

A REGULATION

By Ministry of Health :

Implementing Regulation on the Labeling, Package Leaflet and Tracing of Human Medicinal Products**SECTION ONE****Objective, Scope, Legal Basis and Definitions****Objective**

ARTICLE 1- (1) The objective of this Implementing Regulation is to set the procedures and principles regarding the information which must be available on labeling, package leaflet of authorized or permitted human medicinal products and allow more effective efforts against defective and falsified human medicinal products by tracing and registration system in supply chain to handle public safety.

Scope

ARTICLE 2- (1) This Implementing Regulation shall comprise the minimum compulsory information that must be placed on the labeling, package leaflet and also the real persons and legal entities and institutions and organizations that are in supply chain of human medicinal products and responsible for making compulsory notifications throughout the chain.

Legal Basis

ARTICLE 3- (1) This Implementing Regulation has been prepared on the basis of Law No. 1262 on Pharmaceutical and Medicinal Preparations, dated 14 May 1928, clause (k) of paragraph one in article 3 of Principal Law No. 3359 on Health Services, dated 7/5/1987 and article 24 of Law No. 6197 on Pharmacies and Pharmacists, dated 18 December 1953 and article 27 of Decree-Law No. 663 on Organization and Duties of Ministry of Health and its Affiliated Agencies dated 11 October 2011.

Definitions

ARTICLE 4- (1) For the purposes of this Implementing Regulation, the following definitions shall apply:

- a) Labelling: Information on the immediate or outer packaging.
- b) Human medicinal product:
 - 1) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings or,
 - 2) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis,
- c) Name of the human medicinal product: The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorization holder,
- ç) Strength of the human medicinal product: The content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form,
- d) Notification: Process of inputting actual movement and state of each unit of human medicinal product into Pharmaceutical Track and Trace System through related stakeholders,
- e) Outer packaging: The packaging into which is placed the immediate packaging,

f) Active substance: Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis,

g) Pharmaceutical form: The presentation form of the human medicinal product manufactured according to its purpose of use,

ğ) Global location number: The descriptive used for individualization of stakeholders who are in Pharmaceutical Track and Trace System,

h) Readable information: Descriptive content information placed under or near the descriptive to present contents of barcode and data matrix for end user,

ı) Immediate packaging: The container or other form of packaging immediately in contact with the medicinal product.

ı) Pharmaceutical Track and Trace System: Central register and tracking system which enables the individualization of human medicinal products by data matrix, to track all processes such as production, importation, exportation, purchasing, sale, transfer, consumption, loss and reimbursement of each human medicinal product in the supply chain and also recalling and blocking transactions can be made through this system,

j) Data matrix: Two-dimensional code in data matrix type that provides the individualization of each human medicinal product as a safety feature,

k) Summary of product characteristics: Written information about human medicinal product prepared for health professionals,

l) Kit: Any preparation to be reconstituted or combined with radionuclides in order to get finished radiopharmaceutical, usually prior to administration,

m) Package leaflet: A leaflet containing information prepared for the user which accompanies the human medicinal product,

n) Agency: Turkish Medicines and Medical Devices Agency,

o) Global Trade Item Number (GTIN): GTIN is the number which is included in the barcode of commercial products and defines each package size belonging to the name of human medicinal product based on marketing authorization or permission and identifies the product type around the world as unique,

ö) Licensor company;

1) The company which authorizes the real persons or legal entities for the importation of human medicinal products to Turkey, getting marketing authorization and marketing of them or,

2) The company which authorizes the real persons or legal entities for manufacturing, getting marketing authorization and marketing of licensed manufactured human medicinal products in Turkey,

p) Dose delivery device: Devices which are used for measurement according to posology mentioned in package leaflet like measuring spoons, measuring cups, droppers, cylindrical measuring spoons, oral dosing syringes,

r) Package transfer system: An application having information of data matrix and hierarchical transfer of packs of medicinal products through stakeholders,

s) Batch number (or Lot number): A distinctive combination of numbers and/or letters which specifically identifies the defined quantity of a product produced in one cycle of processes so that it could be expected to be homogeneous,

ş) Stakeholder: Real persons or legal entities or institutions or organizations who are authorized to perform any transaction in supply chain such as manufacturing, importation, exportation, purchasing, sale, using, overturn, consumption, loss and reimbursement related to the human medicinal product although it is limited to the authorized areas,

t) Radiopharmaceutical: Any medicinal product which, when ready for use, contains one or more radionuclides included for a medicinal purpose,

u) Radionuclide: Core undergoes spontaneous degradation, or radioactive characterized atom emitting more ionizing radiation,

ü) Radionuclide generator: Any system incorporating a fixed parent radionuclide from which a daughter radionuclide is produced through elution or by any other method and used in radiopharmaceuticals,

v) Radionuclide precursor: Any other radionuclide produced for the radio-labelling of another substance prior to administration,

y) Marketing authorization or permission holder: The real persons or legal entities who have the marketing authorization or permission of manufacturing or importing of human medicinal products,

z) Falsified human medicinal product: With the exception of unintentional quality defects and without prejudice to infringements of intellectual property rights, any medicinal product with a false representation of:

1) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients; or

2) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorization holder; or

3) its history, including the records and documents relating to the distribution channels used,

aa) Consumption centers: Real persons or legal entities or institutions or organizations who do not have the right of selling human medicinal products but only holding them in stock,

bb) Serial Number - SN: It is the number used in order to identify each unit of the product identified with GTIN,

cc) The expiry date: It shows until when the human medicinal product can be used safely,

çç) International non-proprietary name (INN): The international name of an active substance, accepted or recommended by the World Health Organization, that does not have international proprietorship and should not be used in brand registration in line with the rules of the World Health Organization,

dd) Excipient: Any constituent of a human medicinal product other than the active substance and the packaging material,

ee) Common name: The international non-proprietary name (INN) recommended by the World Health Organization, or, if INN does not exist, the common name which is available in scientifically approved classical references,

ff) High-risk human medicinal product: Human medicinal products which create irrevocable or permanent negative effect on patient when misused.

SECTION TWO

Outer Packaging, Immediate Packaging and Package Leaflet

Outer packaging

ARTICLE 5- (1) The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:

a) The name of the human medicinal product followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults; accepted by the Agency based on marketing authorization or permission. Where the product contains up to three active substances, the common name shall be included,

b) A statement of the active substances expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names,

c) The pharmaceutical form and the contents by weight, by volume or by number of doses of the product,

ç) A list of those excipients known to have a recognized action or effect and included in the detailed guidance published pursuant to paragraph 1 of article 20. However, if the human medicinal product is injectable, or a topical or eye preparation, all excipients must be stated,

d) The method of administration and, if necessary, the route of administration. Space shall be provided for the prescribed dose to be indicated,

e) The special warning stating: “Keep in its package, in a place stored out of the reach and sight of children” is included,

f) The warnings: “Do not purchase packages that have been cut or opened”, “Read the package leaflet before use”, “Consult your doctor if any undesirable effects appear” shall be included,

g) A special warning, if this is necessary for the medicinal product,

ğ) The storage conditions, and if any, the special storage conditions of the product will be indicated,

h) Special precautions relating to the disposal of unused human medicinal products or wastes of them and where necessary, the appropriate collection system shall be indicated,

i) The symbol of recyclable package, the number and abbreviation of the type of package shall be indicated on the packages as per the Implementing Regulation on Packaging and Package Wastes published in the Official Gazette No. 28035 dated 24 August 2011. The management of the wastes of outer packages shall be conducted within the scope of the related Implementing Regulation,

i) The name and address of the marketing authorization holder or permission holder, where applicable, the logo of the marketing authorization holder or of the licensor company shall be indicated,

j) The name and address of the manufacturing site shall be indicated,

k) The marketing authorization / permission date and number of the human medicinal product will be indicated,

l) The batch number shall be indicated. If batch number is placed in readable codes near data matrix it may not be placed on other areas of outer package for the second time,

m) The expiry date shall be indicated. If the expiry date is near data matrix in readable codes there is no need to mention again on outer package for the second time. If the expiry date take place on outer package other than data matrix, the date must be compatible with the date stated in the data matrix,

n) The data matrix and the readable information relating to the content of this data matrix shall be available on the outer package to ensure tracking of human medicinal products. Marketing authorization or permission holders shall place readable information regarding data matrix and its content on outer packages of human medicinal products with manufacturing or importing authorization

in line with the standards in guidelines stated in the first paragraph of article 20 of this Implementing Regulation. The data matrix shall be on the packages of human medicinal products subject to prescription or of non-prescription products and of special nutritional medicinal products including those with hospital packages. Radiopharmaceuticals, large volume parenterals and personalized human medicinal products are out of the scope of implementing data matrix on outer package,

o) The barcode of the medicinal product may be included,

ö) The price of the medicinal product may be indicated,

p) A statement indicating whether the medicinal product is or is not subjected to a prescription shall be included,

r) The statement “It contains dose delivery devices” is indicated for measurement purpose. If the volume of dose delivery device is different from measurement volume, then they are stated separately.

(2) If outer packaging cannot be prepared in Turkish, a Turkish label containing information stated in the first paragraph of this article is attached,

(3) High-risk human medicinal products may contain markings on outer packaging stating that these are high-risk products.

Immediate Packaging

ARTICLE 6- (1) Except for the particulars indicated in clauses (a), (b) and (c) of paragraph two of this article and clauses (f), (n), (o) and (p) of paragraph one of article 5 of this Implementing Regulation, immediate packaging shall bear the properties and information indicated in the first paragraph of article 5 of this Implementing Regulation.

(2) Provided that it can be in accordance with the provisions of the paragraph one of this article, particularly;

a) The following particulars at least shall appear on immediate packaging in the form of blister packs which have outer packaging including requirements on packaging information laid down in articles 5 and 9 of this Implementing Regulation:

1) The name of the human medicinal product as laid down in clause (a) of the paragraph one of article 5 of this Implementing Regulation,

2) The name or logo of the marketing authorization holder/permission holder,

3) The expiry date written in accordance with the date in readable codes near data matrix,

4) The batch number.

b) The following particulars at least shall appear on small immediate packaging on which the particulars laid down in the first paragraphs of articles 5 and 9 of this Implementing Regulation cannot be displayed:

1) The name of the human medicinal product as laid down in clause (a) of the paragraph one of article 5 of this Implementing Regulation and if necessary, the route of administration,

2) The method of administration,

3) The expiry date written in accordance with the date in readable codes near data matrix,

4) The batch number,

5) The contents by weight, by volume or by unit.

c) The name or logo of the marketing authorization holder/permission holder shall appear, if possible, on small immediate packaging on which the particulars laid down in the first paragraphs of articles 5 and 9 cannot be displayed.

(3) The current packaging of the human medicinal products with no outer packaging should comply with article 5 of this Implementing Regulation.

(4) The human medicinal product has an outer packaging prepared in accordance with article 5 of this Implementing Regulation can be accepted only if, an immediate packaging in Turkish cannot be prepared,

(5) The expiry date in immediate packaging must be in accordance with the date in readable codes near data matrix,

(6) Blister immediate packaging which have outer packaging that includes the requirements determined in terms of packaging information in articles 5 and 9 of this Implementing Regulation may be produced in a form that equals to each dosage unit in its content and that includes name, expiry date and batch number of human medicinal product.

(7) High-risk human medicinal products may contain markings on immediate packaging stating that these are high-risk products.

Transparent outer packages

ARTICLE 7 – (1) If the information needed to appear on outer packaging cannot be displayed on transparent outer packaging, it must be available on immediate packaging.

Package leaflet

ARTICLE 8- (1) The package leaflet shall be drawn up in accordance with the summary of the product characteristics of human medicinal product; to be understood easily by the users and shall include information stated below and be prepared in line with guidelines stated in article 20 of this Implementing Regulation,

a) For the identification of human medicinal product:

1) The name of human medicinal product including its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults, accepted by the Agency for marketing authorization or permission shall be written.

2) The active substances and excipients contained in each dosage unit of human medicinal product or the active substances contained in the specific volume or weight of the product according to the route of administration are stated qualitatively and the active substances are expressed quantitatively using their common name.

3) The pharmaceutical form and content by weight, by volume or by dosage units of the human medicinal product shall be indicated.

4) The pharmaco-therapeutic group or type of activity in terms easily comprehensible for the patient shall be indicated.

b) The therapeutic indications shall be indicated.

c) The list of information below which is necessary before the medicinal product is taken:

1) Contra-indications;

2) Appropriate precautions for use;

3) Forms of interaction with other medicinal products and other forms of interaction (e.g. alcohol, tobacco, foodstuffs) which may affect the action of the medicinal product;

4) Warnings for special patient groups such as children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions,

5) Possible effects on the ability to drive vehicles or to operate machinery,

6) Special warnings on excipients which are important for the safe and effective use of the medicinal product,

shall be indicated.

ç) The necessary and usual instructions for proper use of the human medicinal product, and in particular:

1) The dosage,

2) The method and, if necessary, route of administration,

3) The frequency of administration, specifying if necessary the appropriate time at which the medicinal product may or must be administered,

shall be indicated.

d) Depending on the nature of the human medicinal product:

1) The duration of treatment, where it should be limited;

2) Symptoms to be met, precautions to be taken and necessary emergency procedures in case of overdose;

3) What to do when one or more doses have not been taken;

4) Indication, if necessary, of the risk of withdrawal effects;

shall be indicated.

e) A description of the adverse reactions which may occur under normal use of human medicinal product and, if necessary, the action to be taken in such a case and a specific recommendation to consult the doctor or the pharmacist, as appropriate, for any clarification on the use of the product if any adverse reaction, which is stated or not in the package leaflet, occur

shall be indicated.

f) With a reference to that the expiry date is available on the packaging information;

1) A warning against the use of the product after that date;

2) The storage conditions,

3) If necessary, a warning against certain visible signs of deterioration or any change in the product;

4) The name and address of the marketing authorization or permission holder,

5) The name and address of the manufacturing place,

shall be indicated.

g) The date on which the package leaflet was last revised shall be stated.

ğ) Requirements about packaging information stated in “The Implementing Regulation on Safety of Medicinal Products” which was published in the Official Gazette No: 28973 dated 15 April 2014 shall be indicated.

(2) The package leaflet shall be legible and clear.

(3) When animal sources are used in the active substances and excipients of human medicinal product, this source shall be indicated in the package leaflet in accordance with the guidelines stated in paragraph one of article 20 of this Implementing Regulation.

(4) Package leaflet can be prepared in formats appropriate for the blind and partially-sighted persons under suitable circumstances.

Symbols and other information

ARTICLE 9 – (1) The outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information mentioned in articles 5 and 8 of this Implementing Regulation and other information compatible with the summary of the product characteristics which is useful to the patient, provided that these symbols do not have any promotional nature.

(2) The detailed particulars relating to the symbols, pictograms and information mentioned in paragraph one of this article shall be arranged with the guidance indicated in paragraph one of article 20 of this Implementing Regulation.

Information on promotional samples

ARTICLE 10 – (1) According to the provisions of Implementing Regulation on the Promotional Activities of Human Medicinal Products published in the Official Gazette No. 29405 dated 3 July 2015 must comply with the requirements determined by this Implementing Regulation. However, the products which are not obliged to bear data matrix on promotional samples will be decided by the Agency. The data matrix on promotional samples shows that these products cannot be sold.

(2) A promotional sample must have a statement on its outer package as “This is a promotional sample, it cannot be sold.” using the widest surface of the outer package. If possible, the same statements can be used on the immediate package also.

Solvents

ARTICLE 11 – (1) Also the products which are placed on the market as a solvent alone or to be used with another human medicinal product shall comply with the provisions of this Implementing Regulation. Regarding solvents which are presented in the same package with any human medicinal product, the name and/or formula of the solvent and its net content shall be indicated on the outer package and the package leaflet.

Products with a restricted period of use

ARTICLE 12 – (1) The duration of use and storage conditions of products with a restricted period upon being reconstituted, diluted or opened shall be separately indicated on the package and package leaflet.

Other conditions relating to packaging

ARTICLE 13 — (1) Human medicinal products shall be presented with package leaflet. The package leaflet can be conveyed in the outer packaging or on the immediate packaging or on the outer packaging.

(2) It is obligatory that the information relating to the labelling and the package leaflet shall be in Turkish for the product to be marketed. However, where necessary and if desired, the particulars stated in paragraph one of articles 5, 8 and 9 of this Implementing Regulation shall appear in Turkish and also in one of the official languages of the European Union member states with the approval of the Agency and on condition that all information in used languages will be same.

(3) The particulars referred to in the first paragraphs of articles 5 and 9 and the paragraphs 1 and 2 of article 6 of this Implementing Regulation shall be easily legible, clearly comprehensible and indelible.

(4) The name of the human medicinal product, as referred to in clause (a) of the paragraph one of article 5 shall also be expressed in Braille format on the outer packaging.

(5) Any approval shall not be necessary for the applications made by marketing authorization holder with a commitment which states that there would not be any change in outer packaging of authorized or permitted products which need renewal pursuant to fourth paragraph of this article.

(6) On the package information of non-prescription human medicinal products there may be special information belonging to user in the form identified in the guidelines stated in the first paragraph of article 20 of this Implementing Regulation.

Application

ARTICLE 14- (1) In the marketing authorization or permission applications, two samples or draft mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the draft package leaflet, shall be submitted to the Agency by the applicant.

(2) The Agency shall require from the applicant to complete the missing information and the required documents in the premarketing authorization process if the packaging information or the package leaflet or the information in the summary of product characteristic of the human medicinal product are incompatible with each other. If the deficiencies are not submitted by the applicant within one year, or if no action is taken within this period, the file is returned to applicant.

(3) Information that does not take place in summary of product characteristics, however available in labelling and package leaflet shall be submitted to Agency. If Agency have not replied a proposed change within 90 days following the submission of the application, the applicant may put the change into effect. If the implemented change is contrary to the Implementing Regulation and ascertained by the Agency the situation is informed to the applicant. Even if the Agency does not respond to the change to be carried out in labeling and package leaflet, this does not put up the legal responsibility of manufacturer or if necessary, marketing authorization or permission holder.

(4) Marketing authorization or permission holders or the applicant shall commit that outer packages of human medicinal products are designed in such a way to prevent the risk of mix up with outer packages of human medicinal products already authorized or permitted by the Agency.

SECTION THREE

Tracing of Human Medicinal Products

The Pharmaceuticals Track and Trace System

ARTICLE 15- (1) The Pharmaceuticals Track and Trace System depends basically on the follow-up of notifications that the stakeholders identified by the Global Location Number are obliged to perform according to the types they have defined by being recorded in the central data system. The data matrix of human medicinal products are notified to the Pharmaceuticals Track and Trace System by the marketing authorization or permission holder. The Pharmaceuticals Track and Trace System checks the individualization, standards and content of the reported data matrix, records the appropriate ones in the database and rejects those that are not appropriate.

(2) Stakeholders must notify the following information to the Pharmaceuticals Track and Trace System:

a) Marketing authorization or permission holders are obliged and authorized to register each unit of their products to the Pharmaceuticals Track and Trace System with production and importation notification and also make notification for purchase, sale, return, sale cancellation, exportation, exportation cancellation, overturn of the product, cancellation of overturn of the product etc. and deactivation steps of the human medicinal products for expiry date, stealing, decomposition etc.

b) Warehouses and companies authorized to make exportation are obliged to make notification to the System, for purchase, sale, return, sale cancellation, exportation, exportation cancellation, overturn of the product, cancellation of overturn of the product etc. and deactivation steps of the human medicinal products for expiry date, stealing, decomposition etc.

c) Retail pharmacies are obliged to make notification to the System, for purchase, sale, return, overturn of the product, cancellation of overturn of the product etc. and deactivation steps of the human medicinal products for expiry date, stealing, decomposition etc.

ç) Consumption centers are obliged to make notification to the System, for purchase, return, consumption, overturn of the product, cancellation of overturn of the product etc. and deactivation steps of the human medicinal products for expiry date, stealing, decomposition etc.

d) Public or private reimbursement agencies are obliged to make notification of human medicinal products they paid on to the Pharmaceutical Trace and Track System with sale query notification.

(3) Stakeholders are obliged to notify all the activities and transactions cancellations carried out on the products of which data matrix is registered to data base to the Pharmaceutical Track and Trace System. The Pharmaceutical Track and Trace System control the transactions and confirm the convenient ones, refuse the inconvenient ones.

(4) Stakeholders are obliged to store the written documentation of transactions such as production and importation documents, bill of sale, receiving note, prescription which shall verify the notification they made by hard copy or electronically for five years and obliged to submit whenever it is required by the Agency.

(5) When warehouses identify as falsified or suspect to be falsified about large volume parenterals, radiopharmaceuticals and personalized medicines which are not subject to the Pharmaceutical Track and Trace System, they must immediately inform the Agency and if applicable, the marketing authorization holder. When they identify that the human medicinal products subjected to notification as part of the Pharmaceutical Track and Trace System has not been notified to the System, they must immediately inform the Agency and where possible, the marketing authorization holder.

Registration and safety

ARTICLE 16- (1) The transactions registration of human medicinal products are carried out by data matrix and transactions registration of stakeholders are conducted by global location number. The registration information is stored in Ministry of Health's Database Center.

(2) The data matrix is consist of Global Trade Item Number, batch (lot) number, serial number and the expiry date. Global Trade Item Number and the serial number make the product individualized. The Pharmaceutical Track and Trace System does not allow registration of the product having same global trade item number and serial number.

Distribution

ARTICLE 17- (1) In distribution of each human medicinal product, it is obligatory to comply with the provisions of this Implementing Regulation. However, medicinal products in public procurement can bear extra information like "subject to procurement and cannot be sold" provided that it does not contrary to this Implementing Regulation.

(2)When transporting more than one box of human medicinal products, marketing authorization or permission holders shall use "transport packaging" for the safety of these products. Transport packaging can be one within the other as package, parcel, box or bag. The content of transport packaging as numbers must be determined reasonably during the sale till the last point of consumption without opening.

(3) Transport packaging must bear an identifier containing information about this package or identifier carrying all data matrix information of human medicinal products in these packages. Identifiers which are available on transport packaging are implemented in conformity with the guidelines stated in first paragraph of article 20 of this Implementing Regulation. The stakeholders can use Package Transfer System in order to transfer these identifiers among each other.

(4) When there is a data matrix usage difficulty due to the packaging characteristics of human medicinal products, the transport packaging of human medicinal products of more than one box can be sold together, is data matrixed by one code.

(5) Track system rules for large volume parenterals, radiopharmaceuticals and personalized medicines shall be applied according to guidelines stated in the first paragraph of article 20 of this Implementing Regulation.

SECTION FOUR

Radiopharmaceuticals

Labeling for radiopharmaceuticals

ARTICLE 18- (1) The outer packaging and the container of human medicinal products containing radionuclides shall be labelled in accordance with the related legislation of Turkish Atomic Energy Authority and other international legislations. Moreover, the labelling shall comply with the provisions set out in paragraphs 2 and 3 of this article.

(2) The label on the shielding shall include the particulars mentioned in article 5 except for the provisions of clauses (n) and (p) of the paragraph one of article 5 of this Implementing Regulation. In addition, the labelling on the shielding shall explain in full the coding used on the vial and shall indicate the radioactivity marker, for a given time and date, the amount of radioactivity per dose or per vial and the number of capsules, or, for liquids, the number of milliliters in the container.

(3) The vial shall be labelled with the following information:

- a) The name or code of the medicinal product, including the name or chemical symbol of the radionuclide,
- b) The batch number and expiry date,
- c) The international symbol for radioactivity,
- ç) The name and address of the manufacturer,
- d) The amount of radioactivity as specified in paragraph 2 of this article.

Package leaflet of radiopharmaceuticals

ARTICLE 19- (1) It is mandatory for the packaging of radiopharmaceuticals, radionuclide generators, radionuclide kits or radionuclide precursors to include a detailed instruction leaflet.

(2) The package leaflet shall be established in accordance with the provisions of article 8 of this Implementing Regulation. In addition, the leaflet shall include any precautions to be taken by the user and the patient during the preparation and administration of the medicinal product and special precautions for the disposal of the packaging and its unused contents.

SECTION FIVE

Miscellaneous and Final Provisions

Guidance

ARTICLE 20- (1) The Agency shall publish in the form of a guidance the general principles to be complied with where necessary and in relation with the following;

- a) The wording of certain special warnings for certain categories of human medicinal products;
- b) The particular information needs for the users relating to non-prescription human medicinal products;
- c) The legibility of particulars on the labelling and package leaflet;
- ç) The application methods for the Pharmaceutical Track and Trace System,
- d) The list of excipients which must feature on the labelling of human medicinal products and the way in which these excipients must be indicated;

(2) The Agency may issue supplementary guidelines or notifications relating to the enforcement of this Implementing Regulation for conditions not indicated in the Implementing Regulation and where deemed necessary.

Price label and barcode

ARTICLE 21- (1) As the data matrix applied on the labeling of all products manufactured since 1 January 2010 by the marketing authorization or permission holders are used for reimbursement and monitoring purposes, data matrix statement compromise both price label and barcode in other legislations referring to this Implementing Regulation.

Penalty provisions and precautions

ARTICLE 22 – (1) For those who fail to act in accordance with the provisions of this Implementing Regulation, Law No. 1262 on Pharmaceutical and Medicinal Preparations, Law on Pharmacies and Pharmacists No.6197, the Misdemeanor Law dated 30 March 2005 No.5326 and the provisions of Turkish Penal Code, No. 5237, dated 26 September 2004 shall be applied.

(2) Furthermore, in case of detection of violation of the provisions of this Implementing Regulation, the measures and sanctions envisaged by the Implementing Regulation on Regarding the Marketing Authorization to Human Medicinal Products published in the Official Gazette dated 19 January 2005, No. 25705 shall be applied.

References

ARTICLE 23 – (1) References made to Implementing Regulation on Packaging and Labeling of Human Medicinal Products which has been abolished by article 25 are deemed referred to this Implementing Regulation.

European Union legislation harmonization

ARTICLE 24- (1) This Implementing Regulation has been prepared in line with Directive 2001/83/EC on medicinal products for human use and 2011/62/EU on relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, for the purpose of ensuring harmonization with the relevant legislation of the European Union regarding medicinal products for human use.

Abolished regulation

ARTICLE 25 – (1) The Implementing Regulation on the Packaging and Labeling of Human Medicinal Products published in the Official Gazette dated 12 August 2005, No. 25904, has been abolished.

Transition provision

TEMPORARY ARTICLE 1 – (1) Packages and leaflets of current human medicinal products of which marketing authorization or permission application have been made or which were authorized or permitted before the entry into force of this Implementing Regulation, shall be submitted to the

Agency in line with the provisions of this Implementing Regulation until 30 September 2017 at the latest.

(2) Human medicinal products manufactured before 31 December 2017 may be available on the market with current packages until expiry date.

(3) Packages and leaflets of human medicinal products manufactured after 30 December 2017 are obliged to meet provisions of this Implementing Regulation.

(4) Food for special medical purposes which are not subject to reimbursement and included in the data matrix according to clause (n) of paragraph 1 of article 5 of this Implementing Regulation, the date of transfer to data matrix application is 31 December 2018 at the latest.

(5) The date of transfer to data matrix application within the scope of guidelines stated in the first paragraph of article 20 of this Implementing Regulation for large volume parenterals, radiopharmaceuticals and personalized medicines is 31 December 2018 at the latest.

Braille format implementation

TEMPORARY ARTICLE 2 – Requirements stated in the fourth paragraph of article 13 shall be met until 31 December 2018.

Entry into force

ARTICLE 26 – (1) This Implementing Regulation shall enter into force when published.

Enforcement

ARTICLE 27 – (1) The provisions of this Implementing Regulation shall be enforced by the President of Turkish Medicines and Medical Devices Agency.