below listed details;

1) The name of the micro-organism from which it has been manufactured.

2) Batch number and expiry date and the volume of the package and total dosage amount.

3) Route and dose of administration, and the recommended administration frequency.

4) Conditions for storage and handling/shipment.

5) If used, the names and the quantity details of the substances used at inactivation, and any preservative substances, adjuvants.

6) Species of the animal on which it will be administered.

7) The name and the address of the manufacturer, and the name and the address of the animal owner or the enterprise.

8) The warning stating that the product may not be administered at the location or any other animals other than the ones indicated on the label.

9) Name, surname and contact details of the veterinary surgeon responsible for administration of the autovaccine.

10) The warning stating that the shelf life of the autovaccine may not exceed twelf months.

ğ) Any micro-organism culture, which could not be used at manufacturing of autovaccine or at any other product, for which a subsequent marketing authorization may be obtained, as of the date of creation of the pure culture, shall be disposed of by the manufacturing site; or shall be delivered to the diagnosis or research institutions if so requested.

h) No autovaccines may be manufactured against any diseases, for which serving a notification is mandatory as determined by basing on the law.

(2) Autovaccine may be used at the enterprises that are adjacent to or neighboring the enterprises where the disease is diagnosed, or where the micro-organism has been isolated.

(3) In order to enable that the autovaccine can be used at the non-neighboring enterprises, the epidemiological connections or resources such as antigenic similarity of the micro-organisms obtained from both enterprises, existence of common hatchery or water resources between the both enterprises, or animal and equipment shipments/transfers between the enterprises, shall be set out.

(4) Any autovaccines peculiar to flock use may not be kept available at veterinary pharmaceutical warehouses, animal hospitals, veterinary surgeon clinics or polyclinics.

(5) Autovaccines peculiar to individual use may be kept available at animal hospitals, veterinary surgeon clinics and polyclinics. However, the label of the autovaccine shall contain the details about the animals, for which the autovaccine has been prepared, in addition to the other details indicated on the label.

(6) Any livestock enterprises, which employ veterinary surgeons within their organization for animal health-care services, may keep the autovaccine within their organization. The manufacturing site shall deliver the autovaccine to such kind of enterprises at a quantity sufficient for primary and repeated vaccination of the flock for which the autovaccine will be administered. Any products, which will remain after the vaccination, shall be returned to the manufacturer.

(7) The responsibility in respect of storage and administration of autovaccines at the the livestock enterprises, which do not employ veterinary surgeons within their organizations, shall be incumbent on the manufacturing site and the owner of the enterprise. Administration may be performed by the veterinary surgeon or the assistant health-care personnel, working within the organization of the location where the autovaccine is manufactured, or by the veterinary surgeon clinic or the animal hospital which will be mutually determined by the manufacturing site and the livestock enterprise.

(8) The livestock enterprise shall be obliged to keep and retain the details in relation to the storage temperature and administration records, the invoice, and the return documents, if any, of the autovaccine, which it has received, on regular basis.

(9) The manufacturing site shall keep and retain the details about the micro-organism culture and isolation details of the autovaccine, and the manufacturing and control records, the invoices and delivery forms of the same, the dates and quantities of the delivery, the details about the person to administer, and the addresses of the enterprise and the person to administer, and the records regarding the other contact details.

(10) Manufacturing of autovaccine only for exportation purposes shall be carried out in accordance with the below given procedures and principles:

a) Exportation may be carried out in the form of finished product or bulk product.

b) In order for importing the pure micro-organism to be used for manufacturing of autovaccines for exportation purposes, the authorization of the Directorate General shall be obtained. No ill or dead animals, organs or tissue pieces or body fluids may be imported for such purposes.

c) The application for obtaining authorization for the micro-organism culture shall contain the details about the isolation and identification, and the request of the buyer.

ç) The labeling/labels of the products, to be manufactured for exportation purposes, shall be drawn up and prepared in the language as requested by the country to which such products will be exported. Such labeling/label shall contain the warning "Manufactured for use by/in .....", and the name of the country only, in Turkish, to which such products will be exported.

(11) Autovaccine manufacturing of any manufacturing site, which do not comply with, and adhere to the procedures and guidelines specified in this Article, shall be ceased for a period of one year.

(12) **(Insertion:OJ-20/12/2014-29211)** Any other matters in relation to the production, protection and use of autovaccines shall be determined in accordance with the guidance to be published by the Ministry.

CHAPTER NINE

Audits, Penalties, Suspension and Revocation Procedures

Suspension of the marketing authorizations of the products and the activities of the competent pharmacovigilance service institution

ARTICLE 77 – (Amended along with the heading:OJ-20/12/2014-29211)

(1) Marketing authorizations for all products possessed by an authorization holder shall collectively be suspended, when it is clear that:

a) The operating license or authorization is suspended,

b) The mail delivery address of the marketing authorization holder cannot be determined,

c) the information and documents submitted for operating license application prove to be false, forged or counterfeited.

(2) Marketing authorizations shall be suspended in case of any of the following cases:

a) if it is detected that the product proves to be ineffective or unsafe under the recommended conditions of use,

b) the product proves to be harmful under the recommended conditions of use,

c) if the product is not manufactured in compliance with the manufacturing method, pharmaceutical form, leaflet, labeling and presentation form, or if it is not released to market accordingly,

ç) the product has been placed on the market without any sales authorization,

d) there is no antigenic coherence between strains contained in the veterinary biological product and the pathogenic strains found in Turkey,

e) if it is detected that the information and documents submitted to the Ministry regarding the product prove to be false, forged or counterfeited.

f) if it is detected that the marketing authorization holder manufactures the product, has the product manufactured, or releases the product to the market, by failing to comply with the regulations,

g) Quality control testing for each manufactured batch, in combination with production and control tests concerning the by- and intermediate products occurring during the production process for the veterinary medical product or constituents thereof prove to be inconsistent with the defined methods,

ğ) if it is detected that the manufacturing and quality control testing methodologies of the products are not updated in accordance with recent scientific progress,

h) if the pharmacovigilance activities regarding the product are not being performed, or if it is continued to perform insufficient and lacking activities in spite of the warning thereto,

i) if the authorization holder does not inform the Ministry on all incidental developments of the product authorized abroad,

i) if any information or documents is/are not sent to the Ministry within the granted period of time,

(3) The manufacturing or importation of a product, the authorization granted for which has been suspended, will immediately be ceased. Decision concerning the products, which are not placed on the market, and which are being distributed or on sale, will be taken by the Ministry, having due regard to the grounds of suspension.

(4) In the event that it is detected that the product is not in compliance with the formula and specifications that constitute the basis for the marketing authorization of such product, upon the analysis performed on any products having sales authorization by the Ministry, then actions as per the sub-paragraph (d) of the first paragraph of Section 37 of the Law shall be taken.

(5) After the authorization is suspended, the Ministry will cancel the suspension, if it agrees to the counter-arguments put up in documents, information and reasoning revealed by the authorization holder in his objection after receipt of the notification of suspension from the Ministry.

(6) The activities of the competent pharmacovigilance service institutions shall be suspended if;

a) The certificate of authorization is suspended,

b) The mail address of the competent pharmacovigilance service institution cannot be identified,

c) The information and documents submitted for certificate of authorization are proved to be false, forged or counterfeited,

ç) The fact that the Ministry is not informed about the termination of the pharmacovigilance service agreement within the granted period of time is repeated,

d) The competent pharmacovigilance manager resigns from office and it is detected that a new manager is not assigned within the granted period of time,

e) It is detected as a consequence of the audits that no responsibilities are carried out.

Revocation of marketing authorizations for the products

ARTICLE 78 –(Amended:OJ-20/12/2014-29211)

(1) Marketing authorizations for the products will be suspended if;

a) the authorization holder so requests;

b) the products are found to bring no benefit when used as intended and are unnecessary for the practice or domain of veterinary medicine for which they are meant for use or are widely used for purposes other than intended;

c) the authorization holder does not submit any information and documents in relation to the grounds of suspension, to the Ministry within a period of six months as of the date of suspension, at the latest, and does not take and initiate any required measures for grounds of suspension, or does not carry out the relevant processes, or if such information, documents, measures and processes are not deemed appropriate by the Ministry; in respect of the products, authorization of which has been suspended; excluding the provisions of the sixth paragraph of the article 65 of this Regulation,

ç) the assessment is performed based on the matters such as the reason of the cancellation and authorization status of the product in other countries, in case of cancellation of the authorization of the products, which are authorized abroad, in the country, where they are authorized.

(2) The manufacturing or importation of a product, the authorization granted for which has been canceled, will immediately be ceased. Decision concerning the products being distributed or on sale will be taken by the Ministry, having due regard to the grounds of revocation.

(3) The Directorate General will issue a notice to the persons and the related parties involved in the trades of the products, the authorization of which has been revoked, with justification of the reasons entailing to such revocation.

Supervision of manufacturing sites, and sanctions

ARTICLE 79 – (1) The Ministry shall inspect the premises, for which a manufacturing authorization has been obtained, by informing the same in accordance with a schedule for such purpose, and also without informing the same, at any time when it may deem required. The specialists of the Ministry are authorized to examine any and all kinds of manufacturing, quality control, quality assurance documents and such other records, and to take any samples, when and if they deem required, as per the purpose of such inspections. Upon completion of inspections, the authorized representatives will draw up a report which ascertains whether or not the manufacturing site complies with legal requirements stipulated under this Regulation, or not. The report will specify the matters which should be reported to the manufacturer who has undergone an inspection and the Ministry will notify these matters in writing to the manufacturer.

(2) As a result of the inspections carried out, if it becomes obvious that the authorization holder is in breach or violation of the provisions of this Regulation, the Ministry may suspend until such time when non-conformities are removed for certain pharmaceutical forms or completely withdraw the manufacturing authorizations.

(3) The Ministry may further suspend or withdraw the powers of responsible persons of the manufacturing sites found to be operated in violation of the provisions of this Regulation.

(4) Should the powers of the responsible person are revoked, a replacement shall immediately be elected and appointed to this position. In case of suspension of powers of the responsible person, a new replacement should immediately be selected and appointed to hold office also for the duration in which the suspension will stand.

Supervision of sales points and sanctions

ARTICLE 80 – (1) Veterinary pharmaceutical warehouses shall be inspected at least twice, and retail outlets shall be inspected at least once in every year. Other than that, inspections may be carried out, when they are considered necessary. Such inspections shall be carried out by authorized representatives of the provincial directorate in cooperation with personnel of the relevant departments of the Directorate General. If the physical location of the sales points falls within districts, the authorized personnel of the related district directorates will also join the team to carry out inspections.

(2) Inspections shall check and verify whether the wholesalers and/or retail outlets being visited pursue operations in accordance with the applicable laws and information as stated in the filing for operating license/authorization applications, whether the responsible person named in such license or authorization physically attends his office and whether the records are kept regularly and in order. Points discovered as not in compliance with the applicable laws during inspections shall be put on record in the inspection logbook and then duly signed by the responsible person named in the license/authorization.

(3) Action shall be taken with regard to points thus ascertained, as follows:

a) If the point that needs attention involves no risks or threat to safety of the product, then it should be eliminated or made good in a period of fifteen days. If, at the end of such period, non-conformities are found to persist, then activities of warehouses shall totally be ceased and their licenses suspended. In the case of retail outlets, the licenses/authorizations shall be suspended and they are prevented from any further sales of the veterinary medical products, which will be entrusted to an appointed trustee, to keep them in safe custody. If the non-conformities are either eliminated or made good, then necessary set of examinations shall be made and those retail outlets which are found to comply with all applicable law provisions shall be permitted to continue with their operations. However, those retail outlets failing to fulfill their obligations despite a period of two months has passed from the date of inspection shall witness their licenses/ authorizations totally withdrawn.

b) If the point that needs attention involves risks or threat to safety of medical product for veterinary use, then a time allowance of one month at first-time inspections or of six months at secondary inspections or of one year at tertiary and subsequent inspections shall be granted for the elimination of non-conformities. If, at the end of such period, non-conformities are found to have been eliminated or made good after necessary set of inspections have been performed then activities of retail outlets shall totally be authorized or in the case to the contrary, totally revoked.

c) **(Amended:OJ-11/1/2013-28525)[(1)]** Those retail outlets found to have been engaged in sales of veterinary medical products off the record and under the counter or without a validly obtained marketing authorization will receive application of sanctions mentioned in point (b), first paragraph of Section 37 of the Law.

ç) Those veterinary pharmaceutical warehouses and retail outlets conducting sales of veterinary medical products without a wholesale or retail distribution authorization will receive sanctions and penalties delineated in point (g), first paragraph of Section 37 of the Law.

d) Those retail outlets which have demonstrably failed to keep such records as required by the Ministry in relation to medical products for veterinary use will receive application of sanctions mentioned in point (i), first paragraph of Section 37 of the Law.

e) Those retail outlets which retain or hold in possession or market and sell medical products for veterinary use in torn or ripped or otherwise opened packaging or decomposed or outdated veterinary medical products shall receive application of sanctions mentioned in point (j), first paragraph of Section 37 of the Law.

f) Those who have demonstrably failed to comply with the requirements of third, fifth, seventh, eighth and ninth paragraphs of Article 34 of this Regulation in relation to medical products for veterinary use will receive application of sanctions mentioned in point (i), first paragraph of Section 37 of the Law.

g) **(Insertion:OJ-11/1/2013-28525)[(1)]** Any persons, who fail to notify any changes regarding the service conveyance vehicles or their equipment during obtaining retail sales authorizations, shall be warned upon the first detection of such case. Upon any subsequent detections or if it is detected that the products are handled/shipped in an inappropriate manner to affect the quality and reliability of the products, then the actions specified in sub-paragraph (b) of this paragraph shall be taken.

ğ) **(Insertion:OJ-11/1/2013-28525)[1]** Any products, which are detected to have been stored at inappropriate conditions or shipped at veterinary pharmaceutical warehouses, retail outlets or inside any means of conveyance vehicles belonging to the same, and the records for storage or shipment temperatures of which have been detected to have not kept, or kept missing, shall be given to a trustee, and such products shall be had analyzed. Any products, which are detected to be inappropriate/non-conforming upon such analysis, or which are not allowed to be checked/controlled by their owners, shall be sequestrated, and the title to such products shall pass to the public in order to be disposed of. Any costs and expenses for shipment, analysis and disposal of such products shall be borne by the owners of the same.

(4) **(Insertion:OJ-11/1/2013-28525)[1]** Any persons, who fail to keep the records specifed in the seventh paragraph of Article 48, shall be subjected to penal sanctions specified in the sub-paragraph (ç) of the first paragraph of Section 36 of the Law.

Revocation of warehouse license or retail sales authorization

ARTICLE 81 – (1) Warehouse licenses or retail sales authorizations will be revoked or withdrawn, if:-;

a) requested;

b) the information and documents submitted in support of the application prove to be false, forged or counterfeited;

c) **(Abrogated:OJ-11/1/2013-28525)[1]**

ç) the license or authorization for clinics, polyclinics or hospitals have been revoked;

d) the responsible person is prevented to carry out his profession or banned from professional conduct for at least a period of three months or he dies,

e) the operations of the retail outlet is suspended for enforcement of financial and commercial laws;

f) the article governing inspections and sanctions so requires.

(2) The documents and records as well as licenses or authorizations belonging to a warehouse or retail outlet, the operating license or retail sales authorization of which has been withdrawn for any reason whatsoever shall be lodged to the provincial directorate. These documents and records will be kept in safe custody for as long as required by this Regulation, at the provincial directorate. The aforesaid will subsequently be returned or transferred to the manufacturer or legitimate owner or of the wholesaler or retail outlet found in the location of sales of the products. If any transfer or return procedure has been scheduled at a later date, the products shall be brought under control and provisional custody of a trustee. The transfer and return procedures of narcotic and psychotropic products will be conducted in presence and under supervision of authorized representatives of the provincial directorate.

Promotion

ARTICLE 82 – (1) The Ministry shall inspect all kinds of materials and methods employed in promotional activities, as well as the promotional activities themselves, either when it deems necessary or based on a filed complaint. The Ministry shall require from the license/authorization holders that any promotional activities found inconsistent with the

principles set forth in this Regulation or ineligible for public health be ceased or terminated or the information supplied through the promotional materials be revised or withdrawn, depending on the case. Such requests of the Ministry as aforementioned will immediately be fulfilled.

(2) Those who fail to comply with rules and principles applicable to promotional activities shall, pursuant to point (h), first paragraph Section 37 of the Law and depending on the nature and character of their actions, receive treatment in accordance with the relevant provisions of Turkish Penal Code, Law No. 5237 of 26/9/2004, Consumer Protection Law No: 4077 of 23/2/1995, 4054 Numbered Law of 7/12/1994 on the Protection of Competition and 6112 Numbered Law of 15/2/2011 on Radio and Television Enterprises and Broadcast Services.

(3) **(Amended:OJ-11/1/2013-28525)**[1] The Ministry shall, in addition to imposing the sanctions applicable to cases where the products are promoted in such a way contrary to the provisions of this Regulation, warn the authorization holder. If the same misconduct recurs despite such warning as aforementioned, the product authorization shall be suspended for six months at the first time and for twelve months at the second time and finally be revoked at the third time.

(4) The Ministry may publish or require, from the authorization holders, to publish a corrective statement through mass communication means in respect of a promotional activity or material or communication containing erroneous or misleading information, which might lead to undesirable consequences, should it so opts or deems necessary.

(5) If matters connected to promotional activities and materials occur through activities specified in Article 55 of this Regulation, then the authorization holder shall receive an official warning, in addition to the sanction imposed. If the same misconduct recurs despite such warning as aforementioned, the product authorization shall be suspended for six months at the first time and for twelve months at the second time, by such means as specified in Article 55 of this Regulation. If the misconduct occurs for a second time, then authorizations will be suspended for a period of twelve months.

(6) **(Insertion:OJ-20/12/2014-29211)** No promotion may be performed inconsistently with the instruction and guidance of the Ministry. Any promotions performed in such a manner shall be considered as inappropriate promotions, and the provisions of the subparagraph (h) of the first paragraph of the article 37 of the Law shall be applicable.

Pharmacovigilance

ARTICLE 83 – (1) The Ministry will require due remedial action from the license/authorization holder all within three months, should it finds out that there is not a system for monitoring pharmacovigilance activities in place and running, no person has been appointed to assume responsibility for pharmacovigilance and there are non-conformities with or violations of this Regulation, upon conducting the necessary reviews and inspections. At the end of the above mentioned period, should the non-conformities or violations still persist, the sales authorizations of the defaulting holders shall be suspended.

(2)**(Insertion:OJ-20/12/2014-29211)** In the event that it is detected, during the audit carried out by the Ministry at the competent pharmacovigilance service institution, that pharmacovigilance studies, assumed on behalf of the marketing authorization holder, are not

carried out, or in case of detection of any non-conformity or violation in the Regulation, then the deficiency, non-conformity or violation detected shall be requested to be eliminated within a period of three months. In case of any failure in elimination of deficiencies, non-conformities or violations, then the sales authorizations of the holders, who have not eliminated such matters, shall be suspended.

CHAPTER TEN

Miscellaneous and Final Provisions

Lost licenses and authorizations

ARTICLE 84 – (Amended:OJ-11/1/2013-28525)[1]

(1) In case of loss of any product marketing authorization, warehouse license, retail sales authorization, the license or authorization holders shall apply to the competent authority from which they have obtained their licenses or authorizations originally, along with a petition and the receipt, proving that the relevant charge and fee have been fully paid, and also by adding the distorted form of such license or authorization, if the same has been distorted illegibly. The relevant authority shall re-issue such license or authorization.

Objections

ARTICLE 85 – (1) Objections to be raised against official supervisions and inspections conducted by the Ministry will be made according to Section 31 of the Law. Objections against testing and analyses of the products will require repetition thereof at laboratory facilities designated by the Ministry, the resultant findings of which to be final and binding.

Repealed regulation

ARTICLE 86 – (1) Regulation on Licensing of Veterinary Pharmaceutical and Medical Preparations and Products enacted on publication in the Official Journal No: 24915 of 23/10/2002 is hereby repealed.

(2) Regulation on Private Veterinary Laboratories, enacted on publication in the Official Journal No: 23821 of 19/9/1999 is hereby repealed.

Guidance and guidelines

ARTICLE 87 – (1) The guidance and guidelines on pharmacovigilance and manufacturing sites, which have been incorporated into the context of this Regulation by reference, shall be prepared by the Directorate General, and published through the official website of the Ministry, within twelve months following publication of this Regulation, while other guidance and guidelines shall be prepared and published within a period of three months from the same date.

(2) **(Insertion:OJ-20/12/2014-29211)** In the event that there is not any provision in relation to the matters such as development, authorization and manufacturing of the products in the guidance materials published by the Ministry, then the guidance materials of the institutions and organizations such as the European Union, World Health Organization, International Pharmaceutical Inspection Convention (PIC), International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and International Cooperation on Harmonisation (ICH), respectively, shall be taken into account.

Transitional Provision

PROVISIONAL ARTICLE 1 – (1) **(Amended:OJ-11/1/2013-28525)[1]** By the date of effect of this Regulation, the licenses or authorizations previously granted for the products having not been placed on the market, or having not been exported for the last three years will be considered as revoked, should they are not placed on the market or exported within a period of eighteen months as of the date of effect of this Regulation.

(2) The authorizations granted to the products, for which no application has been filed for time extension, up until the date of effect of this Regulation pursuant to Section 34 of the Regulation on Licensing of Veterinary Pharmaceutical and Medical Preparations and Products enacted on publication in the Official Journal No: 24915 of 23/10/2002 shall be deemed as null and void.

(3) Consideration as to which authorizations for the products that meet the requirements of the thirteenth paragraph of Article 5 of this Regulation should be revoked shall be made by the Ministry having due regard to the opinion of the international proprietor concerning empowerment and the agreements between licensees of the products. The time for consideration shall be two years starting as of the date of effect of this Regulation.

(4) Holders of licenses, preliminary authorizations or applicants of any domestic or imported products shall be obliged to submit to the Directorate General within three years following the date of effect of this Regulation, the documents proving that the sites at which the products have been manufactured comply with the requirements of this Regulation. Otherwise authorizations of the products shall be suspended until such time when the documents required are submitted or the site is replaced with another, approved alternative.

(5) The license or authorization holders will apply to the Directorate General for obtaining operating licenses within six months following the date of effect of this Regulation, or for obtaining quality management system certificates, which are essential for operating licenses, within eighteen months following the same date. The operations, falling within the scope of coverage of this Regulation, of those license or authorization holders not having applied for an operating license and presented a quality management system within the granted periods of time shall be ceased.

(6) The license or authorization holders must have at their disposal a person responsible for pharmacovigilance, duly appointed according to the relevant article of this Regulation, within three months following the date of effect of this Regulation. Non-applying license or authorization holders will not be permitted to place their products on the market.

(7) **(Amended:OJ-20/12/2014-29211)** The owners of the products in respect of which formalities were started or concluded for manufacturing authorizations or preliminary authorizations for imports to be issued, or products that are already licensed by the Ministry, before the date of entry into force of this Regulation, should adapt their files to the requirements of this Regulation, and then resubmit them to the Ministry within a period of two years in addition to the period granted for adaptation of the good manufacturing practices specified under the eighth paragraph of this article, and provided that the manufacturing site complies with the fourth paragraph of this article. The licenses, manufacture or importation preliminary authorizations of those who fail to submit the file to the Ministry within the mentioned period shall be revoked. In respect of the files in relation to the products, which are

found out to be considerably insufficient in accordance with the provisions of this Regulation in technical and administrative terms, the owners of such files, who have applied within the granted period of time, shall be informed, and shall be granted with a further period of maximum one year by the Ministry as of the date of notification, starting from the end of the period of two years specified above, at the earliest. Such products may not be manufactured or imported within a period of one year. The licenses or authorizations granted to the products, the files of which have not been harmonized with the requirements of this Regulation, for resubmission in due time shall be revoked.

(8) **(Amended:OJ-20/12/2014-29211)** The periods granted to the veterinary medical product manufacturing sites authorized by the Ministry in order to enable them to obtain the good manufacturing practice (GMP) certificate, and any other matters in relation thereto are provided as follows. The activities of the manufacturing sites, which have not obtained the certificate until the dates specified below, shall be terminated, and the operating and manufacturing authorizations granted by the Ministry shall be deemed to have been canceled.

a) The manufacturing sites of the Foot and Mouth Disease, Brusella, Sheep and Goat Plague, Sheep and Goat Pox, Anthrax and Blue Tongue vaccines and Tuberculin and Mallein tests shall be obliged to obtain good manufacturing practices (GMP) certificate until 24/12/2019 in order for manufacture of such products. In the event that such facilities manufacture any different products, then the marketing authorizations of the respective products and all authorizations granted by the Minister for the manufacturing sites shall be canceled, and the relevant provisions of the article 37 of the Law shall be applicable to the facility and its owner.

b) In respect of the veterinary medical products to be exported, the manufacturing sites, where such products are manufactured, shall be obliged to obtain good manufacturing practices (GMP) certificate until 31/12/2015, provided that the authorization is obtained from the Ministry, and that the products, for which authorization is obtained, are not placed on the market in Turkey, and that only such products are manufactured at the manufacturing sites authorized. In the event that it is acted in breach of such provisions, then the marketing authorizations of the respective products and the manufacturing site authorizations shall be canceled, and the relevant provisions of the article 37 of the Law shall be applicable to the facility and its owner.

c) The manufacturing sites and facilities, where any products other than those specified under the subparagraphs (a) and (b) of this paragraph, shall be obliged to obtain good manufacturing practices (GMP) certificate until 31/10/2015. The authorizations of the facilities, which have failed to obtain their certificates, shall be deemed to have been canceled.

(9) **(Amended:RG-11/1/2013-28525)**[(1)] Any sales points, having previously been granted with retail sales authorizations for veterinary medical products by the Ministry, shall be obliged to obtain a veterinary medical product retail sales authorization in accordance with the provisions of this Regulation until 15/10/2013. Otherwise their current sales authorizations shall be revoked.

(10) All pharmaceutical warehouses selling veterinary medical products, including those licensed by the Ministry of Heath, and veterinary pharmaceutical warehouses storing veterinary biological products must apply to the provincial directorate to obtain a veterinary

pharmaceutical warehouse license within one year following the date of entry into force of this Regulation. Those pharmaceutical warehouses, which fail to make the application as aforementioned, will not be permitted to enter into trade dealings of veterinary medical products; and their previously given biological product warehouse licenses will be deemed null and void.

(11) **(Amended:OJ-20/12/2014-29211)** The operating authorizations, granted to the manufacturing sites of the Foot and Mouth Disease, Brusella, Sheep and Goat Plague, Sheep and Goat Pox, Anthrax and Blue Tongue vaccines and Tuberculin and Mallein tests for the purpose of manufacture of such products, shall be accepted by the Ministry until 24/12/2019; and the manufacturing and operating authorizations granted to the manufacturing sites, where veterinary medical products to be exported are manufactured, shall be accepted by the Ministry until 31/12/2015; and the manufacturing and operating authorizations, granted to the manufacturing sites of any other products, shall be accepted by the Ministry until 31/10/2015.

(12) Any promotional items not complying with the provisions of this Regulation should be removed from use in no later than six moths following the date of entry into force of this Regulation. In this case, the marketing authorization holder will ultimately be held liable for any misinformation in promotional materials.

(13) The charge-free sample dispensing period mentioned in the fourth paragraph of Article 53 hereof will be one year as of the date of entry into force of this Regulation, for all products granted with a license or authorization at any time before enactment of this Regulation.

(14) **(Insertion:OJ-20/12/2014-29211)** The veterinary pharmaceutical warehouses licensed shall be obliged to carry out the requirement for determination of the scope of the activity specified under the first paragraph of the article 36 of this Regulation, and the requirement specified under the twelfth paragraph of the article 39 of this Regulation, within a period of one year following the announcement of the products and quantities thereof, required to be kept available, by the Ministry, and shall be obliged to obtain their licenses for the scope of the activity. The activities of the warehouses, which fail to obtain their licenses, shall be suspended.

(15) **(Insertion:OJ-20/12/2014-29211)** The marketing authorization shall be issued by the Ministry for the veterinary biological products, for which preliminary authorizations for imports or the manufacturing authorization is granted by the Ministry. Such products shall be exempted from any renewal processes specified under the second paragraph of the article 65 of this Regulation until issuance of a new marketing authorization.

Effect

ARTICLE 88 – (1) This Regulation shall come into effect on the date of its promulgation.

Enforcement

ARTICLE 89 – (1) The provisions of this Regulation shall be enforced by the Ministry of Food, Agriculture and Livestock.

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(1) This amendment shall come into effect on the date of its promulgation, to be effective as of 24/12/2012.

(2) By means of Article 29 of the amendment regulation, issued on the Official Journal, dated 11/1/2013, numbered 28525, the fourth paragraph has been added so as to follow the third paragraph of this Article, and the following paragraph has been continued accordingly.

	Details on the Official Journal on which the Regulation has been promulgated	
	Date	**Number**
	24/12/2011	28152
	Details on the Official Journals on which the Regulations Amending this Regulation have been promulgated	
	Date	**Number**
1.	4/4/2012	28254
2.	11/1/2013	28525
3.	20/12/2014	29211