

REGULATION ON PACKAGING INFORMATION, PATIENT INFORMATION LEAFLET AND TRACKING OF MEDICINAL PRODUCTS FOR HUMAN USE

SECTION ONE Purpose, Scope, Legal Basis and Definitions Purpose

ARTICLE 1 – (1) The purpose of this Regulation is to set forth the procedures and principles regarding the information that must be included in the packaging information and the patient information leaflet in order to ensure the correct use of licensed or authorized medicinal products for human use with regard to the health and safety of persons, as well as the tracking and recording of the distribution chain and the establishment of the necessary tracking and recording systems in order to take more effective measures against defective and counterfeit medicinal products for human use. Scope

ARTICLE 2 – (1) This Regulation covers the minimum information that must be included in the packaging information and the patient information leaflet of medicinal products for human use, the notifications to be made for the purpose of tracking and recording the entire distribution chain, and the natural persons and legal entities, institutions and organizations operating within the distribution chain. Legal Basis

ARTICLE 3 – (1) This Regulation has been prepared based on the Law on Pharmaceuticals and Medical Preparations No. 1262 dated 14/5/1928, subparagraph (k) of the first paragraph of Article 3 of the Basic Law on Health Services No. 3359 dated 7/5/1987, Article 24 of the Law on Pharmacists and Pharmacies No. 6197 dated 18/12/1953, and Article 27 of the Decree Law No. 663 dated 11/10/2011 on the Organization and Duties of the Ministry of Health and Its Affiliated Institutions. Definitions

ARTICLE 4 – (1) The following terms used in this Regulation shall denote: a) Packaging information: the information on the immediate or outer packaging, b) Medicinal product for human use: 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 that may be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or making a medical diagnosis, c) Name of the medicinal product for human use: the invented trade name, in such a way as to prevent confusion with the common name of the medicinal product for human use, or the common or scientific name of the medicinal product for human use, given with or without the name or trade mark of the marketing authorisation or licence holder of the medicinal product for human use, ç) Strength of the medicinal product for human use: the quantitative amount of the active substance or substances contained in each dosage unit, unit volume or unit weight of the medicinal product for human use, depending on the pharmaceutical form, d) Notification: the process of communicating the actual movement and status of each unit of the medicinal product for human use to the Pharmaceutical Track and Trace System by the stakeholders, e) Outer packaging: the packaging into which the immediate packaging is placed, f) Active substance: any substance or combination of substances that is intended to be used in the manufacture of a medicinal product for human use and that, when so used, is the active component of the product intended to exert a pharmacological, immunological or metabolic action in order to restore, correct or modify physiological functions or to make a medical diagnosis, g) Pharmaceutical form: the form of presentation of the medicinal product for human use manufactured in accordance with its intended use, ğ) Global location number: the identifier used to uniquely identify stakeholders in the Pharmaceutical Track and Trace System, h) Human-readable information: the identifying content information written in an area below or near the identifier, for the purpose of displaying the contents of the barcode or two-dimensional (2D) code to users, ı) Immediate packaging: the container or other form of packaging in direct contact with the medicinal product for human use, i) Pharmaceutical Track and Trace System: the central recording and tracking system that enables the serialisation of medicinal products for human use using a two-dimensional (2D) code, monitors in real time, through notifications made at the points

through which each unit passes, all movements occurring in the supply chain such as production, importation, exportation, purchase, sale, transfer, consumption, loss and reimbursement, or the cancellations of such movements, and in which operations such as recall and blocking that must be carried out on these products are performed, j) Two-dimensional (2D) code: the datamatrix-type two-dimensional code that enables the serialisation of the product as a security feature, k) Summary of product characteristics: the written information prepared for health professionals regarding the medicinal product for human use, l) Kit: any preparation to be combined with radionuclides, usually at the time of administration, or reconstituted in order to obtain a finished radiopharmaceutical, m) Patient information leaflet: the written information supplied with the medicinal product for human use, prepared for the user, n) Agency: the Turkish Medicines and Medical Devices Agency (TİTCK), o) Global Trade Item Number (GTIN): the number printed in barcode form on commercial products, uniquely identifying worldwide each packaging size of the name of the medicinal product for human use on which the marketing authorisation or licence is based, ö) Licensor company: 1) the company authorising a natural or legal person for the importation into Turkey, marketing authorisation and sale of an imported medicinal product for human use, or 2) the company authorising a natural or legal person for the manufacture, marketing authorisation and sale in Turkey of a licensed domestically manufactured medicinal product for human use, p) Measuring device: the administration device contained in the packaging, such as a spoon, cup, dropper, cylindrical measuring spoon or dosing syringe, scaled in such a way as to ensure use of the medicinal product for human use in accordance with the posology in its patient information leaflet, r) Package transfer system: the application enabling the transfer of the two-dimensional (2D) codes of all products transferred between stakeholders and the hierarchy information of the shipping units containing those products, s) Batch number (serial number): the distinctive combination of digits and/or letters that specifically identifies the quantity obtained in a single production cycle during the manufacture of a product and in which homogeneity is ensured, ş) Stakeholder: natural or legal persons, or institutions or organisations capable of carrying out any movement occurring in the supply chain in relation to medicinal products for human use, such as production, importation, purchase, sale, use, consumption, exportation, transfer, loss and reimbursement, limited to the areas in which they are authorised, t) Radiopharmaceutical: any medicinal product for human use which, when prepared for medicinal use and ready for use, contains one or more radionuclides in its structure, u) Radionuclide: an atom of radioactive nature whose nucleus undergoes spontaneous decay, emitting one or more types of ionising radiation, ü) Radionuclide generator: any system containing a fixed parent radionuclide in its content and from which a daughter radionuclide obtainable from this parent radionuclide by elution or another method is produced, and which is used in radiopharmaceutical products, v) Radionuclide precursor: any other radionuclide produced for the radioactive labelling of another substance prior to administration, y) Marketing authorisation or licence holder: the natural or legal person holding the manufacturing or importation marketing authorisation or licence of medicinal products for human use, z) Falsified medicinal product for human use: a medicinal product for human use that has been falsified, excluding quality defects arising unintentionally and issues of infringement of intellectual property rights, with respect to: 1) its identity, including its packaging, packaging information, label, name or excipients, including one of the substances in its composition and the strength of one of those substances, or 2) its source, including its manufacturer, country of manufacture, country of origin or marketing authorisation or licence holder, or 3) its history, including the records and documents relating to the distribution channels used, aa) Dispensing centres: natural or legal persons, or institutions or organisations not authorised to sell medicinal products for human use but authorised to hold and dispense them, bb) Serial number (SN): the number used to identify each unit of the product identified by the Global Trade Item Number, cc) Expiry date: the date information indicating the end of the shelf life determined in accordance with the storage conditions of medicinal products for human use, çç) International Nonproprietary Name (INN): the international name of an active substance, adopted

or proposed by the World Health Organization, which is not subject to proprietary rights and which should not be used in trade mark registration in accordance with the rules of the World Health Organization, dd) Excipient: any substance other than the active substance and the packaging material contained in the composition of the medicinal product for human use, ee) Common name: the INN recommended by the World Health Organization or, where the INN does not exist, the name of the active substance as it appears in classical sources scientifically accepted as reference, ff) High-risk medicinal product for human use: medicinal products for human use that cause irreversible or permanent adverse effects on the patient when used incorrectly. **SECOND SECTION Outer Packaging, Immediate Packaging and Patient Information Leaflet Outer packaging**

ARTICLE 5 – (1) On the outer packaging of a medicinal product for human use or, where there is no outer packaging, on the immediate packaging: a) The accepted name of the medicinal product for human use, which includes the name of the medicinal product for human use, its strength, pharmaceutical form and, where applicable, information indicating that it is intended for infants, children or adults, as accepted by the Agency as the basis for the licence or authorisation, shall be stated. Where the medicinal product for human use contains up to three active substances, the common name shall be indicated. b) The active substances contained in each dosage unit, or contained in a certain volume or weight according to the method of administration, shall be expressed qualitatively and quantitatively using their common names. c) The contents shall be stated in terms of pharmaceutical form and weight, volume or number of doses. ç) Excipients the effects of which are known to be evident and which are included in the guideline referred to in the first paragraph of Article 20 of this Regulation shall be listed. However, if the medicinal product for human use is an injectable, topical or ophthalmic preparation, all excipients shall be indicated. d) The method of administration and, if necessary, the route of administration shall be stated. The space required to indicate the prescribed dose shall be left blank. e) The special warning "Store out of the reach and sight of children and in its packaging." shall be included. f) The warnings "Do not purchase packages that are cut or opened.", "Read the patient information leaflet before use.", "In case of any unexpected effect, consult your doctor." shall be included. g) Other special warnings pertaining to the medicinal product for human use, if any, shall be indicated. ğ) Storage conditions and, where applicable, special storage conditions shall be stated. h) Special warnings regarding the disposal of unused medicinal products for human use or waste from medicinal products for human use, and, where appropriate, the appropriate collection system shall be indicated. ı) In accordance with the Regulation on the Control of Packaging Waste published in the Official Gazette No. 28035 dated 24/8/2011, the recyclable packaging symbol, the abbreviation indicating the type of packaging and the number of the material type shall be included on the packaging. The management of outer packaging waste of medicinal products for human use shall be carried out in accordance with the relevant legislative provisions. i) The name and address of the licence or authorisation holder shall be included. The emblem or logo of the licence or authorisation holder, and the name and/or emblem or logo of the licensee company may be included. j) The name and address of the manufacturing site shall be included. k) The date and number of the licence or authorisation shall be included. l) The batch number shall be included. On the outer packaging, the batch number need not be repeated elsewhere on the outer packaging if it is already contained in human-readable codes next to the QR code (datamatrix). m) The expiry date shall be included. On the outer packaging, the expiry date need not be repeated elsewhere on the outer packaging if it is already contained in human-readable codes next to the QR code (datamatrix). Where the expiry date is also to be stated separately, it shall be indicated in accordance with the date contained in the human-readable information next to the QR code. n) In order to ensure the traceability of medicinal products for human use, a QR code (datamatrix) and human-readable information on its content shall be placed next to it. Licence or authorisation holders shall apply the QR code (datamatrix) and the human-readable information on its content legibly on the outer packaging of domestically manufactured or imported licensed or authorised medicinal products for human use, in compliance with the standards set out in the guidelines

referred to in the first paragraph of Article 20 of this Regulation. The QR code (datamatrix) shall be placed on the packaging of medicinal products for human use subject to prescription or not subject to prescription, as well as on foods for special medical purposes, including those with hospital packaging. Large-volume parenterals, radiopharmaceuticals and medicinal products for human use manufactured on a patient-specific basis are outside the scope of the QR code (datamatrix) application on the outer packaging. o) A barcode may be included. ö) Pricing information may be included. p) A statement indicating whether the product is subject to prescription or not subject to prescription shall be included. r) For products used with a graduated scale and containing a measuring device, the statement "A measuring device is included." shall be placed. Where the volume of the measuring device differs from the graduated scale, the scale volume and the measuring device volume shall be indicated separately. (2) Where a Turkish outer packaging cannot be prepared, a Turkish label containing the information specified in the first paragraph of this Article shall be affixed to the outer packaging. (3) The outer packaging of high-risk medicinal products for human use may be marked with a symbol indicating that these products are high-risk. Immediate packaging

ARTICLE 6 – (1) The immediate packaging shall bear the characteristics and information laid down in the first paragraph of Article 5 of this Regulation, except for the matters specified in subparagraphs (a), (b) and (c) of the second paragraph of this Article and in subparagraphs (f), (n), (o) and (p) of the first paragraph of Article 5 of this Regulation. (2) Provided that they comply with the provisions of the first paragraph of this Article, in particular: a) In the case of immediate packaging in blister form with an outer packaging containing the matters laid down in Articles 5 and 9 of this Regulation with respect to packaging information, at a minimum: 1) The name of the medicinal product for human use, as specified in subparagraph (a) of the first paragraph of Article 5 of this Regulation, 2) The name, emblem or logo of the licence or authorisation holder, 3) The expiry date, written in accordance with the date contained in the human-readable information next to the QR code (datamatrix), 4) The batch number, shall be included. b) In the case of immediate packaging that is too small to contain the characteristics and information laid down in the first paragraphs of Articles 5 and 9 of this Regulation with respect to packaging information, at a minimum: 1) The name of the medicinal product for human use, as specified in subparagraph (a) of the first paragraph of Article 5 of this Regulation, and, where applicable, the route of administration, 2) The method of administration, 3) The expiry date, written in accordance with the date contained in the human-readable information next to the QR code (datamatrix), 4) The batch number, 5) The content by weight, volume or unit, shall be included. c) In the case of immediate packaging that is too small to contain the characteristics and information laid down in the first paragraphs of Articles 5 and 9 of this Regulation with respect to packaging information, the name, emblem or logo of the licence or authorisation holder shall be included, where possible. (3) The existing packaging of medicinal products for human use without outer packaging shall comply with Article 5 of this Regulation. (4) The impossibility of preparing Turkish immediate packaging shall be accepted only where the product has an outer packaging complying with Article 5 of this Regulation. (5) On the immediate packaging, the expiry date shall be indicated in accordance with the date contained in the human-readable information next to the QR code (datamatrix).

(6) Blister immediate packaging with an outer packaging containing the matters laid down with respect to packaging information in Articles 5 and 9 of this Regulation may be manufactured such that they correspond to each dosage unit contained therein and bear the name of the medicinal product for human use, the expiry date and the batch number. (7) The immediate packaging of high-risk medicinal products for human use may be marked with a symbol indicating that these products are high-risk. Transparent outer packaging

ARTICLE 7 – (1) Where the information required to be on the outer packaging is not present on a transparent outer packaging, it shall be included on the immediate packaging. Patient information leaflet

ARTICLE 8 – (1) The package leaflet shall be prepared in accordance with the summary of product characteristics of the human medicinal product, in a manner easily understandable by the user, containing the following information and in line with the guidelines specified in Article 20 of this Regulation: a) For the identification of the human medicinal product: 1) The approved name on which the licence or permit granted by the Agency is based shall be stated, including the name of the human medicinal product, its strength, pharmaceutical form and, where applicable, the information that it is intended for infants, children or adults. 2) The active substances and excipients contained in each dosage unit of the human medicinal product, or contained in a certain volume or weight according to the method of administration, shall be expressed qualitatively, and the active substances quantitatively, using their common names. 3) The pharmaceutical form of the human medicinal product and its content in terms of weight, volume or dosage unit shall be stated. 4) The pharmacotherapeutic group or type of action shall be stated in terms easily understandable by the patient. b) The therapeutic indications, the position in therapy shall be stated. c) The following information necessary before taking the human medicinal product: 1) Contraindications, 2) Precautions for use, 3) Interactions with other human medicinal products or with alcohol, tobacco, food and other forms of interaction that may affect the effect of the human medicinal product, 4) Warnings for specific patient groups such as children, pregnant or breastfeeding women, the elderly and persons with special pathological conditions, 5) The effects of the human medicinal product on the ability to drive and use machines, 6) Special warnings concerning excipients that are important for the safe and effective use of the human medicinal product, shall be included. ç) The following general and necessary information for the correct use of the human medicinal product: 1) The dose, 2) The method of administration and, if necessary, the route of administration, 3) The frequency of administration, indicating the appropriate time at which the human medicinal product may or must be used, if necessary, shall be included. d) Depending on the nature of the human medicinal product: 1) The duration of treatment where it should be limited, 2) The symptoms that may occur in case of overdose, the measures to be taken and the necessary emergency interventions, 3) The course of action to be followed if one or more doses are not taken, 4) Where necessary, information on the risks that may arise when the use of the human medicinal product is discontinued, shall be included. e) The undesirable effects that may occur during normal use of the human medicinal product, the measures to be taken in such a case where necessary, and the information that the patient should consult his/her physician or pharmacist when encountering any undesirable effect, whether or not included in the package leaflet, shall be included. f) Together with a statement emphasising that the expiry date is stated on the packaging information: 1) A warning not to use the product after this date, 2) Storage conditions, 3) Where applicable, a warning against any visible deterioration or change in the human medicinal product, 4) The name and address of the marketing authorisation or permit holder, 5) The name and address of the manufacturer and the manufacturing site, shall be included. g) The date on which the package leaflet was last updated shall be included. ğ) The requirements regarding packaging information set out in the Regulation on Safety of Medicinal Products published in the Official Gazette No. 28973 dated 15/4/2014 shall be included. (2) The package leaflet shall be easy to read and clearly understandable. (3) In cases where animal-derived materials are used in the active substances and excipients of human medicinal products, such origin shall be indicated in the package leaflet in accordance with the guideline specified in the first paragraph of Article 20 of this Regulation. (4) Where necessary, the package leaflet may be prepared in a suitable format for the visually impaired and the partially sighted. Symbols and other information

ARTICLE 9 – (1) The outer packaging and the package leaflet may contain symbols and pictorial diagrams explaining the information specified in the first paragraphs of Articles 5 and 8 of this Regulation, provided that they are not of a promotional nature and do not serve advertising purposes, and other information useful to users and consistent with the summary of product characteristics of the human medicinal product. (2) Detailed matters concerning the symbols,

pictorial diagrams and information referred to in the first paragraph of this Article are regulated in the guideline specified in the first paragraph of Article 20 of this Regulation. Information on promotional samples

ARTICLE 10 – (1) Products to be used for promotion in accordance with the provisions of the Regulation on Promotional Activities for Human Medicinal Products published in the Official Gazette No. 29405 dated 3/7/2015 shall also be required to comply with the conditions laid down in this Regulation. However, the Agency shall determine which of the products shall be excluded from the QR code application on promotional samples. The QR code on promotional samples shall indicate that the human medicinal product is not for sale. (2) The statements "Promotional sample, not for sale" on the outer packaging of promotional samples shall appear on the largest surface in a conspicuous manner. Where printing is possible, the same statements shall also appear on the immediate packaging. Solvents

ARTICLE 11 – (1) Products presented for use as solvents, either alone or together with a human medicinal product, shall also be required to comply with the provisions of this Regulation. For solvents presented in the same packaging with a human medicinal product, the name and/or formula and net content of the solvent shall be stated on the outer packaging and in the package leaflet of the human medicinal product. Products with a limited period of use

ARTICLE 12 – (1) For human medicinal products with a limited period of use after reconstitution, dilution or opening, the period of use and storage conditions shall additionally be stated on the packaging and in the package leaflet. Other conditions concerning packaging

ARTICLE 13 – (1) A human medicinal product shall be presented together with its package leaflet. The package leaflet shall be contained inside the outer packaging of the human medicinal product or on the immediate packaging or on the outer packaging. (2) For the placing on the market of the human medicinal product, the packaging information and the information in the package leaflet shall be in Turkish. However, where necessary and upon request, the matters specified in the first paragraphs of Articles 5, 8 and 9 of this Regulation may be used, alongside Turkish, in one of the official languages of the European Union member states, subject to the condition that the same matters appear in all languages used, and with the approval of the Agency. (3) The information specified in the first paragraphs of Articles 5 and 9 of this Regulation and in the first and second paragraphs of Article 6 shall be easy to read, clearly understandable and indelible. (4) The name of the human medicinal product referred to in subparagraph (a) of the first paragraph of Article 5 of this Regulation shall also be presented on the outer packaging in embossed print, in Braille format. (5) No approval shall be required for applications made by the marketing authorisation or permit holders regarding the outer packaging of licensed or permitted products that need to be renewed for the reason specified in the fourth paragraph of this Article, provided that it is declared that no other change has been made. (6) The packaging information of human medicinal products not subject to prescription may contain personal information for the user as determined in the guidelines specified in the first paragraph of Article 20 of this Regulation. Application

ARTICLE 14 – (1) In the application for a license or authorization, the applicant shall submit to the Agency two specimens or drafts each of the outer and inner packaging prepared in the form in which the medicinal product for human use is to be placed on the market, together with a draft of the package leaflet. (2) Where the packaging information, the package leaflet of the medicinal product for human use undergoing the licensing process, the information contained in this Regulation or in the summary of product characteristics are not consistent with one another, the Agency shall request the applicant to complete the missing information and documents. If these deficiencies are not remedied by the applicant within one year, or if no action is taken within this period, the file shall be removed from processing and returned. (3) Any changes contemplated in the packaging information or the package leaflet which fall outside the scope of the summary of product characteristics but fall within the scope of this Regulation shall be submitted to the Agency. If the Agency does not respond within ninety days of the date of application, the applicant

may implement the change. Where it is determined by the Agency that the implemented changes are contrary to this Regulation, the applicant shall be notified for correction. The failure of the Agency to respond to a change to be made in the packaging information or the package leaflet shall not relieve the manufacturer or, where applicable, the license or authorization holder of their legal responsibilities. (4) The license, authorization or application holder shall undertake that the outer packaging of medicinal products for human use is designed in such a way as to prevent the risk of confusion with the outer packaging of medicinal products for human use previously licensed or authorized by the Agency. **THIRD SECTION Tracking of Medicinal Products for Human Use Pharmaceutical tracking system**

ARTICLE 15 – (1) The Pharmaceutical Tracking System operates, in principle, on the basis that the notifications which stakeholders, identified by the Global Location Number, are obliged to make according to the types by which they are identified are recorded and tracked in a central data system. The data matrix codes of medicinal products for human use are reported to the Pharmaceutical Tracking System by the license or authorization holder. The Pharmaceutical Tracking System checks the uniqueness, standards and content of the reported data matrix code, records those that are compliant in the database, and rejects those that are not. (2) Stakeholders:

a) License or authorization holders; are obliged and authorized to register each unit of their products in the Pharmaceutical Tracking System through a production notification or import notification. In addition, they shall carry out the deactivation of medicinal products for human use that have lost their characteristics due to expiry, theft, deterioration and similar reasons, along with transactions such as product purchase, sale, return, cancellation of sale, export, cancellation of export, transfer of goods and cancellation of transfer of goods, b) Pharmaceutical warehouses and companies authorized to export; shall carry out the deactivation of medicinal products for human use that have lost their characteristics due to expiry, theft, deterioration and similar reasons, along with transactions such as product purchase, sale, return, cancellation of sale, export, cancellation of export, transfer of goods and cancellation of transfer of goods, c) Community pharmacies; shall carry out the deactivation of medicinal products for human use that have lost their characteristics due to expiry, theft, deterioration and similar reasons, along with transactions such as product purchase, sale, return, transfer of goods and cancellation of transfer of goods, ç) Consumption centers; shall carry out the deactivation of medicinal products for human use that have lost their characteristics due to expiry, theft, deterioration and similar reasons, along with transactions such as product purchase, return, consumption, transfer of goods and cancellation of transfer of goods, d) Public and private reimbursement organizations covering the cost of medicines; the medicinal products for human use for which they have made payment, through a sale inquiry notification, are required to report to the Pharmaceutical Tracking System. (3) Stakeholders are obliged to report to the Pharmaceutical Tracking System all movements and movement cancellations they perform on products whose data matrix code is recorded in the database. The Pharmaceutical Tracking System approves notifications whose standards and content are compliant and rejects those that are not. (4) Stakeholders are obliged to retain, for five years, in physical or electronic form, the originals or legible copies of documents such as production or import documents, invoices, waybills and prescriptions verifying the notifications they have made to the Pharmaceutical Tracking System, in order to submit them upon request by the Agency. (5) Pharmaceutical warehouses are obliged, for large-volume parenterals, radiopharmaceuticals and medicinal products for human use manufactured on a personalized basis, which are outside the scope of the data matrix code application on the outer packaging, to immediately notify the Agency and, where possible, the license holder when they identify or suspect that a product is falsified. Furthermore, in cases where it is determined that a medicinal product for human use subject to notification under the Pharmaceutical Tracking System is not registered in the Pharmaceutical Tracking System, they are obliged to immediately notify the Agency and, where possible, the license holder of the situation. **Registration and security**

ARTICLE 16 – (1) The movement records of medicinal products for human use are kept through the data matrix code, and the stakeholder movement records through the Global Location Number. The records are stored in the Data Center of the Ministry of Health. (2) The data matrix code consists of the Global Trade Item Number, batch number, serial number and expiry date. The Global Trade Item Number and the serial number make the product unique. The Pharmaceutical Tracking System does not permit the registration in the system of a product bearing the same Global Trade Item Number and serial number. Distribution

ARTICLE 17 – (1) Compliance with the provisions of this Regulation is mandatory in the distribution of every medicinal product for human use. However, in procurements to be made by official health institutions and organizations, certain additional information such as "For tender, not for sale" may be used in the packaging information, provided that this does not conflict with this Regulation. (2) License or authorization holders; when dispatching more than one medicinal product for human use, shall use transport packaging in order to ensure the integrity of these products. Transport packaging may be in the form of bundles, cartons, boxes or ties and may be nested within one another. The quantities contained in the transport packaging are determined at reasonable levels to allow transport to the final point without being opened during sale. (3) On the transport packaging there shall mandatorily be an identifier containing information identifying the transport packaging, or an identifier containing all of the data matrix code information of the medicinal products for human use inside the transport packaging. The identifiers to be affixed on the transport packaging are applied in the manner determined in the guides referred to in paragraph one of Article 20 of this Regulation. Stakeholders may use the Package Transfer System for the purpose of transferring these identifiers among themselves. (4) In cases where there are problems in applying the data matrix code due to the nature of the packaging of medicinal products for human use, the transport packaging of medicinal products for human use whose multiple quantities can be sold together shall be coded with a data matrix code as a single product. (5) The rules of the tracking system to be applied to large-volume parenterals, radiopharmaceuticals and medicinal products for human use manufactured on a personalized basis shall be applied in the manner determined in the guides referred to in paragraph one of Article 20 of this Regulation. **FOURTH SECTION Radiopharmaceuticals Packaging information of radiopharmaceuticals**

ARTICLE 18 – (1) Labels shall be affixed to the inner packaging container and the outer packaging of medicinal products for human use containing radionuclides in accordance with the relevant legislation of the Turkish Atomic Energy Authority and other international legislation. In addition, the label must comply with the conditions specified in paragraphs two and three of this Article. (2) The label on the protective shield shall comply with Article 5 of this Regulation, with the exception of the provisions of subparagraphs (n) and (p) of paragraph one of Article 5. In addition, the label must fully explain all coding on the vial. The label shall indicate the radioactivity symbol, the radioactivity amount per dose or per vial and the number of capsules or, for liquids, the quantity in milliliters in the vial, for the determined period and date. (3) On the label on the vial;

a) The name or code of the medicinal product for human use, including the name or chemical symbol of the radionuclide, b) The batch number and expiry date, c) The international radioactivity symbol, ç) The name and address of the site of manufacture and production, d) The radioactivity amount as specified in paragraph two of this Article, shall be included. **Package leaflet of radiopharmaceuticals**

Article 19 – (1) It shall be mandatory for the packaging of radiopharmaceuticals, radionuclide generators, radionuclide kits or radionuclide precursors to contain detailed instructions for use. (2) The instructions for use shall be prepared in accordance with Article 8 of this Regulation. In addition, the instructions for use shall include the special precautions to be taken by the practitioner and the patient during the preparation and administration of the medicinal product for human use, as well as warnings regarding the proper disposal of unused portions or packaging. **SECTION FIVE Miscellaneous and Final Provisions Guidelines**

Article 20 – (1) The Agency, where necessary and in particular; a) in establishing warnings for certain categories of medicinal products for human use, b) in arranging user-specific information for medicinal products for human use not subject to prescription, c) in ensuring the legibility of the information on the packaging and in the instructions for use, ç) in the modalities of implementation of the Pharmaceutical Track and Trace System, d) in the list of excipients to be included on the packaging of medicinal products for human use and the manner of their indication, shall publish general principles to be followed in the form of guidelines. (2) The Agency shall publish additional guidelines or communiqués for the implementation of this Regulation in cases not enumerated in this Regulation and where it deems necessary. Coupon and barcode

Article 21 – (1) Since the datamatrix code affixed by marketing authorization or permit holders to all products manufactured as of 1/1/2010 is used on the packaging of medicinal products for human use for both tracking and reimbursement purposes, the expression 'datamatrix code' also covers the expressions 'coupon' or 'coupon and barcode' contained in other legislation referring to this Regulation. Penalties and measures

Article 22 – (1) The provisions of Law No. 1262 on Pharmaceuticals and Medicinal Preparations, Law No. 6197 on Pharmacists and Pharmacies, Law No. 5326 on Misdemeanors dated 30/3/2005 and the Turkish Penal Code No. 5237 dated 26/9/2004 shall apply to those who fail to comply with the provisions of this Regulation. (2) Furthermore, in the event that a violation of the provisions of this Regulation is detected, the measures and sanctions provided for in the Regulation on the Licensing of Medicinal Products for Human Use published in the Official Gazette No. 25705 dated 19/1/2005 shall be applied. References

Article 23 – (1) References made to the Regulation on the Packaging and Labelling of Medicinal Products for Human Use repealed by Article 25 shall be deemed to have been made to this Regulation. Alignment with European Union legislation

Article 24 – (1) This Regulation has been prepared within the framework of alignment with European Union legislation, taking into consideration Directive 2001/83/EC of the European Parliament and of the Council dated 6/11/2001 on medicinal products for human use and Directive 2011/62/EU dated 8/6/2011 on preventing the entry of falsified medicinal products for human use into the legal supply chain. Repealed regulation

Article 25 – (1) The Regulation on the Packaging and Labelling of Medicinal Products for Human Use published in the Official Gazette No. 25904 dated 12/8/2005 has been repealed. Transitional provision PROVISIONAL ARTICLE 1 – (1) The packaging and instructions for use of existing medicinal products for human use for which a marketing authorization or permit application has been made or which have been licensed or permitted prior to the entry into force of this Regulation shall be submitted to the Agency, at the latest by 30/9/2017, in compliance with the provisions of this Regulation. (2) Medicinal products for human use manufactured before 31/12/2017 may remain on the market in their existing packaging until the end of their shelf life. (3) The packaging information and instructions for use of medicinal products for human use manufactured after 30/12/2017 must comply with the provisions of this Regulation. (4) For special medical purpose foods that have been brought within the scope of the datamatrix code under subparagraph (n) of the first paragraph of Article 5 of this Regulation and that are not subject to reimbursement, the transition date for the datamatrix code application is 31/12/2018 at the latest. (5) For large-volume parenterals, radiopharmaceuticals and medicinal products for human use manufactured on a patient-specific basis, the transition date for the datamatrix code application covered by the guidelines referred to in the first paragraph of Article 20 of this Regulation is 31/12/2018 at the latest. Braille application PROVISIONAL ARTICLE 2 – (1) The obligations specified in the fourth paragraph of Article 13 shall be fulfilled by 31/12/2018 at the latest. Entry into force

Article 26 – (1) This Regulation shall enter into force on the date of its publication. Execution

Article 27 – (1) The provisions of this Regulation shall be executed by the President of TİTCK (Turkish Medicines and Medical Devices Agency).