REPUBLIC OF TURKEY
MINISTRY OF HEALTH
Medicines & Medical Devices Agency

ITS MANAGEMENT GUIDELINE

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Turkish Medicines & Medical Devices Agency, Department of Pharmaceutical Track & Trace System
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LEGAL NOTICE

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1.04	22.05.2012	Revision Information Added. Notification Types and Notification Structures Updated. ITS Workflow Diagram (Appendix 1) Added.
1.05	04.07.2012	Document Format Revised

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1. OBJECTIVE, SCOPE, LEGAL BASIS AND DEFINITIONS

1.1. Objective and Scope

The objective of this guideline is to determine the essentials of gathering data and operating the tracking system to provide the traceability of pharmaceuticals.

The guideline contains the standards of how the works with the Pharmaceutical Track and Trace System will be done and the rules on operating and inspecting the system.

1.2. Legal Basis

This guideline has been drafted by Nart Bilişim Hizmetleri (TechN'arts) according to article 19 of the 12.08.2005 dated and 25904 numbered "Regulation Regarding the Packaging and Labeling of Medicinal Products for Human Use".

1.3. Definitions

To serve the purposes of this guideline, the following terms shall apply:

- **Ministry:** Ministry of Health
- **General Directorate:** Turkish Medicines and Medical Devices Agency
- **GS1:** An international organization whose headquarters are in Brussels and which develops solutions and standards for the Active Supply Chain,
- **Barcode Symbology:** The method used to apply for the coding and decoding of the information which the barcode comprises, (e.g. EAN-13 Barcode Symbology, ITF-14 etc.)
- **Barcoding:** The printing of the data to be read by the barcode reader with the proper barcode symbology and printing method on the defined surface,
- **DataMatrix:** The two dimensional barcode symbology which will be applied in ITS and which will take the "ISO/IEC 16022 International Symbology Specification-DataMatrix ECC 200 Version" as the basis,

- **GTIN:** (Barcode Number, Global Trade Item Number) The item number which provides the identification of trade products uniquely worldwide, whose content (structure) is defined by GS1.
- **GS1 Application Identifier:** (AI-Application Identifier) The data headers which are used in determining the meaning of the information transferred from the barcode reader to the information systems (e.g. 01 GTIN, 17 Expiration Date),
- **Group Separator:** The character which provides that the computer applications distinguish the data of various lengths which is resolved as the ASCII <GS> character (ASCII Value=29) by the barcode readers for the GS1 compatible systems and expresses the FNC1 character which is the equivalent in the barcode symbology,
- **Sender:** Are the institutions or units which provide data to the system like manufacturers, importers, authentication/permit owners, pharmaceutical wholesalers, exporter wholesalers, pharmacies, hospital pharmacies and reimbursement companies,
- **Global Location Number:** (GLN) The 13 byte long international location number which has been determined by GS1 and is used to identify units like importers, logistical operation centers, pharmaceutical wholesalers, hospitals and pharmacies according to the manner and rules which are determined in the GS1 Barcode Application Guideline,
- **Product Pedigree:** Expresses the electronic record or electronic form or document which, are held in the general data standards according to the ownership statuses of the products which change with every transfer.
- **ITS:** Pharmaceutical Track and Trace System
- **Querier:** Institutions or units whose data query authentication have been defined in the system.
- **İEGM2007:** Expresses the Turkish Medicines and Medical Devices Agency Automation.

2. SYSTEM AND SYSTEM OPERATION

2.1. Definition of the System

The Turkish "Pharmaceutical Track and Trace System" (abbreviated as ITS) defines the infrastructure constructed to track and trace all units belonging to each pharmaceutical product in Turkey. ITS is the application of the well-known "Track & Trace" structure applied to the pharmaceutical industry. The serialization providing the uniqueness of the units is ensured by the DataMatrix code instead of formerly used barcode. The ability to track each drug unit is provided by gathering the information of each unit in every single step and action; and traceability is provided by its pedigree.

ITS is the first successful and unique application of "Pharmaceutical Track and Trace System" in the world. ITS is designed to track the location of every drug unit to ensure the reliable supply of drugs to patients. Therefore, all the drugs on the market are traced by notifications in all phases from production to consumption. Thus; the sale of fraudulent drugs, drug theft and barcode scams are prevented. In addition, if required, drugs can easily be recalled due to traceability of stocks.

2.5 billion drug units per year and about 10 transactions for each drug unit is tracked and traced with the Pharmaceutical Track and Trace System.

The Pharmaceutical Track and Trace System is a system that contains computers, databases, computer software that serve the purpose of operating this database and contains the communication infrastructure which have been installed to provide the traceability of drug units whose traceability is provided by DataMatrix through notifications from every step that the drug unit passes starting with its production or importation notification.

The Pharmaceutical Track and Trace System prevent the drugs from counterfeiting and provide them to be tracked for security reasons. With the notifications received from the

manufacturers, importer wholesalers, pharmaceutical wholesalers and pharmacies and the dispatch approvals from the reimbursement companies the Pharmaceutical Track and Trace System will provide and control that a drug unit is sold only once. The Pharmaceutical Track and Trace System does not have a financial side.

2.2. Access to the System

Access to the System is bilateral. These can be divided into two as sending data and for the purpose of query:

- Sending Data:
  - Sending data for one product: Is the sending of data from the units which will be making the notification for one product by using the ITS Web Services.
  - Sending data as a whole: Is the method of sending data to the system as a whole through software using ITS Web Services.
  - The processes of sending data, is determined by the Ministry.
- Query:
  - Standard queries:
    i. Stock queries,
    ii. Expiration date queries,
    iii. Queries that will be the base for recalling operations,
    iv. Other standard queries.
  - Nonstandard queries: Are the other queries that can be made by the ITS administration.

Sending data and queries can be made in accordance with the data safety principles determined in this guideline.

All the operations that are made are recorded into the database as transactions. The transactions are defined as stated below:

i. Insert: Inserting a record which did not exist before into the database as desired. Making a notification is an insertion.
ii. Delete: Deleting certain products from the notifications which have already been made. If an error has been made in the notification, the information of some products which are included to the notification can be deleted from the notification.
iii. Update: The method of changing information within the system will not be used. The update notification will be made in the form of deleting a product and inserting another product.
iv. Reimbursement Query: Is the transaction in which the products which have been dispatched to the reimbursement companies are queried by these companies. As a result of this query, the dispatch cannot be cancelled and the notifications made for the products inside cannot be taken back. This query is obligatory for reimbursement companies.
v. Log: Is the logging of all the transactions in the system for the purpose of tracking the database transactions and generating meaningful results in situations necessary for safety.

2.3. Acceptance Conditions of Data

The acceptance conditions of data are as follows:

- Authentication/Permit owners make the production and importation notifications. The notifications of the pharmaceutical wholesalers, exporter wholesalers, hospitals and pharmacies are made by the related units.

- As the transmitted data that reach the system are accepted as documents, only one of the repetitive data will be accepted.
- The data will not be accepted into the system when the sender identity and the identity of the one making the notification do not match.
- The content of the data will be controlled by the system itself and the information that does not match will not be accepted while the system will send feedback to the sender.

2.4. Storing Data

The data sent to the system will be stored in a center determined by the Ministry.

The data storage time with regards to the system and the other parties making the notifications, is at least 3 years in addition to their date of expiration.

3. DATA TRANSFER STANDARDS

3.1. Notifications

Notifications are the data transfers to be done by senders. The places to make notifications are determined as such: Manufacturers, importer wholesalers, pharmaceutical wholesalers, pharmacies and hospital pharmacies.

As a result of the notifications, some messages will be returned to the senders from the system. The messages which are product based are labeled with <UC> code while the notification based messages are labeled with <FC> code. The explanations of these messages are published in the Error Codes part of the Online Services and in the Error Codes Reference Service. As a result of these notifications only the error code will be returned for the product based messages while the error definition will be revoked along with the error code in the notification based messages.

3.2. Notification Types

The data that will be generated for notifications are comprised of the following fields:

- **Production Notification:** Is the notification that the manufacturer companies make to introduce their products to the system after their production. It is coded as “M” in the system.
- **Importation Notification:** Is the notification which the pharmaceutical companies make to introduce the imported products to the system. It is coded as “I” in the system.
- **Dispatch Notification:** Is the notification made by manufacturer companies, pharmaceutical wholesalers and pharmacies to notify the system that the product has been dispatched to another stakeholder or a patient. The dispatch notifications are coded as “S” in the system. Every dispatch is subject to a separate notification.

To whom the manufacturer companies, pharmaceutical wholesalers and pharmacies can make dispatches to is designated in the legislation in effect. The limitations subject to dispatch notifications are designated according to the provisions of the legislation in effect. According to this manufacturer companies can make dispatches to pharmaceutical wholesalers, pharmacies, pharmaceutical companies which work as distributors and to hospitals. Pharmaceutical wholesalers can make dispatches to hospitals, *companies*, exporter wholesalers or other pharmaceutical wholesalers. Pharmacies can only make dispatches to patients.

- **Product Turnover Notification:** Stakeholders can make product turnover notifications to other stakeholders which have the same stakeholder role to provide the patients' access to drugs. Manufacturer companies can only make a product turnover notification to manufacturer companies; pharmaceutical wholesalers only to pharmaceutical wholesalers; pharmacies only to pharmacies; and hospitals only to hospitals. In the case when products are sent from one hospital to another hospital free of charge, the hospital which sends the products must make a turnover notification for these products.
- **Consumption Notification:** The notifications of the hospital pharmacies for the purpose of consumption.

This notification is made in the works of the hospitals where products are consumed for more than one patient or when the place of consumption is not definite. When a single product has been consumed for a patient and it is not possible to state this clearly in the invoice, a consumption notification can be made again.

The hospital product return notifications are not interpreted as consumption notifications and must be notified as returns of a purchase to the system.

No consumption notification can be made for expired products however deactivation notifications can be made for them.

- **Product Return Notification:** Is the notification for the exit of a returned drug unit from a pharmacy, hospital, pharmaceutical wholesaler or distributor company due to a recall, expiry or another reason. It is coded as "F" in the system.
- **Deactivation Notification:** Is a notification that is made for products which have been taken out of the system for various reasons. Deactivation notifications are coded as "D" in the system.

Deactivation is the request of closing the record of certain drugs in the system due to several reasons like taking out the products from the system which have to be destroyed because they have either been defectively manufactured or expired, products becoming unsalable due to a reason or the request to take a product out of the system due to an operation. With this notification, the serial numbers of these products are closed and no other products with the same number can be notified again. The reason of deactivation takes place in the notifications in simple terms.

CODE	DEACTIVATION REASON
10	"TAKING OUT OF THE SYSTEM"
20	"PRODUCTION DEFICIENCIES"
30	"DESTROYING DUE TO RECALLS"
40	"DESTROYING DUE TO EXPIRY"
50	"REVISION"

Table 1: Deactivation Reasons

The reason of "PRODUCTION DEFICIENCIES" is used for taking out all the products from the system which come out of the course of production as deficiencies and products which can be considered as waste. The "REVISION" and "PRODUCTION DEFICIENCIES" reasoned deactivation notifications can only be made by manufacturer companies.

The deactivation notifications of products which have not been notified to the system will not be made.

Recalls due to other reasons and deactivation notifications due to expiry can be done by pharmaceutical wholesalers, exporter wholesalers, pharmacies and hospitals.

- **Product Purchase Notification:** Has been designed as an approval mechanism which expresses the control and acceptance of the products by the recipient. In order to make a dispatch turnover, exportation, deactivation or consumption notification for a product, a stakeholder must first make a product purchase notification. It is coded as "A" in the system. Pharmacies are subject to control and approve the products using this notification. Manufacturers, importers, pharmaceutical wholesalers, importer wholesalers, hospitals, and representative pharmaceutical wholesalers must take their purchases under control this way.
- **Exportation Notification:** Are the notifications which are made by companies to introduce the exported products with DataMatrix to the system. This notification is also a notification to take the products out of the system, the products which are specified in the exportation notification become unsalable in our country. The recipient information should only be entered as the country. It is coded as "X" in the system. It is used by manufacturer companies, pharmaceutical wholesalers and exporter wholesalers. The system generates a number for the exportation notifications.
- **Dispatch Cancellation Notification:** It has been made possible for pharmacies to cancel their dispatches. According to this, the dispatches made without reimbursement are cancelled on the basis of products while the dispatches made to the reimbursement companies are cancelled on the basis of prescriptions. It is coded as "C" in the system.

When manufacturers and pharmaceutical wholesalers have to retrieve the products which they have dispatched they make a "dispatch cancellation". If the transferee stakeholder has gained the ownership of the product through a product purchase notification, the dispatch cancellation cannot be made before this stakeholder makes a product return notification.

When pharmacies have to retrieve the products, which they have dispatched they make "dispatch cancellation".

- **Product Turnover Cancellation Notification:** For a stakeholder to take the ownership of a product for which they have made a product turnover notification, they make a product turnover cancellation notification.

As summary the notification types are shown in the table below:

NOTIFICATION TYPE	CODE
Production	M
Importation	I
Dispatch & Product Turnover	S
Deactivation & Consumption	D
Exportation	X
Product Return	F
Product Purchase	A
Dispatch & Product Turnover Cancellation	C

Table 2: Notification Types

The method to be used for the alterations on the mistakes made on stock transactions are not defined as a separate notification type, thus the alterations on production or importation notifications will be done in the form of a product cancellation which has not gone through any transactions, while the products which have gone through transactions will not be cancelled.

The stakeholder groups, which are authorized to make notifications and the reverse stakeholder groups to whom the notifications will be made for the above stated notifications are given in the Appendix 1.

3.3. Fields to be Used in the Notifications

The common definitions of the fields to be used in the notifications are made. These are in the below stated form:

- **Manufacturer/Importer:** Manufacturers are the ones who will enter the products into the system. The indicator **<MI>** is used for this field. The manufacturers or importers will take place with their GLN codes in the system. They will only be able to send data of the drugs whose license or permits they own to the system.
- **Vendor:** Are the sector players, which are in the position of selling products. These are; manufacturers, importers, pharmaceutical wholesalers, hospitals or pharmacies. The indicator **<FR>** is used for this field and it takes place with the GLN code.
- **Recipient:** Are the sector players, which, are in the position of receiving the product, or are directly the citizens. These are; manufacturers, importers, pharmaceutical wholesalers, pharmacies, hospitals or patients. The indicator **<TO>** is used fort his field. The recipients except for patients take place with their GLN code in the system.
- **Production Date:** The basis of the notification is the date of production. The indicator **<MD>** is used for this field. The XML date style takes place as (YYYY-MM-DD).
- **Notification Type:** Is the field, which indicates the type of the notification that has been made. The indicator **<DT>** is used for this field. It takes up 2 character long alphanumerical space.
- **Deactivation Reason:** Is the field in which the reason of the deactivation will be entered. The indicator **<DS>** will be used for this field.
- **Doctor:** Is the identifier of the doctor, which prescribes the product. The "National Identity Number" is used for the doctor identifier. The indicator **<DR>** is used for this field. It takes up a 11 character long numerical space.
- **Product Type:** The indicator **<PT>** is used for this field. It takes up a 2 character long alphanumerical space. The indicator **<PP>** is used for he drug, **<BP>** is used for the derivative product, and **<FP>** for the nutrition products.

- **Product Barcode (GTIN):** The indicator **<GTIN>** is used for this field. It takes up a 14 character long alphanumerical space.
- **Product Expiration Date:** The indicator **<XD>** is used for this field. The XML style of the expiration date in the notifications is as (YYYY-MM-DD).
- **Product Batch Number:** The indicator **<BN>** is used for this field. It takes up a 20 character long alphanumerical space. Only upper case letters and numbers can be used. Turkish characters cannot be used.
- **Product Serial Number:** The indicator **<SN>** is used for this field. It takes up a 20 character long alphanumerical space.
- **Explicit Recipient Information:** It is used to show the recipients, which are not registered into the system in operations like exportation.
- **Explanation:** Is the field, which is assigned for the necessary explanations related to the operation. It is used in the deactivation operations.
- **Document Date:** If there is a document, which will form the base of a certain notification, then this is the date of that document. This document can be a document that is not financial or one, which does not have any financial features. The usage of the document number is optional in the system.
- **Document Number:** If there is a document, which will form the base of a certain notification, then this is the number of that document. This document can be a document that is not financial or one, which does not have any financial features. The usage of the document number is optional in the system.

As summary the fields to be used in the notifications are shown in the table below:

FIELD NAME	LABEL	TYPE	LENGTH	CONTENT
Manufacturer / Importer	MI	Numerical	13	GLN
Vendor	FR	Numerical	13	GLN
Recipient	TO	Numerical	13	GLN
Production Date	MD	Date	12	Date (XML - Type)
Notification Type	DT	Alphanumerical	1	Type Code
Deactivation Reason	DS	Alphanumerical	2	Explanation
Doctor	DR	Numerical	11	National ID Number
Patient	CP	Numerical	11	National ID Number
Product Type	PT	Alphanumerical	2	Product Type
Product GTIN	GTIN	Numerical	14	Barcode Number
Product Expiration Date	XD	Date	12	Date (XML type)
Product Batch Number	BN	Alphanumerical	20	Batch or Lot Number
Product Serial Number	SN	Alphanumerical	20	Serial Number
Explicit Recipient Information	RT	Alphanumerical	100	Recipient Information, which is not registered into the system
Explanation	ISACIKLAMA	Alphanumerical	250	General explanation
Document Date	DD		10	Document date related to the notification
Document Number	DN	Alphanumerical	20	Document number related to the notification

Table 3: Fields to be Used in Notifications

- **Global Location Number:** GLN defines the legal, functional or physical location unit in a working place or within an organization. It is given so that it identifies that certain place uniquely worldwide, which is determined by the GS1 system. To get more

information about GLN you may refer to the "GLN appointing Rules" document published by the GS1 system.

In the Pharmaceutical Track and Trace System, The GLN number for pharmacies, pharmaceutical wholesalers, exporter wholesalers, public hospitals and public universities are provided by the Ministry from a determined interval.

Manufacturers, importers, reimbursement companies and private hospitals can obtain their GLN numbers through a GS1 membership.

3.4. Notification Structures

The contents of the notifications are comprised of the fields defined in the Fields to be Used in the Notifications part. Data other than these fields cannot take place in the notifications.

The notification structures according to the notification types are as follows:

- Production Notification:
  - Notification Type "<DT>"
  - Manufacturer/Importer "<MI>"
  - Product Type "<PT>"
  - Production Date "<MD>"
  - Product GTIN "<GTIN>"
  - Product Expiration Date "<XD>"
  - Product Batch Number "<BN>"
  - Product Serial Number "<SN>"
  - Document Date "<DD>" (optional)
  - Document Number "<DN>" (optional)

- Importation Notification:
  - Notification Type “<DT>”
  - Manufacturer/Importer “<MI>”
  - Product Type “<PT>”
  - Production Date “<MD>”
  - Product GTIN “<GTIN>”
  - Product Expiration Date “<XD>”
  - Product Batch Number “<BN>”
  - Product Serial Number “<SN>”
  - Document Date “<DD>” (optional)
  - Document Number “<DN>” (optional)
- Manufacturer/Importer Dispatch Notification:
  - Notification Type “<DT>”
  - Vendor “<FR>”
  - Recipient “<TO>”
  - Document Date “<DD>” (optional)
  - Document Number “<DN>” (optional)
  - Product GTIN “<GTIN>”
  - Product Expiration Date “<XD>”
  - Product Batch Number “<BN>”
  - Product Serial Number “<SN>”
- Pharmaceutical Wholesalers Dispatch Notification:
  - Notification Type “<DT>”

- Vendor “<FR>”
- Recipient “<TO>”
- Document Date “<DD>” (optional)
- Document Number “<DN>” (optional)
- Product GTIN “<GTIN>”
- Product Expiration Date “<XD>”
- Product Batch Number “<BN>”
- Product Serial Number “<SN>”

▲ Pharmacy Dispatch Notification:

- Notification Type “<DT>”
- Vendor “<FR>”
- Recipient “<TO>” (If it is invoiced to a reimbursement company, the code of the reimbursement company will be entered into this field.)
- Document Date “<DD>” (optional)
- Document Number “<DN>” (optional)
- Doctor “<DR>” (optional)
- Patient “<CP>” (optional, if there is a reimbursement company in the dispatch <TO> field, then the <National ID number> of the patient must be entered into this field.)
- Product GTIN “<GTIN>”
- Product Expiration Date “<XD>”
- Product Batch Number “<BN>”
- Product Serial Number “<SN>”

▲ Consumption Notification:

- Notification Type “<DT>”
- Vendor “<FR>”
- Recipient “<TO>”
- Document Date “<DD>” (optional)
- Document Number “<DN>” (optional)
- Product GTIN “<GTIN>”
- Product Expiration Date “<XD>”
- Product Batch Number “<BN>”
- Product Serial Number “<SN>”

▲ Deactivation Notification:

- Notification Type “<DT>”
- Vendor “<FR>”
- Document Date “<DD>” (optional)
- Document Number “<DN>” (optional)
- Deactivation Reason “<DS>”
- Explanation “<CT>”
- Product GTIN “<GTIN>”
- Product Expiration Date “<XD>”
- Product Batch Number “<BN>”
- Product Serial Number “<SN>”

▲ Exportation Notification:

- Notification Type “<DT>”
- Vendor “<FR>”

- Explicit Recipient Information “<RT>”
- Document Date “<DD>” (optional)
- Document Number “<DN>” (optional)
- Product GTIN “<GTIN>”
- Product Expiration Date “<XD>”
- Product Batch Number “<BN>”
- Product Serial Number “<SN>”

▲ Product Return Notification:

- Notification Type “<DT>”
- Vendor “<FR>”
- Recipient “<TO>”
- Document Date “<DD>” (optional)
- Document Number “<DN>” (optional)
- Product GTIN “<GTIN>”
- Product Expiration Date “<XD>”
- Product Batch Number “<BN>”
- Product Serial Number “<SN>”

▲ Product Turnover Notification:

- Product GTIN “<GTIN>”
- Product Expiration Date “<XD>”
- Product Batch Number “<BN>”
- Product Serial Number “<SN>”

The XML schemes of all notifications can be accessed from this address http://www.itsportal.saglik.gov.tr.

These notifications must have content appropriate to this standard as all the notifications will be accepted into the system through “XML Web Services”.

4. DATA SAFETY AND SYSTEM OPERATION

4.1. Data Safety Standards

The System Operation is based on the **TSE ISO/EN 27001** Data Safety Standards.

Identity Verification: The identities and passwords to access the system will be determined and verified.

The system access and data query requests will be evaluated according to the authorization rules and thus the necessary permits will be given accordingly.

The sent information will be accepted as documents at the same time.

The user verification information necessary to access the system are under the responsibility of the user.

The content information of the data to be transferred to the system are under the responsibility of the sender. When necessary the system returns notifications to control the data.

4.2. Rules of Access

Accessing the system is bounded by rules. Access to the system is determined and authorized by the identity management service in the system.

System Access Authorities: ITS programmers, ITS help desk officials, senders and queriers can access the system. The authorization of these units is done according to the authorization rules explained in this document.

4.3. Authorization

The system access authorization is made by the System Administration.

The authorization rules are as follows:

- Authorization is made through the application to the system.
- A user name is assigned to each company by the system administration. The user authorization within the company for this username will be made by the company.
- The authorization and the identification of pharmaceutical wholesalers and pharmacies as users to the system will be made by Local Health Authorities through the registrations made to the İEGM2007 system by the system administration.
- A user is assigned to reimbursement companies so that they can make the prescription controls. The authorization of this user or these users is determined with the protocols made with these institutions.

4.4. System Operation

- The system is operated by the Ministry.
- The development of the system is documented by following software and versions of documents.
- The gathering of data for the system is done via notifications. The notifications are done by senders, from senders towards the system.
- The system runs with XML Web Services and the notifications are accepted through these web services.
- The system requests senders to obtain a “Qualified Electronic Certificate” for production and importation notifications and sign these notifications along with this certificate and encode it symmetrically.
- All senders are provided with a user name and password for all notifications including production and importation notifications.
- The system returns an approval code to the sender confirm that the notification has gone through.
- If necessary, the system returns code or notification to the owner of the notification for the verification of notifications.

- Information and documents related to the XML Web Services on the system can be accessed from this address http://www.iegm.gov.tr.
- The ITS system operates integrated with İEGM2007. The necessary information to identify products, companies, pharmacies, hospitals, exporter wholesalers or pharmaceutical wholesalers are obtained from the İEGM2007 system or are provided by the system administration.

    - Identification information is transferred from İEGM2007 to the system in intervals determined by the system administration.
    - According to the information received in the İEGM2007 system, activation mails are sent to the e-mail addresses within the shortest time so that users can be activated.

5. INSPECTION

5.1. Data Inspection

- The inspection of data is made by the system administration. The competent authorities are notified with the results of the data by the system administration.
- Generating a pedigree through the system: Is the listing of a history by the system by tracing the route of products with the notifications. In cases when tracing can be applied to all units, the pedigree is evaluated by the system administration.
- The data transmissions are inspected according to the authorization rules, and the data transmissions which are appropriate to the rules are accepted to the system. The accuracy of the transmitted data is inspected by the system administration by tracing. It is requested from the sender to either retransmit or take out the inaccurately entered data received during the transmission.
- Interfaces have been created so that senders test their systems.
- The consumer complaints that are within the scope of the Pharmaceutical Track and Trace System are taken and evaluated by the system administration.
- The data transmitted to the system should be able to be retransmitted on request.

6. MISCELLANEOUS PROVISIONS

6.1. Notification Times

It us up to the user at which time the notifications are made.

The limitations for the notification times are as follows:

- Products whose production or importation notifications are not made cannot be released to the market by manufacturers or importers.
- Pharmacies will not give DataMatrix products which have not been verified by the system to the patients.
- Pharmaceutical wholesalers will not accept returns of products with DataMatrix which have not been notified to the system.
- Exportations should only be notified after the exportation has taken place.
- Pharmacies must make product purchase notifications when the products have been purchased.

6.2. System Infringements

The Pharmaceutical Track and Trace System will act as stated below when an infringement is determined.

- The consumer complaints made by declaring the retail invoice of the dispatch will be used in the Pharmaceutical Track and Trace System studies to reveal infringements.
- If the dispatch notifications of the products sold in cash are not made and it has been located that they are tried to be resold to the reimbursement companies, the related users' access to the system will be suspended.
- Users whose transferred information of the products is not approved by the system are obliged to prove the resource of the products on request.

6.3. Transport Packages

A serial number which will uniquely define each transport package will be used on transport packages. These serial numbers can be produced on the basis of products or notwithstanding products if the uniqueness can be provided for the company. The method of numbering of transport packages are under the authority of the company.

The product information which the transport packages contain and the number of the transport package are stored so that they match to be sent to their next destination. There will be a standard used to transfer this information.

The information of the transport packages will not be transferred to the Pharmaceutical Track and Trace System.

If the numbers of the transport packages are used again, the printed serial numbers must be renewed and the old numbers will not be used again.

In situations where the transport packages are printed with DataMatrix to be used as external packing, operations will be made taking the barcodes and the multipliers which are stated in the "List of Products with Transport Packages" published by our General Directorate into consideration. This way, the products will be tracked with the serial numbers on the transport packages. In this case, the transport packages are considered as a product package regardless of the number of products that it contains.

Example:

8690123123450 Peritoneum Dialysis Solution 1 piece plastic package.

8690123001230 Peritoneum Dialysis Solution - Parcel containing 5 pieces.

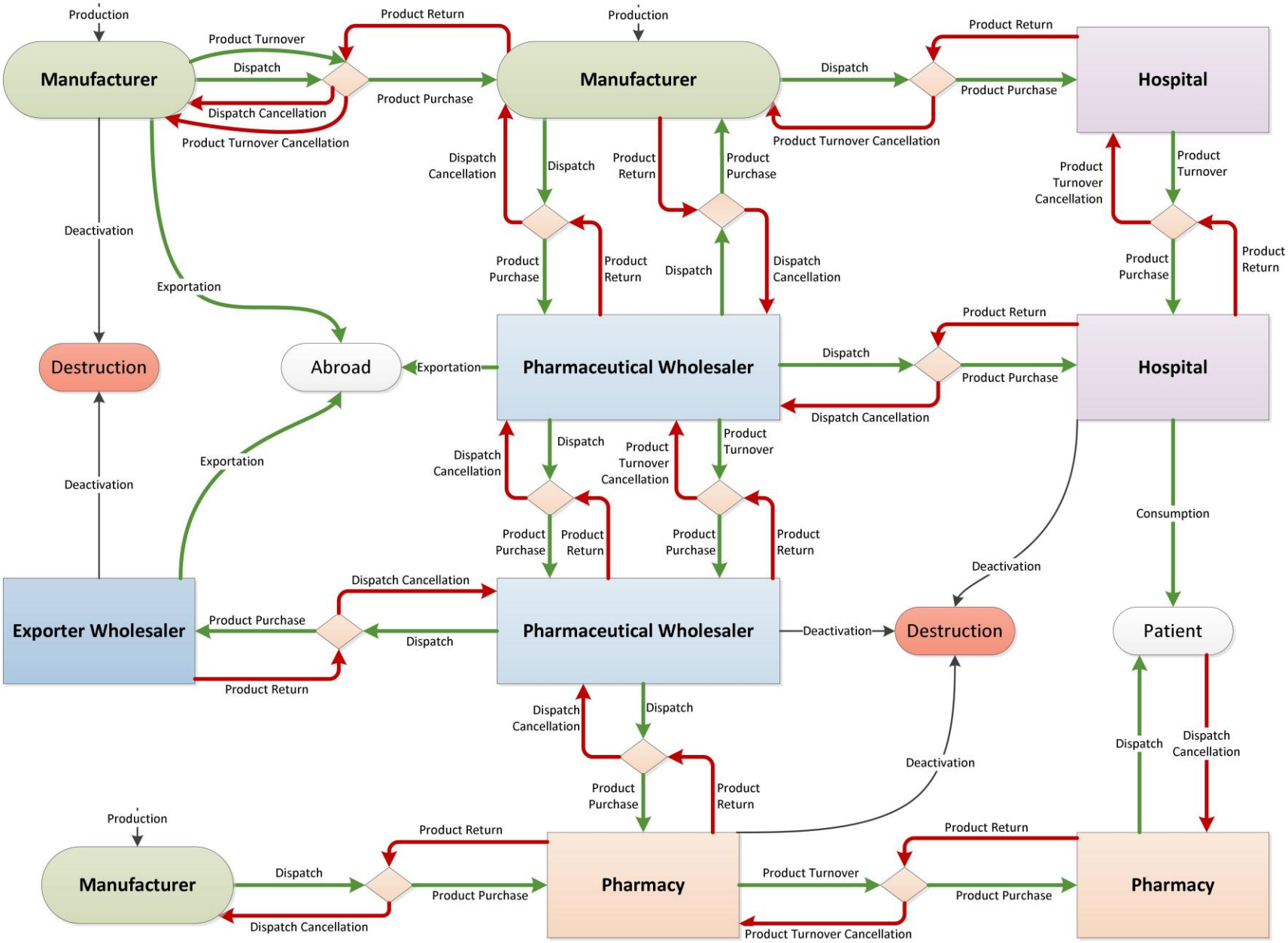
The second product out of the two contains 5 pieces of the first product. The price of the product has been determined for the first product by our General Directorate and has been

put into the lists. The dispatch will be made with the second product information given in the example. Product will be tracked with the serial number of the second product given in the example. Reimbursement companies will take the result of multiplying the multiplier stated in the List of Products with Transport Packages and the price of the first product as the basis of the payments.

The amounts in the packages of the products with transport packages must be evaluated by the systems of all the parties and patients must be provided with the access to proper amounts of drugs according to the amounts stated in the lists.

7. APPENDIX

7.1. Appendix 1 – ITS Workflow


Production
Manufacturer
Product Turnover
Dispatch
Dispatch Cancellation
Product Turnover Cancellation
Product Return
Product Purchase
Production
Manufacturer
Dispatch
Product Return
Product Purchase
Product Turnover Cancellation
Hospital
Deactivation
Exportation
Destruction
Abroad
Exportation
Dispatch Cancellation
Dispatch
Product Return
Product Purchase
Dispatch
Dispatch Cancellation
Product Turnover Cancellation
Product Turnover
Product Purchase
Product Return
Pharmaceutical Wholesaler
Dispatch
Product Return
Product Purchase
Dispatch Cancellation
Hospital
Deactivation
Exportation
Dispatch Cancellation
Dispatch
Product Turnover Cancellation
Product Turnover
Consumption
Product Purchase
Product Return
Product Purchase
Product Return
Exporter Wholesaler
Dispatch Cancellation
Product Purchase
Dispatch
Product Return
Pharmaceutical Wholesaler
Deactivation
Destruction
Patient
Dispatch Cancellation
Dispatch
Deactivation
Product Purchase
Product Return
Production
Manufacturer
Dispatch
Dispatch Cancellation
Product Return
Product Purchase
Pharmacy
Product Turnover
Product Turnover Cancellation
Product Return
Product Purchase
Pharmacy
Dispatch
Dispatch Cancellation