



SELECTED SAFETY FEATURES FOR MEDICINES SOLD IN TRADITIONAL PHARMACIES

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Abstract

Nowadays, every EU resident can easily find advertisements of non-prescription medicinal products (over-the-counter drugs) on the Internet. They get to mailboxes as the so-called commercial information or can be seen on websites devoted to health in general or a specific disease. Certain drugs can also be found on various websites or via search engines. It is thus possible for patients to buy medicines through legal websites run by traditional pharmacies, but also through websites run by shady entities that can not be considered pharmacies or any other entities. That is why additional safety features for batches and individual packagings of medicines introduced on 9 February 2019 are so important.

Keywords: law, Internet, safety, falsification of medicines, medicine serialization, EAN code

1 INTRODUCTION

Nowadays, every EU resident can easily find advertisements of non-prescription medicinal products (over-the-counter drugs) on the Internet. They get to mailboxes as the so-called commercial information or can be seen on websites devoted to health in general or a specific disease. Certain drugs can also be found on various websites or via search engines. It is thus possible for patients to buy medicines through legal websites run by traditional pharmacies, but also through websites run by shady entities that can not be considered pharmacies or any other entities.

Purchasing medicines at a distance entails certain risks, such as:

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- no personal contact and full identification of the parties, especially the pharmacy (risk of fraud),
- low level of patient's knowledge about rules governing the safe purchase of medicines,
- sale of medicines that have not been legally authorized,
- sale of counterfeit medicines (falsified medicines),
- sale of expired medicines.

That is why additional safety features for batches and individual packagings of medicines introduced on 9 February 2019 are so important.

The article attempts to answer the following questions: what safety features have been introduced by the new EU regulations, and how can we protect ourselves from buying medicines that come from uncertain sources, e.g. the Internet.

The article employs the dogmatic and legal research method, which consists in analyzing and interpreting EU regulations and selected literature.

A hypothesis has been put in the paper: The newly introduced additional safety features for batches of medicines increase the safety of purchase when buying medicines both online and in traditional pharmacies.

The article ends with conclusions.

2 THE LEGAL BASIS – CORE NOTIONS

In Polish law, the sale of medicines has been regulated in Article 68 Paragraph 3 of the Act of 6 September 2001 - Pharmaceutical Law (EC, 2001). This provision allows pharmacies and rural pharmacy shops¹ to sell non-prescription medicinal products at a distance, except for medicinal products that can be dispensed only to patients of a certain age².

Distance selling³ has been defined in Article 2 Paragraph 37aa of the above Act as an agreement for sale of medicinal products concluded with the patient without the simultaneous presence of both parties⁴, using means of distance communication, in particular, a printed or electronic order form, unaddressed or addressed, serial letter in printed or electronic form, press advertisement with printed order form, electronic advertisement, catalog, telephone, facsimile, radio, television, automatic calling device, video telephone, video text, e-mail, or other means of electronic communication within the meaning of the Act of 18 July 2002 on the provision of electronic services (Polish law, 2017).

The Regulation of the Minister of Health of 26 March 2015 on distance selling of medicinal products (Regulation, 2015), issued in order to implement the provisions of the said Act, lays down the requirements concerning distance selling⁵. Pursuant to Paragraph 2 Subparagraph 1 of this legal act, the sale of medicinal products

¹ According to data published by the Central Statistical Office of Poland, at the end of 2018 there were 12.9 thousand pharmacies and 1.2 thousand rural pharmacy shops (a type of pharmacy that can be located only in rural areas and can not sell certain strong medicines) in Poland; they employed 60.3 thousand pharmacy masters and technicians.

² Judgment of the Court of Justice of 21 June 2012, C-84/11: Judgment of the Court (Third Chamber) of 21 June 2012. Marja-Liisa Susisalo, Olli Tuomaala and Merja Ritala. Reference for a preliminary ruling: Korkein hallinto-oikeus - Finland. Article 49 of TFEU - Freedom of establishment - Public health - Pharmacies - National authorization system for operating pharmacies - Establishment of branches - Different conditions depending on whether they apply to private pharmacies or to the pharmacy of the University of Helsinki - the University of Helsinki pharmacy with specific obligations related to pharmaceutical training and drug supply. Case C-84/11, (EU law, 2012).

Order of the Court of Justice of 29 September 2011, C-315/08: Order of the Court (Seventh Chamber) of 29 September 2011 (reference for a preliminary ruling from the Consiglio di Stato - Italy) - Angelo Grisoli v Regione Lombardia (Article 104(3), first indent, of the Rules of Procedure — Article 49 TFEU — Freedom of establishment — Public health — Pharmacies — Proximity — Supply of medicinal products to the population — Operating authorisation — Territorial distribution of pharmacies — Minimum distance between pharmacies), (EU law, 2012), Legalis.

³ Judgment of the Supreme Administrative Court of 2 September 2009, II GSK 5/09, Reasoning:

Provision of Article 544 § 1 of the Civil Code does not use the term "distance selling", nor does it contain interpretative rules such as the following: "means", "should be understood as", "is considered", etc., which would allow the assumption that the legislator has included a legal definition of "distance selling" in this legal norm. In a situation where the Act of 6 September 2001 - the Pharmaceutical Law (Journal of Laws of 2004 No. 53, item 533, as amended) also does not contain such a definition, the resolution of the disputed issue requires an analysis of this Act's regulations regarding the principles of: marketing of medicinal products, operating a pharmacy (or a rural pharmacy shop), conditions for distance selling of non-prescription medicinal products (Article 68 Paragraph 3a), as well as the rules for dispensing compounded drugs (Article 96 Paragraph 7), Legalis.

⁴ Judgment of the Voivodeship Administrative Court in Warsaw of 7 May 2009, VII SA/Wa 392/09, Reasoning: Since the Act of 6 September 2001 - the Pharmaceutical Law (Journal of Laws of 2004 No. 53, item 533, as amended) does not contain a legal definition of "distance selling", therefore one should refer to the regulations of this Act stipulating the rules of medicinal products marketing, operating a pharmacy and dispensing medicinal products to patients by traditional pharmacies. This applies in particular to the analysis of regulations on the terms of "distance selling" of non-prescription medicinal products and regulations on the dispensing of compounded drugs (Article Article 68 Paragraph 3a and Article 96 Paragraph 7 of the said Act), Legalis.

⁵ In 2017, 280 pharmacies and 4 rural pharmacy shops declared selling medicinal products online.

at a distance is possible after the patient has placed an order:

1. in the premises of a pharmacy or rural pharmacy shop;
2. by phone;
3. by fax;
4. via email;
5. using a form on the pharmacy's website.

A question arises about the above-mentioned form: should it be allowed only on websites of pharmacies or also on fora about health and websites of intermediaries?

A linguistic interpretation of the provision suggests that an online medicine purchase form should be allowed on websites run by pharmacies legally operating in Poland⁶. However, if we concentrate on the legislator's intention, then the form can be allowed on web portals devoted to health, internet fora, and websites of intermediaries selling diverse products. In practice, it does not mean such entities can act as mediators in concluding online contracts. It would contradict the provisions of the above-mentioned Regulation, which allow distance selling only in cases stipulated in the provisions, and one of them is selling "using a form on the pharmacy's website".

The provisions of the said Regulation should receive a negative assessment because they do not fully achieve the legislator's goal. The so-called "third party" acting as a mediator in the online sale does not conclude a distance purchase/sale agreement.

3 INTERNET PHARMACIES

The EU pharmaceutical industry (pharmacies, rural pharmacy shops, pharmaceutical wholesalers) is nowadays a special sector of the economy characterized by innovativeness and technological sophistication. Poland is currently the largest pharmaceutical market in Central and Eastern Europe.

One of the industry's major problems is the falsification of medicines⁷. It poses a threat to the safety⁸ of patients, especially when they purchase medicines on the Internet⁹.

On 9 February 2019, traditional pharmacies faced a new technological challenge (Naughton, 2017). The quality of Internet connection in some regions of Poland can significantly delay the process of receiving information about the authenticity of medicines¹⁰. At the same time, most of the scanners used by pharmacies can not read the new code introduced by the 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 (Regulations, 2015).

Due to the newly introduced obligation of serialization, it will be possible, during the transitional period, to use both the existing EAN-13 (the so-called EAN code) and GS1 DataMatrix code on the packaging of medicinal products.

⁶ In November 2018, the value of online sales of medicines amounted to PLN 55 million, showing a 27% dynamics compared to November 2017. (AM, 2018)

⁷ "WHO perceives Poland as a high risk country in terms of drug counterfeiting. It is also a transit country through which counterfeit pharmaceuticals get to the West. In recent years, customs services have intercepted between 100,000 and 160,000 counterfeit drugs annually. (...) 430,000 steroids in ampoules, 100,000 Viagra tablets and 48 machines for their production (...)" (Sitek, 2018) 50% of antimicrobial drugs in the world may be counterfeit. In developing countries, this can amount up to 76%. According to WHO quality tests, 7.6% of the most popular antibiotics lack their active substance, and among substandard drugs (coming from legal sources where such a defect is due to e.g. technological error) that problem occurs in 17.8% of antibiotics and 13% antiparasitic drugs. Up to 90% of antimalarial drugs in Africa are of poor quality. (NIL, 2018)

⁸ Article 37 of the 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 (Regulations, Commission delegated regulation (EU) 2016/161, 2016, p. 1).

⁹ Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (Legislative acts, 2011).

¹⁰ In Poland, the average internet connection speed is increasing and is currently above the global average - 54.5 Mbps compared to 54.33 Mbps (the study We Are Social - Digital 2019). However, compared to many European countries, e.g. Germany, Sweden, Switzerland, Belgium or Spain, where the average Internet speed is 70-100 Mbps, the Polish Internet is relatively low. (PAP, 2019)

4 SAFETY FEATURES FOR MEDICINAL PRODUCT PACKAGINGS

The first question to be answered in this section of the paper should be what the EAN code is. The EAN code is a number assigned to medicine together with its marketing authorization by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The EAN code is an identifier of each medicinal product packaging registered in Poland. In order to assign the right code, the drug's active substance, its strength, form and dosage, as well as the size and type of packaging must be considered. As a result, the code on the packaging of medicine containing 1 mg of an active substance will be different from the code on the packaging of medicine containing 2 mg of that substance. Different codes will be assigned to medicines with the same strength (active substance) but sold in different packs, e.g. 10 or 20 tablets.

The EAN code is composed of the following elements (Bondaryk & Kruk, 2011):

- the first three digits - 590 - are the EAN prefix for the EAN national organization in Poland;
- the next three digits - 999 - are the coding unit number assigned to the Ministry of Health;
- the next five digits are the number of the product's marketing authorization;
 - the next (12th) digit indicates the type and size of the packaging;
 - the last (13th) digit is a check digit.

The second question is whether there is an obligation to change the code in certain cases. The EAN code does not have to be changed whenever the wording of the marketing authorization is changed. However, it has to be changed in the event of changes in the parameters, that is the changes affecting the medicine's active substance and strength, its pharmaceutical form (tablets, liquid) and dosage, or the size and type of the packaging.

Pursuant to the Annexes to the Regulation of the Minister of Health on making changes in marketing authorizations and documentation of medicines (n.d., 2014), a change in all of the above-mentioned parameters, except for the change in the size of the packaging, requires the submission of a new application for marketing authorization.

Therefore, the conclusion is that if there are changes in the medicine's active substance, strength, pharmaceutical form and dosage, the EAN code will necessarily be changed as a result of a new marketing authorization.

An analysis of the Annexes to the said Regulation shows that a change in the size and type of the packaging does not require the submission of a new application for marketing authorization. It will be a Type II change in the authorization. In this case, however, the EAN code should be changed, which stems from the wording of Article 23 Paragraph 3 of the Pharmaceutical Law. This provision enumerates the following elements of the marketing authorization:

- name and common name of the medicine provided the latter exists,
- form,
- method of administration,
- strength (potency),
- dosage of an active substance,
- full qualitative composition,
- size and type of packaging.

The obligatory use of the EAN UCC code is mentioned in Paragraph 10.

Taking into account the code's functions, the provision's wording seems justified. Therefore, the EAN code should be changed also when the medicine's name is changed. However, pursuant to the said Annexes to the Regulation of the Minister of Health, this is a Type I change in authorization, which does not require the submission of a new application, and does not affect any medically significant parameters.

Conclusion: the name of the medicine is usually changed only for marketing purposes, therefore there is no justification (purpose) for changing the EAN code.

What effect will the change of name have?

If pursuant to Article 23 Paragraph 3 of the Pharmaceutical Law, the aforementioned elements remain unchanged, the change of name entails in fact only the change of the packaging appearance. Thus, it is reasonable to conclude that changing the medicine's name is not a reason for changing the EAN code.

The recent changes were forced by the implementation of the so-called Falsified Medicines Directive. Therefore, in his

Communication of 7 February 2019, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Kolakowski, 2019) allowed changes in the Electronic Register of Medicinal Products Authorized for Marketing on the territory of the Republic of Poland: the 13-digit number GTIN (EAN-13) shall be changed to a 14-digit GTIN code. An insignificant zero shall appear in front of the 13-digit GTIN (EAN-13) to form a 14-digit GTIN. At the same time, the existing marketing authorizations do not have to undergo post-authorization changes regarding GTIN (EAN-13) identification numbers. When it comes to new marketing authorizations, the 13-digit GTIN (EAN-13) identification numbers will be entered as before, irrespective of the medicine's category (prescription, non-prescription, etc.).

Another change was implemented by the Information of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of 28 May 2019 on identification numbers (EAN/GTIN codes) placed on the packagings of medicinal products (Cessak, 2019). A medicine packaging can only be identified by a single identification number (EAN/GTIN code) stipulated in the marketing authorization. The aforementioned authorization assigns 13-digit identification numbers (the so-called EAN codes) to individual pack sizes. Using the EAN code, the marketing authorization holder (MAH) creates a 14-digit identification number by adding a zero before the existing 13-digit number. The 14-digit number is placed on the packaging of medicinal products as "PC" (product code) and in the two-dimensional DataMatrix code (2D code). The Office permits two codes to be placed on the packaging at the same time: EAN code and 2D code provided that the identification numbers are the same (except for the zero added). It is not permissible for the 2D code to contain an identification number different than the one in the EAN code and marketing authorization. It is

forbidden to place two different identification numbers on the medicinal product packaging, one from the marketing authorization and the other from the marketing authorization holder. If the MAH wants to use their own GTIN code, they must notify the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and obtain a decision on the change of the marketing authorization.

5 SERIALIZATION OF MEDICINES

The Commission Delegated Regulation (EU) 2016/161 published on 9 February 2016 lays down the requirements for marketing authorization holders, wholesalers and pharmacies (regular and hospital ones) regarding the serialization of medicinal products and confirmation of their authenticity. Serialization involves more detailed identification of medicines and makes it possible to distinguish particular packagings within one range of medicinal products (Arnould, et al., 2019).

The currently used bar code is a linear code, i.e. the EAN-13 code. Under the new legal requirements, the symbology for serialization purposes will be two-dimensional, like the GS1 DataMatrix code (Walczak, 2018).

All pharmacies will have to purchase special scanners able to read the 2D Data Matrix code¹¹. The new code is printed on the unit packaging in an online mode as part medicine packaging process. It includes, e.g.:

- information about the batch number,
- expiry date,
- GTIN (Global Trade Item Number), i.e. a unique code of the medicine being a sequence of digits denoting the country of origin, manufacturer, product type (enables to include much more information in a small space). In a square consisting of 32 rows and 32 columns (ECC200 mode), it is possible to encode 60 8-bit ASCII characters or a

¹¹ In 2007-2008, the US (FDA), France (AFSSAPS) and Turkey (Ministry of Health) introduced a requirement to mark and identify medical products for human use with a special code. The so-called online coding in the form of 2D Data Matrix replaced the classic barcode. Article 5 Paragraph 2 of the Delegated Regulation: The barcode shall be a machine-readable Data Matrix and have error detection and correction equivalent to or

higher than those of the Data Matrix ECC200. Barcodes conforming to the International Organization for Standardisation/International Electrotechnical Commission standard ('ISO/IEC') 16022:2006 shall be presumed to fulfil the requirements set out in this paragraph.

sequence of 91 alphanumeric characters (Rzadca, 2013). Additionally, the 2D code contains redundant data. The algorithm allows one to decode it even if it is damaged or poorly printed.

The main goal of the solutions introduced by the Falsified Medicines Directive is to eliminate counterfeit medicines from the market.

"Unique identifier" is provided for in Article 3 Paragraph 2 Subparagraph a) of the Delegated Regulation as "the safety feature enabling the verification of the authenticity and the identification of an individual pack of a medicinal product". The composition of the unique identifier is stipulated in Article 4 of the Commission Delegated Regulation (EU) 2016/161:

- a code allowing the identification of at least the name, the common name, the pharmaceutical firm, the strength, the pack size and the pack type of the medicinal product ("product code"),
- a numeric or alphanumeric sequence of maximum 20 characters, generated by an algorithm ("serial number"),
- the batch number,
- the expiry date.

Pursuant to the provisions of Article 9 of the aforementioned Regulation, barcodes on the packagings of medicines "which must bear the safety features pursuant to Article 54a of Directive 2001/83/EC shall not bear on their packaging, for the purpose of their identification and verification of their authenticity, any other visible two-dimensional barcode than the two-dimensional barcode carrying the unique identifier".

6 COMMON LOGO

Another safety feature is the so-called "Common logo" defined by the provisions of Commission Implementing Regulation (EU) No 699/2014 of 24 June 2014 on the design of the common logo to identify persons offering medicinal products for sale at a distance to the public and the technical, electronic and cryptographic requirements for verification of its authenticity (Barroso, 2014). This basic graphic identifier of a legally operating online pharmacy is common to the entire European Union. It consists of a white cross against green stripes and the flag of a Member State.



Figure 1 The model of online pharmacy logo
Source: Commission Implementing Regulation (EU) No 699/2014

Under the common logo there is a flag of a Member State, which denotes the place of residence or the registered office of an entity selling medicines at a distance, and information "Click to verify if the website is operating legally" in the language of a given Member State.

Clicking on the common logo will automatically redirect one to the website confirming that the pharmacy or rural pharmacy operates legally, i.e. is authorized to sell medicines at a distance via the Internet.

As regards Polish regulations, pursuant to Article 115 Paragraph 2 Subparagraph 5 of the Pharmaceutical Law, the Main Pharmaceutical Inspector publishes the current list of Polish pharmacies and rural pharmacy shops authorized to sell non-prescription medicinal products at a distance in the "Public Information Bulletin" of the Main Pharmaceutical Inspectorate.

A question that needs to be answered now is about the mandatory elements of the website run by a legally operating online pharmacy.

The pharmacy website must contain, in a visible place, a set of relevant information that will allow each user to identify it:

- every pharmaceutical seller must have their registered office. Selling medicines without a registered office is illegal, so every pharmacy must have an address,
- a precise list of terms and conditions, e.g. time and method of delivery, rules of return and complaint,
- medicine prices must be set clearly and unambiguously.

Legally operating online pharmacies can not:

- offer discounts,
- sell prescription-only medicines,
- conduct advertising activities.

7 CONCLUSION

All medicinal products subject to serialization and placed on the market after 9 February 2019 have to have a unique identifier and 2D code. Needless to say, in the initial stage of the new system implementation, medicinal products that received marketing authorization before 9 February 2019, and thus do not have the discussed safety features, will be still available on the market until they are sold out or expire. It is estimated that 90% of medicines will have had the new safety features three years after the new system was implemented. A lack of safety features on the packaging of a medicinal product should not be a reason for refusing to dispense it to the patient.

The conducted analysis of the European and national legal regulations allows to draw the following conclusions regarding the Internet:

- it is a channel for disseminating information about medicines and their prices via web portals devoted to health,
- it enables patients to place orders for specific medicines and pick them up in traditional

pharmacies or get them delivered to their home addresses,

- the transaction is carried out at a distance via the web.

Will the new safety measures protect potential patients against counterfeit medicines? At the moment - yes, but it should be borne in mind that medicine counterfeiters will always stay up-to-date with innovation processes taking place in the administration and IT. This means that after a certain period of time the safety features may be broken by entities operating illegally on the medicine market.

The activity of the Polish Main Pharmaceutical Inspector should be assessed critically. In the legal state as of today, the Inspector does not meet social expectations regarding supervision over the online sale of medicines.

A *de lege ferenda* suggestion to be put forward is to establish the so-called pharmaceutical police and a special section to counteract the sale of falsified medicines online.

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