Supply Chain Regulation of Pharmaceutical Samples

European Union • Japan •Turkey

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Comparative Summary

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This research surveys several countries' regulations regarding "serialization" of pharmaceutical products and whether these regulations apply to free medicinal product samples. The attached reports explore the specific "track and trace" or "serialization" laws and regulations in the European Union, Japan, and Turkey.

In the United States, the Drug Quality and Security Act (DQSA)[1] creates track and trace requirements for drug manufacturers, wholesale distributors, repackagers, and dispensers. The DQSA, however, expressly exempts free samples from regulation, as they are not included in the definition of a "transaction."[2]

Under **European Union** (EU) law, free samples can only be provided in exceptional cases and only to persons qualified to prescribe such products.[3] Furthermore, the European Commission also enacted a delegation regulation that further specifies detailed safety rules for the handling of samples, including ensuring the decommissioning of a sample product's unique identifier.[4]

While the EU is arguably the prime example of serialization regulations applying to drug samples, other jurisdictions were also researched to explore whether drug samples were covered by serialization regulations.

In **Japan**, the Implementation Guidelines for the Barcode Labeling of Prescription Drugs provide that pharmaceutical manufacturers and distributors do not have to place barcodes on packages of sample medicines,[5] but have developed standards for sample drugs that limit the quantity that can be provided to medical practitioners.[6]

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[1] Drug Quality and Security Act, 581 U.S.C. § 24 (B) (v) (2013), https://perma.cc/3LSZ-K7P4.

[2] Id. See also Agata Dabrowska and Susan Thaul, Cong. Research Serv., R41983, How FDA Approves Drugs and Regulates Their Safety and Effectiveness 16 (2018, updated), https://perma.cc/8G89-GBXQ.

[3] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, 2001 O.J. (L 311/67, 94), art. 96, https://perma.cc/TSW3-DEP9.

[4] Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 Supplementing Directive 2001/83/EC of the European Parliament and of the Council by Laying Down Detailed Rules for the Safety Features Appearing on the Packaging of Medicinal Products for Human Use, 2016 O.J. (L 32,1), https://perma.cc/J7K9-AMBR.

[5] Regarding Partial Amendment to the Implementation Guidelines of Barcode Labeling of Prescription Drugs, MHLW, 0830 No. 1 (Aug. 30, 2016), https://perma.cc/K2XT-VXTW.

[6] Standards on Sample Drugs, reported to FCC (Jan. 20, 1998), amended and reported to FCC and CAA (June 16, 2014), sec. 2.1, https://perma.cc/5RGZ-6RNH.

In **Turkey**, it is unclear whether or not free samples are subject to serialization, as the existing law is conflicting.[7] However, the existing law does require pharmaceutical companies to establish an "adequate system" to record the manufacture, importation, and distribution of free samples.[8]

While technical aspects of serialization differ across jurisdictions, one widely used benchmark for legislation is the voluntary GS1 standards, and specifically the Global Trade Item Number (GTIN). Globally, it is estimated that 70 countries have based their regulatory requirements for traceability of pharmaceuticals on these standards.[9] GS1 describes free samples as a product category that can be in or out of the scope of the traceability system, depending on the regulatory preferences of the country.[10]

[7] See appended Turkey country survey contrasting the 2015 Promotion Regulation with the 2017 Package Regulation.

[8] Guidelines on the Applications for the Distribution of Free Promotional Samples and Press Releases under the Regulation on Promotional Activities for Medicinal Products for Human Use (published on July 3, 2015, in Official Journal No. 29405, entry into force Nov. 16, 2015), https://perma.cc/VPF4-ABDY.

[9] GS1, Discussion Paper on Medicines Identification Requirements on Primary Level Packaging Using GS1 Standards (2019), https://perma.cc/Q36D-5GHS.

[10] GS1, Regulatory Roadmap: Traceability of Medicinal Products (2018), https://perma.cc/DP6K-6GS9.

European Union

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SUMMARY The European Union (EU) has rulemaking authority in the area of public health. EU law requires that all prescription medicine, including samples, be serialized and tracked from production to end user (patient). To facilitate such tracking, medicinal packages must be furnished with unique identifying information contained in a two-dimensional bar code that can be scanned at each point along the distribution channel.

Medicinal product samples may not be distributed to patients and must be removed from the tracking system (decommissioned) by the supplier of the sample before they are sent to the pharmacist, doctor, or nurse to whom the samples are provided. Medicinal products that qualify as narcotics may not be distributed as samples.

I. The European Union Medicinal Product Regulatory Framework

The European Union Member States have vested rule-making power with the European Union in the area of public health.[1] The European Union has used this rule-making power to adopt regulations and directives pertaining to, among other things, medicines verification systems, the distribution of medicinal product samples, and the tracking of samples.[2]

Regulations are of general application in the Member States.[3] Directives are binding upon the Member States as to the results to be achieved, but require Member States to transpose them into national law,[4] which allows Member States to choose the form and methods to be used to obtain the results.[5] The Commission oversees the Member States' transposing of directives. If a Member State does not transpose a directive within the time allotted in the directive, the European Commission may bring the Member State before the European Court of Justice.[6]

In addition, the European Commission may receive delegated authority to adopt nonlegislative acts to supplement and amend nonessential elements of a legislative act pursuant to article 290 of

[1] Treaty on the Functioning of the European Union (TFEU) art. 168, 2012 O.J. (C 326) 1 (consolidated version), https://perma.cc/3TQA-U2VX.

[2] Directive 2011/62/EU, 2011 O.J. (L 174) 74), https://perma.cc/3AJF-T9BY, amending Directive 2001/83/EC, 2001 O.J. (L 311) 67, https://perma.cc/89R8-H46S. The legal power to adopt these directives is found in TFEU arts. 114 and 168.4C, and in art. 95 of the Treaty Establishing the European Community, 1997 O.J. (C 340) 173 (consolidated version), https://perma.cc/Y7MT-TTNE.

[3] TFEU, supra note 1, art. 88.

[4] Id. art. 288.

[5] Id.

[6] Id. art. 258.

the Treaty on the Functioning of the European Union (TFEU).[7] A legislative act containing such delegation of power must explicitly state the conditions for the delegation of power, and the Council and Parliament may revoke the power.[8] The European Commission was given such power in article 54(a)2 of Directive 2001/83/EC and exercised this power when adopting Commission Delegated Regulation (EU) 2016/161, which details the rules for how safety features must appear on packaging of medicinal products within the EU.[9]

Thus, Member States are responsible for transposing the Directive into national law and must also implement rules penalizing violations of the transposed provisions.[10] In 2018, the European Commission conducted a study of the Member States and found that the penalties adopted were satisfactory and efficient throughout the European Union.[11]

II. Tracking of Medicinal Products

A. Legal Requirements of Serialization

In accordance with the Falsified Medicines Directive (2011/62/EU),[12] which amends Directive 2001/83/EC on the Community Code relating to medicinal products for human use[13], EU Member States must put in place a system whereby "Marketing Authorisation Holders" (MAHs) and manufacturers include safety measures on packaging of medicinal products in order for others to be able to verify the authenticity of the medicinal product.[14] The purpose of the uniform EU-wide system is to guarantee the authenticity of a given medicinal product through an "end-to-end verification,"[15] thereby preventing counterfeit products from reaching the patient. This system should have been set up by February 9, 2019,[16] and the commission delegated Regulation

[7] Id. art. 290.

[8] Id. art. 290(2)(a).

[9] Directive 2001/83/EC, supra note 2, art. 54a(2);Commission Delegated Regulation (EU) 2016/161, 2016 O.J. (L 32) 1, https://perma.cc/MF3K-ACP4.

[10] Directive 2001/83/EU, supra note 2, art. 118a.

[11] European Commission, Report on the Commission to the European Parliament and the Council on the Member States' transposition of Article 118a of Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use as amended by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 at 8 (Jan. 26, 2018), https://perma.cc/Z8BC-L4QT; European Commission, *Study on the Transposition Measures of Member States in Relation to the Pharmaceutical Legislation (Art. 118a of Directive 2001/83/EC): Final Report* (2018), https://perma.cc/2M6A-GDZH .

[12] Directive 2011/62/EU, supra note 2.

[13] Directive 2001/83/EC, supra note 2.

[14] Id. art. 54.

[15] Commission Delegated Regulation (EU) 2016/161, supra note 9, pmbl., para. 15; see also European Medicines Verification System (EMVS), https://perma.cc/4SG8-BRWM.

[16] Three years after the delegation regulation was published in the Official Journal of the European Union. See Commission Delegated Regulation (EU) 2016/161, supra note 9.

2016/161 (EU) specifies how the serialization takes place.[17] Accordingly, the manufacturers must encode the packaging with a unique identifier (UID), using a two-dimensional (2D) barcode.[18] The UID must be a "sequence of numeric or alphanumeric characters that is unique to a given pack of medicinal product, and consist of

> (a) The unique identifier shall be a sequence of numeric or alphanumeric characters that is unique to a given pack of a medicinal product.
>
> (b) The unique identifier shall consist of the following data elements:
>
> (i) a code allowing the identification of at least the name, the common name, the pharmaceutical form, the strength, the pack size and the pack type of the medicinal product bearing the unique identifier ('product code');
>
> (ii) a numeric or alphanumeric sequence of maximum 20 characters, generated by a deterministic or a non-deterministic randomisation algorithm ('serial number');
>
> (iii) a national reimbursement number or other national number identifying the medicinal product, if required by the Member State where the product is intended to be placed on the market;
>
> (iv) the batch number;
>
> (v) the expiry date.
>
> (c) The probability that the serial number can be guessed shall be negligible and in any case lower than one in ten thousand.
>
> (d) The character sequence resulting from the combination of the product code and the serial number shall be unique to a given pack of a medicinal product until at least one year after the expiry date of the pack or five years after the pack has been released for sale or distribution in accordance with Article 51(3) of Directive 2001/83/EC, whichever is the longer period.
>
> (e) Where the national reimbursement number or other national number identifying the medicinal product is contained in the product code, it is not required to be repeated within the unique identifier.[19]

In addition, the UID must continue to be unique for one year longer than the expiry date listed on the package or five year from the release, whichever is longer.[20] The code must also be encoded in a two-dimensional barcode.[21] Further details on the specific configuration of the UID is specified in article 5 of Delegated Regulation (EU) 2016/161.[22] Member States may also include additional nonmandatory information in the UID.[23]

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[17] Id. Note that this Delegated Regulation applies to all EEA countries, i.e. all EU Member Countries as well as Lichtenstein, Norway, and Switzerland.

[18] Id. art. 5.

[19] Id. art. 4 (a).

[20] Id. art. 4 (d).

[21] Id. art. 5 (1).

[22] Id. art. 5.

[23] Id. art. 8.

According to the European Commission, a UID that also complies with the ISO standard requirements contains a product code (such as (01) 09876543210982) followed by serial number (such as (21) 12345AZRQF1234567890) followed by batch number (such as (10) A1C2E3G4I5) followed by an expiry date (such as (17)180531), [24] and carries a 2D barcode (Data Matrix ECC200).[25] Note that a package may contain multiple UIDs if the product is sold using "multi-language packs" that sell in more than one Member Country.[26] However, the European Commission recommends the use of only one 2D bar code.[27]

The deadline for serialization was February 9, 2019, a deadline certain countries have reportedly struggled with.[28] Because the Directive only applies to medicines released prior to February 9, 2019, it is estimated that patients will continue to encounter medicines without these markers for up to five years (until 2024).

B. How the Serialization System Operates

The serialization system works through the use of both a National Medicines Verification Systems (NMVS) and the European Medicines Verification System (EMVS), which is controlled by the European Medicines Verification Organisation (EMVO).[29] As of March 2019, all EU Member States, except Greece and Italy who had both been given an extension until February 9, 2025,[30] had set up an NMVS.[31] The NMVS looks different in all Member States.[32] The main purposes of an NMVS are as follows:

- Holding the relevant product serialization data for the national market.
- Receiving revised/new product serialization data from the EU-Hub.
- Serving as the verification platform for pharmacies or other registered parties such as wholesalers and hospitals to certify the authenticity of a product.

[24] Patizia Tosetti, DG Sante & European Commission, *Medicines Verification in Europe: What to Expect* 9 (Stakeholders' Workshop, Feb. 26, 2016), https://perma.cc/BAA9-FVXR.

[25] Id. at 10.

[26] Id. at 11. See also EFPIA, *Multi-Market Pack Coding Requirements EFPIA Position, Medicines and Healthcare products Regulatory Agency* (July 2017), https://perma.cc/VWK8-FECK.

[27] Commission Delegated Regulation (EU) 2016/161, supra note 9, pmbl., para. 14.

[28] Sean Milmo, *Meeting the EU Serialization Deadline*, 42(6) PharmTech (June 1, 2018), https://perma.cc/JQ29-8DC5.

[29] Commission Delegated Regulation (EU) 2016/161, supra note 9, arts. 31-37; see also EMVS, supra note 15.

[30] European Commission Directorate-General for Health and Food Safety, *Safety Features for Medicinal Products for Human Use, Questions and Answers – Version 10* 3 (Discussion Draft, July 2018), https://perma.cc/VN2P-R8ND.

[31] Tobias Beer, *NMVO's Fee Models Status*, 3 (Mar. 8, 2019), https://perma.cc/63LP-HMV4. Certain Member States have adopted a stabilization period during the initial phase (rolled out Feb. 9, 2019), as a result of a larger number of alerts on mismatched information. For instance the Swedish NMVS e-Vis (e-verifikation i Sverige) will end its stabilization process on October 1, 2019.

[32] Id.

- Serving as the platform for wholesalers in the case of member states application of Art. 23 DR, to mark a product pack as decommissioned prior to handing it over the patient.
- Serving as the platform for wholesalers to mark a product pack as "decommissioned" e.g. 'exported out of EU'[33]

The EMVS describes the process of serialization as the pharmaceutical manufacturer produces the medicine and assigns each package containing information on a unique serialization with random numbers; that number is then uploaded, together with a product code, an S/N code, a batch number, and an expiry number, to the NMVS.[34] Before placing the product on the market the wholesaler checks the number against the verification system throughout the supply chain process (transport, etc.); the pharmacist, doctor, or nurse who dispenses the medicine then verifies the information before dispensing it to the patient.[35] The system is set up and governed by the MAHs and other stakeholders, but is overseen by competent authorities.[36] Each NMVS[37] must then connect to the EMVS via the "European HUB" (EU Hub), a central database and router for the EMVS.[38]

Member States are charged with supervising the national repository system and enforcing the requirements of the delegated regulation (including the use of the UIDs).[39] Any reports on the supervision of the work of the NMVS must be shared with the EMA and the European Commission.[40]

III. Regulation of Distribution of Medicinal Product Samples

In accordance with European Union law, medicinal product samples may only be provided very restrictively. Article 96 of Directive 2001/83/EC on the Community Code relating to medicinal products for human use, states that free samples of "psychotropic or narcotic substances" may not be provided under any circumstances.[41] Moreover, free samples may only be provided in exceptional cases and only to persons qualified to prescribe such products (i.e., doctors, dentists, nurses, pharmacists) if the following conditions are met:

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[33] EMVS, supra note 15.

[34] Id. For discussion on the nature of the identification numbering see also European Association of Euro-Pharmaceutical Companies et al., *Coding & Serialisation Delegated Act on the Detailed Rules for a Unique Identifier for Medicinal Products for Human Use, and Its Verification*, Concept Paper Submitted for Public Consultation, Joint Response (EAEPC-EFPIA-GIRP-PGEU) (Apr. 26, 2012), https://perma.cc/W6SR-2X6Y.

[35] EMVS, supra note 15, Product Flow Chart & Responsibilities of the Supply Chain Partners Chart.

[36] Commission Delegated Regulation (EU) 2016/161, supra note 9, art. 31.

[37] For a full list of Member State NMVSs see EMVS, supra note 15. Examples of NMVOs include SecurMed, https://www.securmed.org.uk/ (United Kingdom); DMVO, https://www.dmvo.dk/Pages/Welcome.aspx (Denmark); and e-VIS, https://e-vis.se/ (Sweden).

[38] Commission Delegated Regulation (EU) 2016/161, supra note 9, arts. 32-37.

[39] Id. art. 44.

[40] Id. See also Tosetti, supra note 24, at 26.

[41] Directive 2001/83/EC, supra note 2, art. 96.1(g).

> 1. . . .
>
> (a) the number of samples for each medicinal product each year on prescription shall be limited;
>
> (b) any supply of samples shall be in response to a written request, signed and dated, from the prescribing agent;
>
> (c) those supplying samples shall maintain an adequate system of control and accountability;
>
> (d) each sample shall be identical with the smallest presentation on the market;
>
> (e) each sample shall be marked 'free medical sample' – 'not for sale' or shall show some other wording having the same meaning;
>
> (f) each sample shall be accompanied by a copy of the summary of product characteristics;
>
> (g) no samples of medicinal products containing psychotropic or narcotic substances within the meaning of international conventions, such as the United Nations Conventions of 1961 and 1971, may be supplied.
>
> 2. Member States may also place further restrictions on the distribution of samples of certain medicinal products.[42]

As stipulated in the preamble of the Directive, the purpose of the use of samples is, "within certain restrictive conditions to provide samples of medicinal products free of charge to persons qualified to prescribe or supply them so that they can familiarize themselves with new products and acquire experience in dealing with them."[43] As noted in the preamble, the "distribution of samples free of charge to the general public for promotional ends must be prohibited."[44]

IV. Tracking of Medicinal Product Samples

As discussed in Part II, above, in 2016, the European Commission, through a delegation regulation, published accompanying provisions to Directive 2001/83 requiring that all medicinal products, including free samples, be fashioned with safety features, specifically requiring both a unique code as well as a safety features that enable users to see whether or not the product has been tampered with.[45] Thus, it requires serialization of medicinal products. Nonprescription medicinal products are generally exempt, whereas only a limited number of designated

[42] Id. art. 96(1)-(2).

[43] Id. pmbl., para. 51.

[44] Id. pmbl., para. 46.

[45] Commission Delegated Regulation (EU) 2016/161, supra note 9.

prescription medicines are exempt.[46] In addition, Member States may also optionally require that also otherwise exempted medicinal products bear the safety features.[47]

The handling of samples is specifically regulated in the delegation regulation. Article 41 of Commission Delegated Regulation (EU) 2016/161 requires that a marketing authorization holder that intends to supply any of its medicinal products as a free sample must, where that product bears the safety features, indicate that it is a free sample in the repositories system and ensure the decommissioning of its unique identifier before providing it to the persons qualified to prescribe it.[48] Consequently, free samples are covered by the delegation regulation and have to bear the safety features.[49] Moreover, the decommissioning of the unique identifier means that the sample is taken out of circulation, and not intended to be given to a patient as the end user. By decommissioning the number and by marking the sample with a logo that designates it at a sample, the sample is more likely to be recognized as a sample before erroneously being transferred to a patient.[50] When decommissioning the sample the category code "sample" must be used in the EU Hub system.[51]

V. Funding Serialization

The industry itself bears the cost of the serialization and does not receive funding from the European Union.[52] The funding structure and the fees associated with participating in the NMVS vary between Member Countries, with most assigning a combination of fees and six countries (Estonia, Malta, Portugal, Slovakia, Slovenia, and Sweden) not assigning any fee, or not reporting the fee.[53] The fees assigned typically include both a one-time "entrance fee" to gain access to the verification system and an annual fee collected from either corporations or the MAHs.[54] There appears to be no cost to pharmacists, doctors, or nurses for using the system.[55]

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[46] Commission Delegated Regulation (EU) 2016/161, supra note 9, Annexes I & II. The nonprescription product *omeprazole* was also subject to the safety features requirement, because of reported incidents of falsification. Tosetti, supra note 24, at 29). Note that whether a medicinal product is considered a prescription drug or a nonprescription drug may differ between the Member Countries, cf. Delegated Regulation 2016/161, supra note 9, pmbl., para. 40, and thus the same medicinal product may be subject to differing serialization requirements even within the EU.

[47] Directive 2001/83/EC, supra note 2, art. 54a(5).

[48] Commission Delegated Regulation (EU) 2016/161, supra note 9, art. 41; see also id. pmbl., para. 22, which explains the nature of the decommissioning process, and its role in ensuring that a sample does not inadvertently reach a patient.

[49] Id. art. 41.

[50] Id. pmbl., para. 22.

[51] See *Q&A*, e-VIS, https://perma.cc/3VH5-2EX7 (in Swedish).

[52] See European Commission Directorate-General for Health and Food Safety, supra note 30.

[53] Beer, supra note 31.

[54] Id.

[55] Id.

VI. National Guidelines

Some Member States have produced national guidelines that explain the EU obligations. For example, in 2019, the Health Products Regulatory Authority of Ireland issued a report titled *Good Distribution Practice of Medicinal Products for Human Use*.[56] It provides that "samples of medicinal products that may be given to, or administered to, patients must be stored and transported to the end customer in accordance with GDP [good distribution practice]."[57] In addition, "[s]ales representatives may not hold or supply free medicinal samples unless there are systems in place to guarantee that those samples are not given to, or administered to, patients."[58]

The EMVS published pack coding guidelines in 2017, in anticipation of the 2019 serialization.[59] It noted that manufacturers appear to prefer the GTIN (Global Trade Item Number) but that the European Hub supports both the use of GTINs, NTINs (National Trade Item Numbers), and PPNs (Pharmacy Product Numbers).[60] Examples of numbering systems used in 2017 in Europe include the following:

- France 3400 + CIP/ACL Code + check digit (France)
- 4150 + 8-digit PZN + check digit (Germany)
- 704626 + Nordic Drug Code issued by Nordic Number office + check digit (Nordic Countries Denmark, Finland, Iceland, Norway, and Sweden)[61]

[56] Health Products Regulatory Authority, *Guide to Good Distribution Practice of Medicinal Products for Human Use*, IA-G0046-4 (May 9, 2019), https://perma.cc/VS2V-WYNK. For other examples see the United Kingdom, Gov.Uk, *Guidance: Implementing the Falsified Medicines Directive: Safety Features* (updated July 11, 2019), https://perma.cc/MSW2-LVM5, and Italy, Minsitero della Salute & AIFA, *Bollino: The Italian Security Label for Pharmaceutical Products* (undated), https://perma.cc/9AJ2-FHW7.

[57] Health Products Regulatory Authority, supra note 56, at 24; see also *Good Distribution Practice*, European Medicines Agency, https://perma.cc/4LG4-JMYD.

[58] Id.

[59] EMVS, *European Pack Coding Guidelines* Version 4.0 (July 2017), https://perma.cc/L75E-7GPM.

[60] Id. at 5.

[61] Id. at 6.

Japan

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SUMMARY The Ministry of Health, Labour and Welfare issued the Implementation Guidelines for Bar Code Labeling of Prescription Drugs and notified the Federation of Pharmaceutical Manufacturers' Associations and others about them in 2006. The GS1 bar code system was adopted. Currently, dispensing, sales, and bulk packaging units of specified biological products are required to have bar codes that include information on product codes, expiration dates, and manufacturing numbers or codes. Beginning in April 2021, bar codes on packaging units for all types of prescription drugs will be required to have this information. The Implementation Guidelines require that bar codes on dispensing packaging units of prescription drugs (except for specified biological products) include the product code, but the expiration date and manufacturing number or code may be voluntarily included. The Implementation Guidelines do not require that a dispensing packaging unit of sample drugs have a bar code.

I. Bar Code Guidelines

A Japanese medical industry organization established the Medical Material Product Code/Bar Code Standards Guidelines in 1999 for the systematization of drug and medical material data input for healthcare management systems, the efficient distribution of drugs and medical material, and efficient and appropriate medical billing operations.[1] In 2006, in order to prevent accidents involving a mix-up of pharmaceuticals and to ensure the traceability of pharmaceuticals, the Ministry of Health, Labour and Welfare (MHLW) issued the Implementation Guidelines for Bar Code Labeling of Prescription Drugs (Implementation Guidelines) and notified the Federation of Pharmaceutical Manufacturers' Associations and others about the Guidelines.[2] The MHLW adopted the GS1 bar code system in the Implementation Guidelines.[3] The Implementation Guidelines were amended most recently in

[1] 医療材料標準バーコード [*Medical Materials Standard Bar Code*], Ainix (2016), https://perma.cc/Y3RP-F2K9.

[2] 医療用医薬品へのバーコード表示の実施について [Regarding Implementation of Bar Code Labeling of Prescription Drugs (hereinafter Implementation Guidelines)], MHLW, 薬食安発 No. 0915001 (Sept. 15, 2006), https://perma.cc/PCQ8-QPAH. The MHLW requests the pharmaceutical industry to follow the Implementation Guidelines that was issued as a notification. This suggests the Guidelines are not legally binding. However, the MHLW also suggests the bar codes requirements are mandatory. Legal effect of the Guidelines is ambiguous. See 2 医療用医薬品へのバーコード表示の実施要項の改正について (Regarding Amendment of the Implementation Guidelines for Bar Code Labeling of Prescription Drugs), 医薬品・医療機器等安全性情報 No.337, at 16 (Oct. 2016), https://perma.cc/R976-DKWU.

[3] Id. sec. 4.

2016.[4] In December 2018, the Pharmaceuticals and Medical Equipment System Subcommittee of the Health Sciences Council under the MHLW recommended that the government obligate pharmaceutical manufacturers and distributors to place bar codes that comply with international standards on dispensing and sales packages of prescription drugs.[5]

The Implementation Guidelines require that pharmaceutical manufacturers and distributors place bar codes on the packaging of prescription drugs that include certain information, depending on the kind of drugs. Each unit of a dispensing package, sales package, or bulk package needs a bar code.[6] The Implementation Guidelines classify prescription drugs in five categories: specified biological products,[7] biological product (other than specified biological products),[8] oral medicine (excluding biological products), injections (excluding biological products), and external medicine (excluding biological products).[9]

The Implementation Guidelines require all three package units of a specified biological product to have a bar code that includes the product code, expiration date, and manufacturing number or code of the product.[10]

For biological products, other than specified biological products, bar codes on sales package and bulk package units must have this information. However, a dispensing package unit of such biological products is required only to have product codes, and other information can be included voluntarily.[11]

Sales and dispensing package units of oral and external medicines and injections are required to have bar codes bearing product codes. The expiration date and manufacturing number or code can be included in the bar codes. Bulk package units of these medicines and injections do not

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[4] 「医療用医薬品へのバーコード表示の実施要項」の一部改正について [Regarding Partial Amendment to the Implementation Guidelines of Bar Code Labeling of Prescription Drugs], MHLW, 医 政 経 発 0830 No. 1, 薬 生 安 発 0830 No. 1, 薬 生監麻発 0830 No. １ (Aug. 30, 2016), https://perma.cc/K2XT-VXTW.

[5] 薬機法等制度改正に関するとりまとめ [Discussion Summaries on Amendment of Pharmaceuticals and Medical Equipment Act], Pharmaceuticals and Medical Equipment System Subcommittee of the Health Sciences Council, at 5 (Dec. 25, 2018), https://perma.cc/25WB-ZK7Q.

[6] Id.

[7] "Specified biological product" refers to biological products (see infra) designated by the Minister of MHLW as those requiring measures to prevent the occurrence or spread of health and hygiene hazards. Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, Act No. 145 of 1960, amended by Act No. 70 of 2018, art. 2, item 11 (unofficial translation of the Act as amended by Act No. 50 of 2015), https://perma.cc/YV35-CXUQ.

[8] "Biological product" refers to a product that was produced using raw materials or materials of human or other animal (excluding plant) origin, and that was designated by the Minister of Health, Labour and Welfare as requiring special attention with regard to health and hygiene. Id. art. 2, item 12.

[9] See Implementation Guidelines, supra note 2, sec. 1.

[10] Id.

[11] Id.

have to have a bar code, but can have bar codes with all or any of this information.[12] The 2016 Implementation Guidelines require that bulk package units of oral and external medicines and injections have bar codes and that bar codes on sales and bulk package units of these products include the expiration dates and manufacturing numbers or codes starting in April 2021. If there are special circumstances [13] pharmaceutical manufacturers and distributors may delay the implementation of the new requirements until April 2023.[14]

These provisions are expressed by charts in the Implementation Guidelines (◎ indicates that the information is required to be included; ○ indicates that the information is voluntarily included), as follows:[15]

1. Dispensing package unit[16]

Type of prescription drugs	**Product code**	**Expiration date**	**Manufacturing number or code**
Specified biological products	◎	◎	◎
Biological product (other than specified biological products)	◎	○	○
Oral medicine (excluding biological products)	◎	○	○
Injections (excluding biological products)	◎	○	○
External medicine (excluding biological products)	◎	○	○

[12] Id.

[13] For example, the manufacturing plant is under renovation before 2021, 薬読 (Sept. 5, 2016), https://perma.cc/K9Z2-GQHR.

[14] Implementation Guidelines, supra note 2, sec. 6 (3).

[15] Id. sec. 1, note 1.

[16] The dispensing package unit refers to the smallest unit of the package of drugs marketed by licensed marketers, e.g., a PTP (push through pack) sheet and a pill bottle for tablets and capsules, and an ampule and vial for injections. Implementation Guidelines, sec. 1, note 2.

2. Sales package unit[17]

Type of prescription drugs	Product code	Expiration date	Manufacturing number or code
Specified biological products	◎	◎	◎
Biological product (other than specified biological products)	◎	◎	◎
Oral medicine (excluding biological products)	◎	○ (◎ from 2021)	○ (◎ from 2021)
Injections (excluding biological products)	◎	○ (◎ from 2021)	○ (◎ from 2021)
External medicine (excluding biological products)	◎	○ (◎ from 2021)	○ (◎ from 2021)

3. Bulk package unit[18]

Type of prescription drugs	Product code	Expiration date	Manufacturing number or code	Quantity per unit
Specified biological products	◎	◎	◎	◎
Biological product (other than specified biological products)	◎	◎	◎	◎
Oral medicine (excluding biological products)	○ (◎ from 2021)	○ (◎ from 2021)	○ (◎ from 2021)	○ (◎ from 2021)
Injections (excluding biological products)	○ (◎ from 2021)	○ (◎ from 2021)	○ (◎ from 2021)	○ (◎ from 2021)

[17] The sales package unit refers to, in general, the smallest package unit of drugs sold by wholesale distributors to medical institutions, e.g., a box containing 100 PTP sheets that are dispensing packages for tablets and capsules, and a box containing ten ampules for injections. Id. sec. 1, note 3.

[18] The bulk package unit refers to a package unit of multiple sales packages packed by licensed marketers. Id. sec. 1, note 4.

Type of prescription drugs	Product code	Expiration date	Manufacturing number or code	Quantity per unit
External medicine (excluding biological products)	○ (◎ from 2021)	○ (◎ from 2021)	○ (◎ from 2021)	○ (◎ from 2021)

Source: 医療用医薬品へのバーコード表示の実施について [Regarding Implementation of Bar Code Labeling of Prescription Drugs], MHLW, 薬食安発 No. 0915001, sec. 1, note 1 (Sept. 15, 2006), https://perma.cc/PCQ8-QPAH, as translated and modified by author.

II. Sample Drugs

The Implementation Guidelines state that pharmaceutical manufacturers and distributors do not have to place bar codes on dispensing package units of sample medicines. If they place bar codes on dispensing package units, the bar code of the samples must be the same as those for the same drugs for sale.[19]

In Japan, quantities of sample prescription drugs are limited. The Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry established the Code of Fair Competition and its implementation rule, which were approved by the Fair Trade Commission (FTC) and Consumer Affairs Agency (CAA).[20] Under the Code and the rule, the Standards for Sample Drugs were established. The Standards set the maximum numbers of sample drugs per unit depending on the form of drugs. For example, the maximum number of tablets per unit of a sample package is six.[21] Pharmaceutical manufacturers and distributors may provide "minimally necessary" quantities of sample drugs for the purpose of testing shapes, colors, tastes, smells, and other external characters of the drugs with medical doctors.[22] Minimally necessary quantities are generally one to two packages per medical practitioner, and providing such samples cannot be routinely repeated.[23]

[19] Implementation Guidelines, supra note 2, sec. 1, note 8.

[20] 医療用医薬品製造販売業における景品類の提供の 制限に関する公正競争規約 [Code of Fair Competition on Limitations of Provision of Premiums for Prescription Drugs Distributors], FTC Notification No. 8 (Mar. 14, 1984), amended by FTC & CAA Notification No. 1 (Apr. 1, 2016), https://perma.cc/CQP9-7X86. A"code of fair competition" is a set of rules that an industry organization voluntarily establish, therefore not applicable for other companies that do not belong to the organization. 公正競争規約 (Code of Fair Competition), CAA, https://perma.cc/UL26-EGLT.

[21] 試用医薬品に関する基準 [Standards on Sample Drugs] sec. 2.1, reported to FCC (Jan. 20, 1998), amended and reported to FCC and CAA (June 16, 2014), https://perma.cc/5RGZ-6RNH.

[22] Id. secs. 1-1(1) & 2-1.

[23] Id. sec. 2-1.

Turkey

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SUMMARY Turkey appears to have in place an extensive national track-and-trace system for pharmaceuticals that involves serialization of all drugs (with certain exceptions) placed in the domestic market and validation of transactions at various points of the supply chain. However, whether or not free samples are subject to serialization within the national tracking system is not clear due to the existence in the current legal framework of certain rules that appear to conflict. Regardless of whether samples are required to be serialized within the national tracking system, Turkish law requires pharmaceutical companies to set their own systems for recording the manufacture, importation, and distribution of free samples and to submit records for administrative auditing when requested.

I. The Serialization of Pharmaceuticals in Turkey

According to the Turkish Pharmaceutical Market 2018 Report, published by the Pharmaceutical Manufacturers Association of Turkey, the volume of the Turkish pharmaceutical market in 2018 was 2.3 billion units (up from 1.62 billion units in 2010), with companies with foreign capital accounting for 66% of the market in value and 69% in volume.[1]

The serialization and tracking of pharmaceuticals is implemented by the Drug Tracking System (*Ilac Takip Sistemi*, "ITS"),[2] which was first implemented by the amendment in 2008 of the 2005 Regulation on Packaging and Labeling of Medicinal Products for Human Use.[3] Currently, the main framework for the serialization of medicinal products for human use (MPHUs) and the operation of the ITS is provided by the 2017 Regulation on the Packaging Information, Use Instructions, and Tracking of Medicinal Products for Human Use ("2017 Packaging Regulation").[4]

[1] Pharm. Mfrs. Ass'n of Turkey, *Turkish Pharmaceutical Market 2018*, 3 (2019), https://perma.cc/EAP5-JTVQ.

[2] ITS website (in English): https://www.its.gov.tr/index.php?run=home.

[3] Regulation on Packaging and Labeling of Medicinal Products for Human Use (repealed) as amended (published on Aug. 12, 2005, in Official Journal No. 25904), https://perma.cc/2UYD-AARY, repealed by Regulation on the Packaging Information, Use Instructions, and Tracking of Medicinal Products for Human Use (published on Apr. 25, 2017, in Official Journal No. 30048, entered into force on date of publication) ("2017 Packaging Regulation"), https://perma.cc/MMU9-4GN6.

[4] 2017 Packaging Regulation, note 3. The objective of the serialization and tracking framework set by the 2017 Packaging Regulation is stated as "the tracking and recording of the supply chain of medicinal products for human use for the creation of more efficient measures against defective and falsified products" (art. 1), medicinal products for human use (MPHUs) being defined as "substance or combination of substances that are (1) presented as having curative or preventative properties with regards to human diseases, and (2) used on or administered to humans for the purposes of restoring, healing, or changing physiological functions through pharmacologic, immunologic, or metabolic effects" (art. 4(1)(b)).

Details concerning the implementation of the ITS are laid down by a number of binding Guidelines published by the Turkish Medicines and Medical Devices Agency (Agency). In a nutshell, the ITS is a "track-and-trace" system that operates through the validation within a real-time database of each transaction that is made within the supply chain of the product. Stakeholders located at the various points of the supply chain must provide notification of each transaction involving the uniquely serialized product and obtain validation for that transaction. Upon notification, the system validates the transaction if the supply chain data is consistent or declines the transaction if it is not.[5]

MPHUs are serialized by affixing a two-dimensional square-shaped error-correcting matrix barcode, the ECC 200 standard GS1-DataMatrix ("data matrix code")[6], to the packaging of each manufactured unit. A data matrix code is not required on large-volume parenteral (administered other than by mouth) products, radiopharmaceuticals, and custom-made products for individual patients.[7] The data matrix code includes four types of information:

(1) the Global Trade Item Number (GS1 standard GTIN) that identifies the product,

(2) a serial number (SN) unique for each item of the same type,

(3) the expiration date of the product, and

(4) a batch/lot number identifying the production cycle in which the item was manufactured.[8]

The combination of the GTIN and the SN makes every unit uniquely identifiable.[9]

Each unit is then tracked in the real-time database by scanning the data matrix code accompanied with a coded notification made in the system by the stakeholders at certain transaction points in the supply chain, as determined by the serialization framework. Stakeholders are identified by GS1 standard Global Location Numbers issued for each of their activity locations.[10] The data created is stored by the Ministry of Health for at least three years after the expiration date of the individual unit.[11] According to article 15 of the 2017 Packaging Regulation and article 9 of the

[5] See generally the Drug Tracking System Operation Guidelines, version 1.03 (2009), https://perma.cc/9M2Z-JWUZ.

[6] For technical information on the GS1-DataMatrix, see https://perma.cc/9EQT-ZKYL. GS1 is a not-for-profit organization maintaining global business communication code standards.

[7] 2017 Packaging Regulation, art. 5(n). Article 2(2) of the Medicinal Products for Human Use Barcode and Data Matrix Application Guidelines (date unknown, issued on or after the date of publication of the 2017 Packaging Regulation, https://perma.cc/LR2V-VMZZ) also appears to exempt MPHUs manufactured exclusively for export from the data matrix code affixation requirement. Notably, such an exemption does not appear to be provided in the 2017 Packaging Regulation.

[8] Medicinal Products for Human Use Barcode and Data Matrix Application Guidelines, art. 5, supra note 7.

[9] 2017 Packaging Regulation, art. 16 (2).

[10] 2017 Packaging Regulation, art. 15(1); Medicinal Products for Human Use Barcode and Data Matrix Application Guidelines, art. 12, supra note 7.

[11] Drug Tracking System Operation Guidelines, version 1.03, art. 7, supra note 5.

Drug Tracking System Operation Guidelines,[12] the transactions requiring notification and validation are as follows:

Stakeholders	Transaction in supply chain requiring ITS notification
Drug producer/importer	**Manufacture** [first entry of domestically manufactured item into ITS] **Importation** [first entry of imported item into ITS] **Sale** [at time of sale to a pharmaceutical warehouse, pharmacy, distributor pharmaceutical company, or hospital] **Sales return** [if product is returned by the buyer for any reason] **Confirmation of receipt** [notification made to the system by stakeholders receiving the products to be cross-checked with the corresponding transfer notification] **Exportation** **Deactivation** [Removes a serial number from the system, which renders further movement of the serialized item in the supply chain impossible. Deactivation notification is given in cases such as consumption, manufacturing wastage, destruction of recalled or expired products, or removal of serial numbers from the system in other justifiable cases. The reason for deactivation is recorded in the system in code.]
Pharmaceutical warehouse (wholesaler)	**Sale** [sales allowed only to pharmacies, hospitals, or other pharmaceutical warehouses] **Sale return** **Confirmation of receipt** **Deactivation**
Pharmacy	**Sale** [sales allowed only to patients or other pharmacies] **Sale cancellation** [only for retail sales in pharmacies] **Confirmation of receipt** **Deactivation**
Hospital pharmacy	**Sale** [when product is billed to patient] **Consumption notification** [indicates consumption of product in a hospital] **Confirmation of receipt** **Deactivation**
Reimbursement agency [public or private]	**Sales confirmation** [for products whose costs were reimbursed]

[12] Drug Tracking System Operation Guidelines, version 1.03 (2009), supra note 5.

It appears that by January 1, 2010, all MPHUs in the Turkish market that were not exempted were required to be serialized and carry a data matrix code.[13]

II. The Rules Concerning Free Samples

A. Legal Framework

The general framework that regulates the marketing and promotion of MPHUs is provided by the 2015 Regulation on Promotional Activities for Medicinal Products for Human Use ("2015 Promotion Regulation").[14] Article 9 of this Regulation lays down the rules for the supply of free samples by a licensed drug manufacturer or distributor or an authorized importer. Article 7 of the 2015 Guidelines on Promotional Activities (2015 Promotion Guidelines),[15] which was published by the Agency on the same day as the 2015 Promotion Regulation to provide guidance on the application of its rules, details certain parts of the procedure provided in Article 9 of the regulation.

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[13] Provisional art. 2 of the (repealed) 2005 Regulation on Packaging and Labeling of Medicinal Products for Human Use, note 3; Circular 2009/83 of the (ex) General Directorate of Pharmaceuticals and Pharmacies of Dec. 31, 2009, https://perma.cc/X5KU-WCMS; Carlos Cordon et al., *Strategy is Digital, Management for Professionals*, 54 (2016).

[14] Regulation on Promotional Activities for Medicinal Products for Human Use (published on July 3, 2015, in Official Journal No. 29405, relevant provisions entered into force on date of publication) ("2015 Promotion Regulation"), https://perma.cc/32PY-4Y58. The 2015 Promotion Regulation essentially harmonizes the Turkish framework for the supply of free MPHU samples with European Union law set by article 96 of Directive 2001/83/EC, as amended, https://perma.cc/SK53-3WWJ. However, some rules appear not to be harmonized, notably, the rule of article 96(1) of the directive limiting the supply of free samples to "persons qualified to prescribe them" and article 96(1)(b) requiring supply of samples to be "in response to a written request, signed and dated, from the prescribing agent." Concerning the former rule, the Turkish framework allows the supply of free samples to pharmacists, who are not qualified to prescribe MPHUs under Turkish law. Regarding the latter rule, Turkish law does not include a written request requirement. The Association of Research-Based Pharmaceutical Companies, an industry association composed of some of the largest multinational pharmaceutical companies operating in Turkey, which publishes codes and guidelines for good practices, points out discrepancies between Turkish and EU laws in art. 13 of its *Code of Good Promotional Practice and Good Communication* (edition 6.01, effective Apr. 1, 2017), https://perma.cc/AQT4-GK56, and requires its members to abide by the EU rules (art. 13.12.1), noting: "In accordance with EU directives and the EFPIA Code [Eur. Fed'n of Pharm. Indus. & Ass'ns, EFPIA Code archived at https://perma.cc/DL7B-28GB], distribution of free reduced samples of prescription-only drugs may only be allowed in special cases to prescribers (physicians and dentists), for a limited period of time and in a limited amount, upon a written, dated and signed request. Although a restriction is imposed on the amount of samples to be distributed by the legislation of the Republic of Turkey, the period of distribution is not restricted, provision of samples to pharmacists is not prevented, and distribution is not bound to the written, dated and signed request of physicians and dentists [. . .] In line with EFPIA's interpretation of the EU Directive, AIFD does not regard [as] suitable the supply of samples of prescription-only drugs to pharmacists [. . .] The EFPIA Code indicates that the samples are distributed upon the 'unsolicited request of physicians.' Therefore, the relevant physician shall submit his/her sample request in written [sic] and with a date and sign it." Ass'n of Research-Based Pharm. Cos., Code of Good Promotional Practice and Good Communication (Apr. 1, 2017), at art. 13.12.1 "Article Clarifications and Justifications."

[15] Guidelines on the Applications for the Distribution of Free Promotional Samples and Press Releases under the Regulation on Promotional Activities for Medicinal Products for Human Use (published on July 3, 2015, in Official Journal No. 29405, entry into force Nov. 16, 2015), https://perma.cc/VPF4-ABDY.

B. The Rule Regarding the Serialization of Free Samples Is Not Clear

Although the 2015 Promotion Regulation requires pharmaceutical companies to create their own registration and control system for free samples in accordance with the framework applicable to recalling MPHUs,[16] it is silent on whether sample packages must carry data matrix codes. Nevertheless, article 7(3) of the 2015 Promotion Guidelines states "in principle, promotional samples shall not have affixed a data matrix code / bar code" and adds that the Agency's written approval is required for free samples to bear a data matrix code (art 7(4)).[17]

On the other hand, article 10 of the 2017 Packaging Regulation establishes a general rule that the framework set by the regulation (thus including serialization within the ITS) also applies to free samples. Nevertheless, the same provision authorizes the Agency to exempt free samples from carrying data matrix codes. The language of the provision is not clear on whether the Agency has the authority to categorically exempt free samples. Rather, it appears to authorize the Agency to determine which samples are to be exempt.

Thus, the serialization rule currently applicable to free samples is unclear. Under Turkish law, a regulation issued by a ministry is higher on the hierarchy of norms than guidelines published by an administrative agency. Therefore, the rule in the 2017 Packaging Regulation may be interpreted as abrogating the rule in the 2015 Promotion Guidelines. On the other hand, the 2015 Promotion Regulation is still in force, and the Guidelines were published based on the authorization provided by article 14 of that regulation. While it might be argued that, according to the Turkish administrative law maxim that a later law repeals an earlier one,[18] the provisions of the 2017 Packaging Regulation regarding the labeling of free samples override the rules regarding the same matter in the 2015 Promotion Regulation, article 10 of the 2017 Packaging Regulation still authorizes the Agency to determine which samples will be exempted from the 2017 serialization requirements.

The Association of Research-Based Pharmaceutical Companies, in the most recent edition of its *Code of Good Promotional Practice and Good Communication* (Apr. 1, 2017) (Code),[19] states that "[i]t is essential that no commercial barcodes/datamatrixes or price tags are used on the packages of promotional samples," and that "[i]n case of [the] presence of a barcode/datamatrix on the packages of Free Promotional Samples planned to be distributed, a written permission shall be requested from the Ministry [of Health] along with its justification [. . .] sale of samples shall be

[16] Article 9(1)(a) of the 2015 Promotion Regulation. Recalls and recall systems are regulated in the Recall Regulation (published on Nov. 19, 2015, in Official Journal No. 29537, entered into force on date of publication), https://perma.cc/ZC6Z-BURH.

[17] Notably, article 9(1)(e) of the repealed 2011 Regulation on Promotional Activities for Medicinal Products for Human Use (published on Aug. 26, 2011, in Official Journal No. 28037, repealed by 2015 Promotion Regulation) (https://perma.cc/9GJD-ZD99), had explicitly provided that the samples would, in principle, not have data matrix codes on their packaging. This rule was left out in the 2015 Packaging Regulation, but included in the 2015 Packaging Guidelines.

[18] Kemal Gözler, *Yorum İlkeleri*, Anayasa Hukukunda Yorum ve Norm Somutaşması, 100 (2012); Kemal Gözler, *İdare Hukuku*, vol. 1, 1133-1134.

[19] Ass'n of Research-Based Pharm. Cos., *Code of Good Promotional Practice and Good Communication* (Apr. 1, 2017), supra note 14.

prevented in the Drug Tracking System of the Ministry," citing article 9(1) of the 2015 Promotion Regulation.[20] It seems that, without a data matrix code, free samples are not entered into the ITS and are recorded only in a pharmaceutical company's internal system established according to article 9 of the 2015 Promotion Regulation. However, it is not clear whether, in practice, the standardized unique identifiers are assigned to free samples within the ITS, and subsequently deactivated. It must be noted that the Code is dated April 1, 2017, which is before the date of publication of the 2017 Packaging Regulation on April 25, 2017, and the entry into force of its provisions that appear to require, in principle, the serialization of free samples within the ITS.

That said, the Agency has not issued new guidelines that would shed light on the application of article 10 of the 2017 Packaging Regulation. Thus, taking into consideration the lack of any attempts by the Agency or industry groups to clarify the application of the new rule, we conclude that it is possible that the rule provided by the 2015 Promotion Guidelines is still in force, and free samples are left outside of the ITS serialization system for the time being. Regardless of the rule regarding the ITS, however, the current framework explicitly requires pharmaceutical companies to establish an adequate system to record the manufacture, importation, and distribution of free samples and to provide the Agency these records for auditing.[21]

[20] Ass'n of Research-Based Pharm. Cos., *Code of Good Promotional Practice and Good Communication*, supra note 14, article 13.5. Although the Code cites article 9(1)(e) of the 2015 Promotion Regulation as justification for its rules concerning data matrix codes on packaging, as noted above, such a rule does not exist in article 9 of that regulation. Rather, the relevant rules exist in art. 7 of the 2015 Promotion Guidelines. However, such a rule existed in art. 9(1)(e) of the repealed 2011 Promotion Regulation, supra note 17.

[21] Article 9(1)(a) of the 2015 Promotion Regulation.