

**COMMITTEE OF EXPERTS
ON THE CLASSIFICATION OF MEDICINES
AS REGARDS THEIR SUPPLY
(CD-P-PH/PHO)**

New trends as regards the supply modes of medicines

Survey report

Table of Contents

	Page
Background	3
Disclaimer	5
Survey results	6

Background

The availability of medicines with or without a medical prescription has implications on patient safety, accessibility of medicines to patients and responsible management of healthcare expenditure.

The decision on prescription status and related supply conditions is a core competency of national health authorities. The conditions of the supply of medicines vary considerably in Council of Europe member states, due to the fact that the provisions are differently interpreted and implemented by the member states, and that important additional classification criteria are not harmonised.

The Committee of Experts on the Classification of Medicines as regards their Supply (CD-P-PH/PHO)¹ is coordinated by the European Directorate for the Quality of Medicines and HealthCare (EDQM, Council of Europe) and its working programme is based on Committee of Ministers Resolution CM/Res(2018)1 on the classification of medicines as regards their supply².

In its work, the CD-P-PH/PHO focuses on public health promotion and uses scientific approaches, taking account of the national assessments of direct and indirect risks which may occur under normal treatment conditions and under medical surveillance, as well as from foreseeable misuse or abuse of medicines.

The CD-P-PH/PHO issues twice a year recommendations to health authorities of the Council of Europe member states parties to the Convention on the Elaboration of a European Pharmacopoeia (Ph. Eur.) on the classification of medicines and establishes good classification practices.

The recommendations are also useful for pharmaceutical manufacturers and commercial operators of mail-order trade in medicines where such trade is legal.

A pioneer in this field, Council of Europe bodies have been concerned since 1961 with issues relating to the classification of medicines into prescription and non-prescription medicines and have inspired relevant EU legislation.

The classification criteria set out in the Council of Europe resolutions have been supplanted by Directives 92/26/CEE and 2001/83/EC (art. 70-75). Directive 2001/83/EC refers to the Council of Europe in its Whereas 32: *“It is therefore appropriate, as an initial step, to harmonise the basic principles applicable to the classification for the supply of medicinal products in the Community or in the Member State concerned, while taking as a starting point the principles already established on this subject by the Council of Europe”*³.

It is important to note that:

- The CD-P-PH/PHO does not issue recommendations on the classification of particular medicines, but on active substances used in a medicine for a specific therapeutic purpose.
- In its work, the CD-P-PH/PHO uses the Anatomical Therapeutic Chemical (ATC) classification maintained by the WHO Collaborating Centre for Drug Statistics Methodology⁴ to identify active substances or combinations of active substances.
- The CD-P-PH/PHO does not give advice relating to pending marketing authorisation procedures.

The CD-P-PH/PHO supervises a database (i.e. *Melclass*⁵), hosted by the EDQM, which stores the recommendations that the Committee of Experts issues twice a year to health authorities of the Council of Europe member states which are parties to the Ph. Eur. Convention, as well as national information about the classification status and supply conditions of medicines in these member states. The information is publicly available. Recommendations about 2100 medicines are published in the *Melclass* database.

Providing a platform for dialogue and consensus building on the supply conditions of medicines in Europe as facilitated by Council of Europe Committee of Ministers Resolution CM/Res(2018)1, the CD-P-PH/PHO

¹ <http://go.edqm.eu/PHO>

² <http://go.edqm.eu/CMRes20181>

³ <https://goo.gl/at4RZo>

⁴ <https://goo.gl/KvqKir>

⁵ <https://melclass.edqm.eu/>

promotes patient safety and, where appropriate, access to medicines without a prescription across Europe, which helps to foster public health and to responsibly manage healthcare resources.

Disclaimer

This document is published for information only.

It presents the outcomes of a survey that the Committee of Experts CD-P-PH/PHO performed in 2019 among the experts participating in the CD-P-PH/PHO's work (Ph. Eur. member and observer states).

The aim of the survey was to gather information about the sale of medicines (with a valid marketing authorisation) in establishments other than community pharmacies⁶ (part 1) and internet pharmacies (part 2), and the impact that this may have on medicine classification practices.

The content of this document does not commit the parent authorities of the experts nor the Council of Europe/EDQM.

⁶ *Establishments other than community pharmacies* is a general term that refers to all those stores that are not licensed retail pharmacies but are authorised to sell medications. These establishments may include, but are not limited to, OTC dispensaries, drugstores, "drogueries", "parapharmacies", and supermarkets.

Survey Results

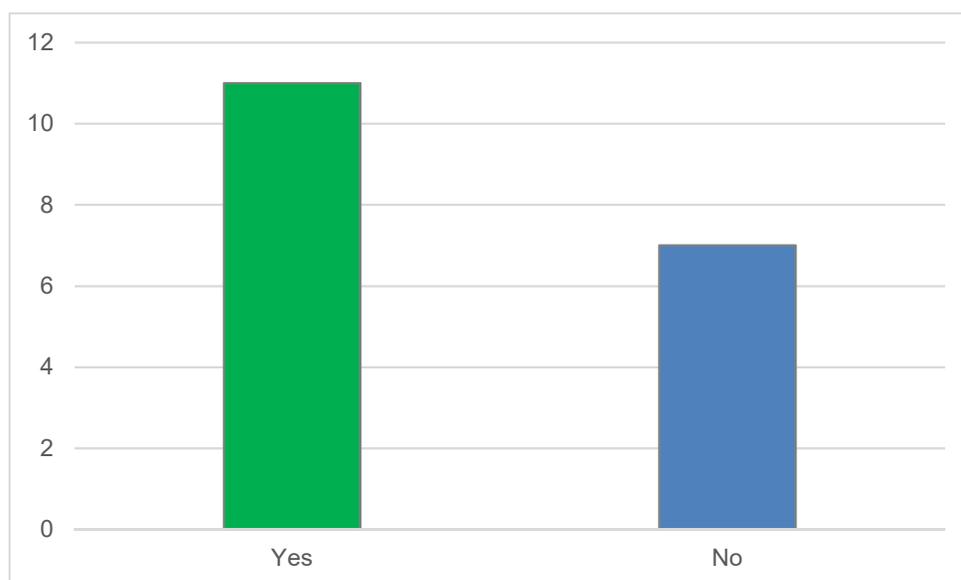
Response rate: 18 delegates completed the questionnaire.

Respondents: Armenia; Austria; Belgium; Bosnia and Herzegovina; France; Georgia; Germany; Hungary; Ireland; Italy; Lithuania; North Macedonia; Portugal; Romania; Serbia; Spain; Switzerland; United Kingdom.

Questions and Answers

Part 1 - Sale of medicines in establishments other than community pharmacies

1. Are there establishments other than community pharmacies that can supply medicines to patients?



Yes: Austria; Georgia; Germany; Hungary; Ireland; Italy; Lithuania; Portugal; North Macedonia; Switzerland; UK

No: Armenia; Belgium; Bosnia and Herzegovina; France; Romania; Serbia; Spain

Comments

Georgia: the term “community pharmacy” in Georgia is applicable and equal to “authorised pharmacy”, which may dispense medicines belonging to all three groups of classification, i.e. Group I (prescription-only medicines under special control including narcotics, psychotropics and some other substances that are not controlled on international level but may be subject to off-label use, like baclofen, gabapentin, tropicamide, trihexyphenidyl, zolpidem, etc.), Group II (other prescription-only medicines) and Group III (non-prescription medicines). Group II and Group III medicinal products may be dispensed by pharmacies, whereas Group III medicines (non-prescription medicines) can also be dispensed by non-specialised retailers/stores.

Germany: in Germany, non-prescription drugs are divided into products which are only available in pharmacies and products which can also be supplied outside pharmacies, e.g. in drugstores or supermarkets.

Hungary: “drogeries”, grocery stores, petrol stations.

Ireland: non-pharmacy retail outlets such as groceries, petrol stations, and convenience stores may supply certain non-prescription items that are considered suitable for general sale (see list: <https://bit.ly/3ctmS46>).

Italy: “para-pharmacies” are available throughout the country.

Lithuania: retail stores: supermarkets, gas stations, etc.

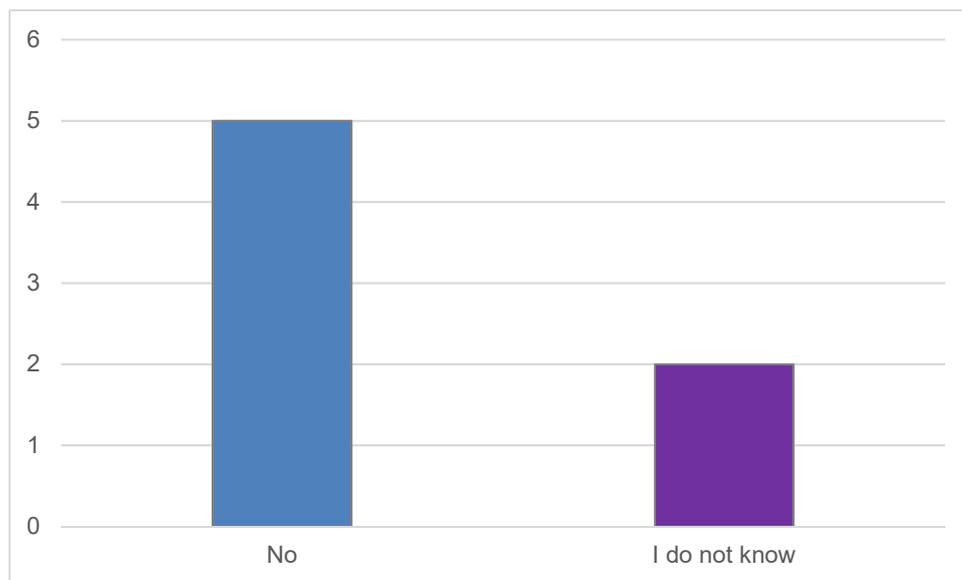
North Macedonia: non-prescription medicines in North Macedonia are divided into non-prescription medicines that can be dispensed only in pharmacies and non-prescription medicines that under special criteria can be supplied outside pharmacies (e.g. “drogeries”, retail stores, petrol stations).

Portugal: over the counter (OTC) outlets can supply non-prescription medicines.

Romania: the selling of medicines in stores other than pharmacies is not possible.

Switzerland: specialist stores (drugstore), retail stores, supermarkets. Hospitals and medical doctors can also dispense medications to patients.

2. If establishments other than community pharmacies are not present in your country, do you think that they could be there in the near future (e.g. 2-5 years)?



No: Armenia; Belgium; France; Romania; Spain

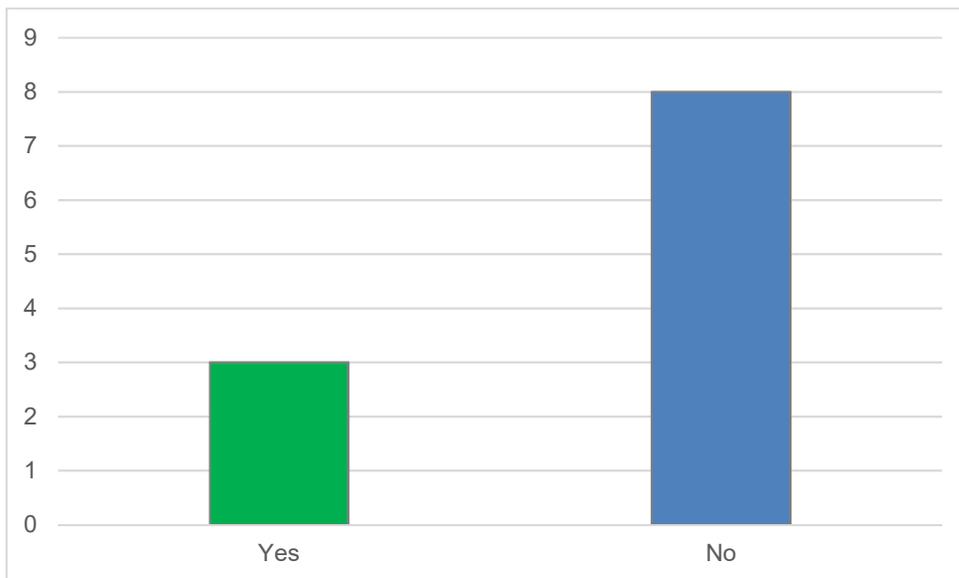
I do not know: Bosnia and Herzegovina and Serbia

Yes: -

Comments

Armenia: there is no provision in the current legislation and no intention or suggestion to make legislation changes regarding this issue.

3. Is the presence of a pharmacist mandatory in establishments other than community pharmacies?



Yes: Georgia; Italy; Portugal

No: Austria; Germany; Hungary; Ireland; Lithuania; North Macedonia; Switzerland; UK

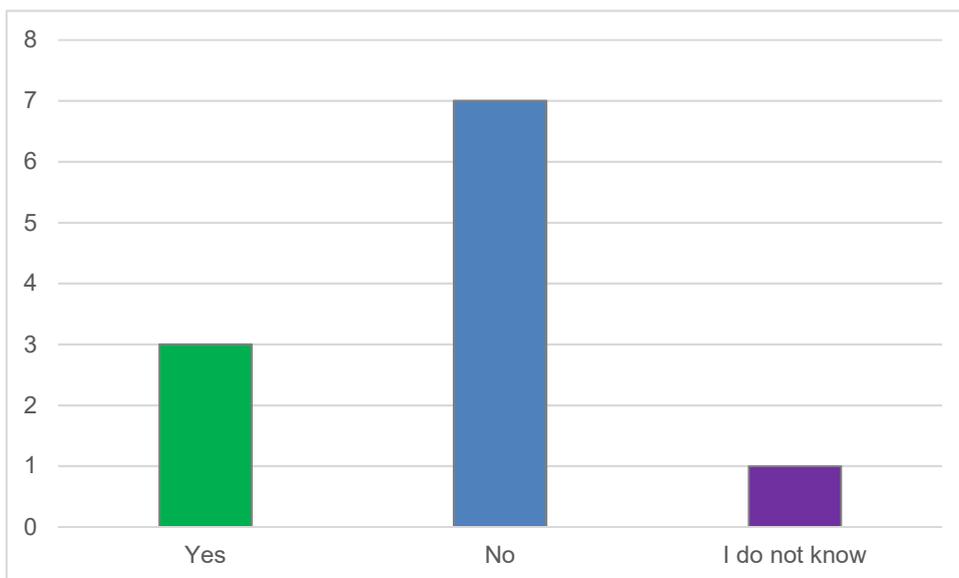
Comments

Georgia: even in a non-specialised retail outlet/shop, overall responsibility is on the pharmacist, while non-prescription medicines may be dispensed by non-pharmacists.

Portugal: in OTC outlets, non-pharmacists can supply non-prescription medicines but this has to be done under a pharmacist's supervision.

Switzerland: in hospital pharmacies, the presence of a pharmacist is mandatory, whereas in physicians' practices it is not obligatory.

4. Are there any specific training requirements for the staff of establishments other than community pharmacies?



Yes: Austria; Germany; Italy

No: Georgia; Hungary; Ireland; Lithuania; North Macedonia; Portugal; UK

I do not know: Switzerland

Comments

Austria: “drogist” is a scholastic profession.

Germany: according to the German Medicinal Product Act, one person with specific expertise must be available for each site.

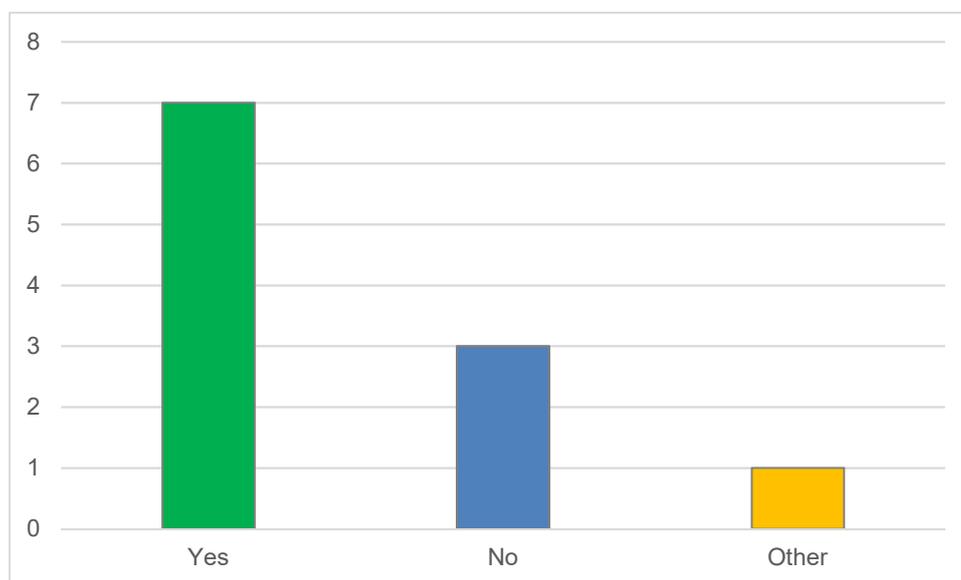
Ireland: there are restrictions on the supply of paracetamol in non-pharmacy retail outlets. The cash till will not permit sale of more than one pack containing 12 tablets. Staff may get training on this restriction.

Italy: staff must have a master’s degree in pharmacy.

North Macedonia: no specific training requirements but at the moment amendments to the Law on Medicines are ongoing and it is probable that some criteria will be set.

Switzerland: specialist store (drugstore): specialist with education at university of applied sciences, whereas GSL: no education.

5. Do establishments other than community pharmacies also receive alerts from national competent authorities (e.g. quality defect alerts; pharmacovigilance alerts; product recall alerts; etc.)?



Yes: Georgia; Hungary; Ireland; Italy; Portugal; North Macedonia; Switzerland

No: Germany; Lithuania; UK

Other: Austria (see comments below)

Comments

Austria: the marketing authorisation holders (MAH) are informed by the national competent authority and, depending on the case, the measures which have to be taken by MAHs are part of the decision, which may include information for the “drogueries”, too.

Germany: in general, communication takes place with healthcare professionals. However, for certain aspects, an extended communication is under discussion.

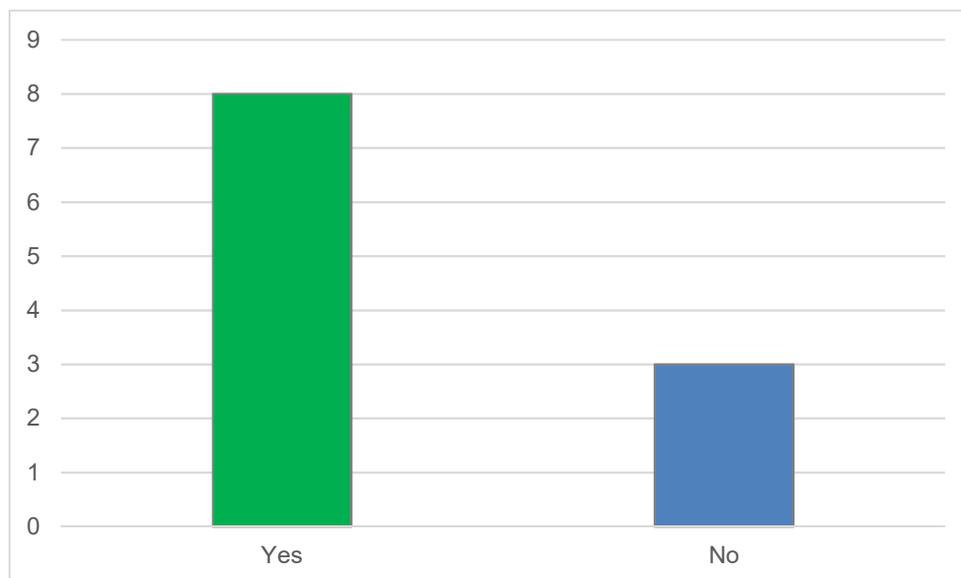
Ireland: yes, if the alert is relevant to the products distributed by the non-pharmacy retail outlet e.g. a recall letter. Such outlets would not receive healthcare communications, but may access these if signed up to our alert system.

Italy: alerts are received only with regard to the medicines that they are allowed to sell.

Portugal: yes, if applicable (alerts related to non-prescription medicines).

Switzerland: manufacturer must inform all establishments that ordered medicines. Swissmedic, the Swiss Agency on Therapeutic Products, publishes all recalls and healthcare professional communications on the website www.swissmedic.ch.

6. Are there lists of medicines that can be supplied via establishments other than community pharmacies (e.g. general sales list)?



Yes: Austria; Georgia; Germany; Hungary; Ireland; Italy; Lithuania; North Macedonia

No: Portugal; Switzerland; UK

Comments

Austria: there is a regulation called “Abgrenzungsverordnung” which regulates the Terms and conditions for those medicines (<https://bit.ly/2GkHSfp>).

Germany: there are lists of active substances but not lists of specific medicinal products.

Hungary: the list of medicines that can be supplied via these establishments is shorter than the list of medicines that community pharmacies can supply. This list is determined by national law.

Ireland: general sales list: <https://bit.ly/2Uo0Q9W> Pharmacy-only medicines not subject to prescription: <https://bit.ly/2UGWr76>

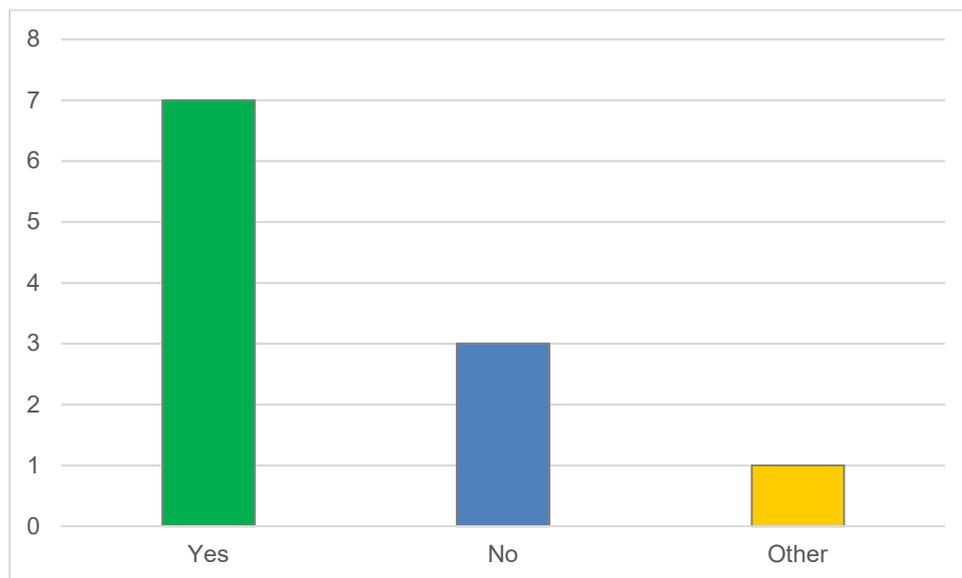
Italy: non-prescription medicines only.

Lithuania: a medicinal product shall be entered, in accordance with the procedure established by the Minister of Health, in the list of medicinal products authorised for sale in retail trade enterprises, provided that the product meets all of the following conditions: 1) It is a non-prescription medicinal product; 2) it contains only one active substance; 3) it is intended for adults and/or children from 12 years of age; 4) it is for oral use and does not contain ethanol; 5) If the packaging of the medicinal product, according to Article 8, Paragraph 81 (2) of this Law, does not contain safety features; 6) It is classified according to ATC classification as code N02BA01, N02BE01, M01AE01 or M01AE02 or an ATC code beginning with A02BC, and packed in a solid oral form of the same generic name and with a strength corresponding to the lowest dosage of the medicine; 7) The active substance belongs to the following ATC codes R01AC03, R06AX13, R06AX26, R06AE07, R06AX27, R06AE09, R06AX22, R06AX18, R06AX29, R06AX28, R06AX25, N07BA or R02AA, and it contains the smallest amount of active substance in the packaging; 8) It has a code beginning with D08A according to the ATC classification.

Portugal: yes, a list of non-prescription medicines is available on the website of the national competent authority (National Authority of Medicines and Health Products (INFARMED)).

Switzerland: the legal classification determines the supply channel. Medical doctors with an authorisation to supply medicines (received from the cantonal/local authorities) have no specific restrictions but can in principle supply all medicines authorised in Switzerland.

7. Are medicines supplied in establishments other than community pharmacies subject to restrictions such as maximal pack size, restricted list of indications, oral forms only?



Yes: Austria; Germany; Hungary; Ireland; Lithuania; North Macedonia; UK

No: Georgia; Italy; Portugal

Other: Switzerland

Comments

Austria: according to “Abgrenzungsverordnung 2004” (i.e. a national regulation) certain products can be dispensed outside pharmacies under the circumstances laid down in the regulation.

Germany: according to the “Verordnung über apothekenpflichtige und freiverkäufliche Arzneimittel” (i.e. a national ordinance) certain products can be dispensed outside pharmacies under the circumstances laid down in the above regulation.

Hungary: see answer to question no.6 (in certain cases, pack size and/or maximum strength is limited).

Ireland: as of 24th October 2019, a total of 319 individual medicines are available in pharmacies and non-pharmacy outlets. Products are generally subject to restrictions including pack size and strength, for example paracetamol. List of medicines available in pharmacies and non-pharmacy outlets: <https://bit.ly/2JVhAmw>

Italy: as stated above, only non-prescription medicines can be sold in these establishments.

Lithuania: see answer to question no. 6.

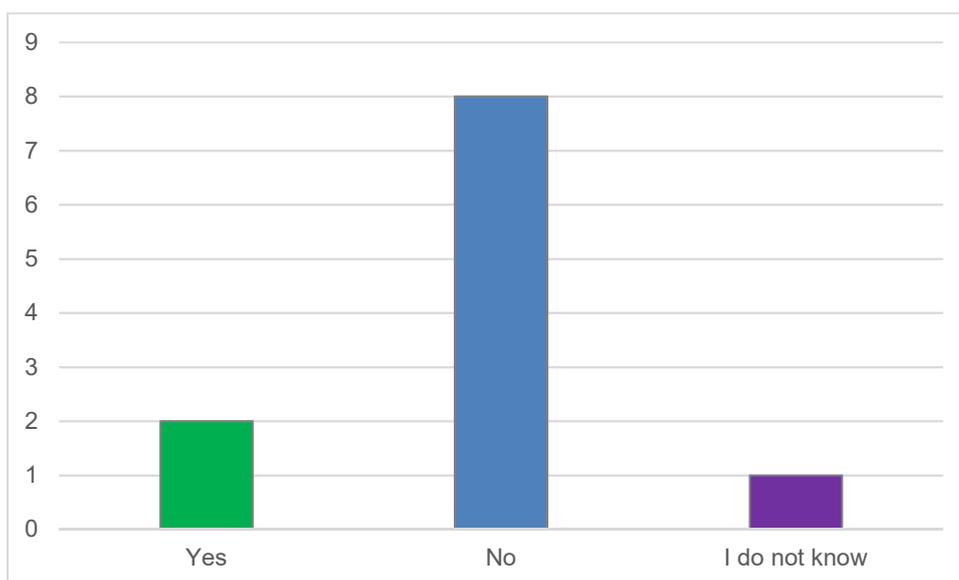
North Macedonia: there are restrictions on pack size, pharmaceutical form and strength.

Switzerland: the legal classification determines the supply channel. There are two legal classifications for non-prescription medicines: medicines which are supplied after experts’ advice (this could be in pharmacies, where a pharmacist is responsible, or a drugstore, where a specialist educated in applied science at university is responsible). The second classification of non-prescription medicines is general sale. Medical doctors with an

authorisation to supply medicines (received from the cantonal/local authorities) have no specific restrictions but, in principle, can supply all medicines authorised in Switzerland.

UK: medicines which may be sold in outlets other than pharmacies in the UK are known as general sales list (GSL) medicines. Under the provisions of the UK Human Medicines Regulations 2012, regulation 62(5), GSL is appropriate for medicines which can, with reasonable safety, be sold or supplied otherwise than by or under the supervision of a pharmacist. The term “with reasonable safety” is defined as “where the hazard to health, the risk of misuse, or the need to take special precautions in handling is small and where wider sale would be a convenience to the public”. Risk minimisation measures for ensuring reasonable safety of a medicine for GSL status may include (but are not limited to) the following: restrictions on pack size, restricted indications, limited populations (age restrictions), maximum permitted strength, maximum duration of use, specific requirements (e.g. warnings) to be included in the product information (summary of product characteristics, patient information leaflet, label).

8. Has your country changed the criteria for classification of medicines since the introduction of establishments other than community pharmacies?



Yes: Switzerland; Portugal

No: Austria; Georgia; Hungary; Ireland; Italy; Lithuania; North Macedonia; UK

I do not know: Germany

Comments

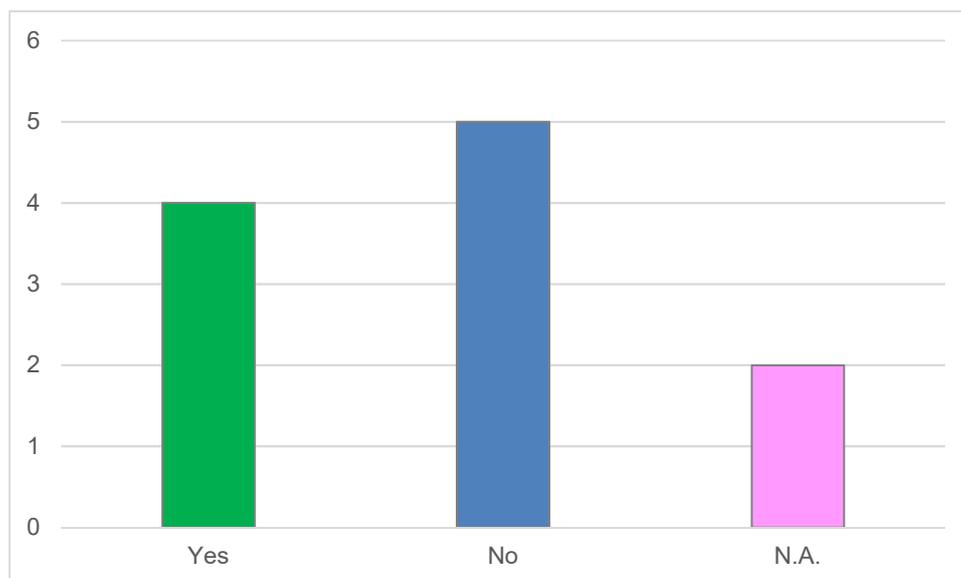
Georgia: after the introduction of establishments other than community pharmacies in 2009, criteria for classification of medicines were changed in 2014, but these changes were not made in connection with introduction of such establishments, e.g. changes were made in order to increase or reduce the number of medicines that could be dispensed through establishments other than community pharmacies.

Italy: no, because the full-time presence of a pharmacist is mandatory.

Portugal: yes, pharmacy-only is a new classification since 2013 (i.e. non-prescription medicines to be supplied by pharmacies only).

Switzerland: the “Swiss Therapeutic products Act” as well as the specific ordinances were changed on 01.01.2019. The category “pharmacy only” no longer exists. Instead pharmacists can supply certain prescription medicines after personal instruction of patients and on the other hand, all non-prescription medicines can also be supplied in the “drogueries” (they only exist in Switzerland and a 4-year apprenticeship and further training is required to be the responsible person of a “droguerie”).

9. During the process of classification of a medicinal product are the particularities of establishments other than community pharmacies taken into consideration (e.g. possible absence of a pharmacist)?



Yes: Austria; Ireland; Switzerland; UK

No: Georgia; Hungary; Italy, North Macedonia; Portugal

N.A.: Germany; Lithuania

Comments

Austria: it is also possible to supply medicinal products in “drogueries” on an individual product basis if the marketing authorisation holder applies for permission. In those cases, the circumstances and properties have to be thoroughly assessed.

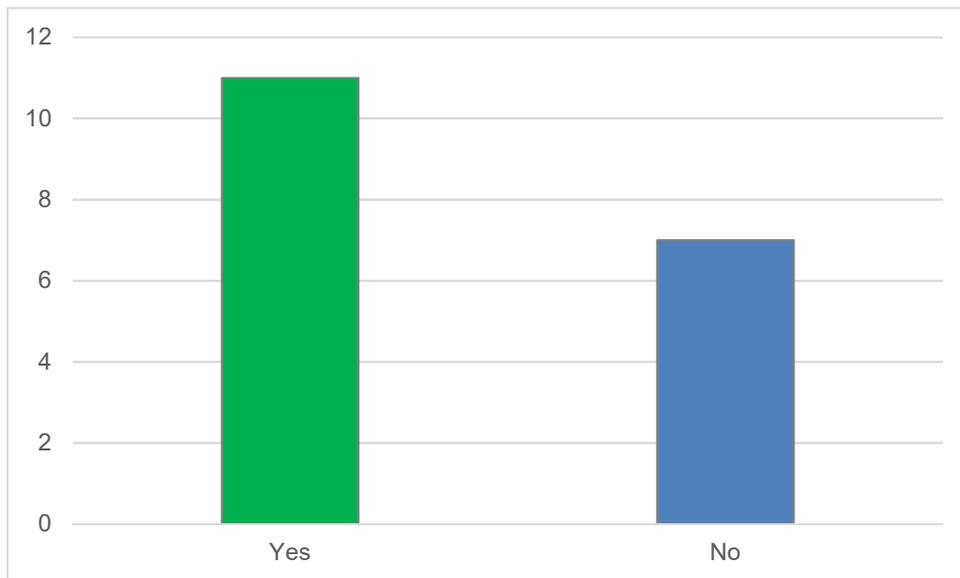
Germany: lists of active substances for supply outside pharmacies exist and medicinal products will be classified in line with the lists. However, during the process of classification of an active substance the particularities of establishments other than community pharmacies are taken into consideration e.g. possible absence of a pharmacist, indication, pharmaceutical form.

Ireland: we require the MAH/applicant to consider whether the medicine can be safely used without the input of a pharmacist (see page 16 of Health Products Regulatory Authority (HPRA) Guide for further details - <https://bit.ly/2VOL16Z>).

UK: for a product to be classified as General Sales List, (sold in retail outlets other than community pharmacies) it must be demonstrated that the criterion for GSL classification as set out in the Human Medicines Regulations 2012 is met: “GSL may be appropriate for medicines which can, with reasonable safety be sold or supplied otherwise than by, or under the supervision of a pharmacist.” “Reasonable safety” may usefully be defined as “Where the hazard to health and the risk of misuse and the need for special precautions in handling are small, and where wider sale would be a convenience to the purchaser”.

Part 2 - Internet pharmacies

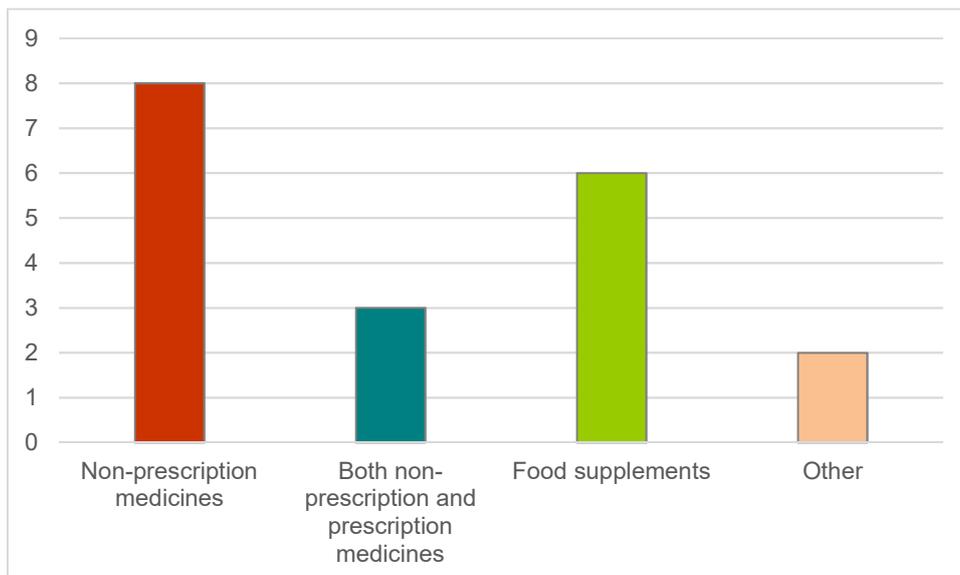
10. Is the supply of medicines by internet pharmacies (e-pharmacies) legal in your country?



Yes: Austria; Belgium; France; Germany; Hungary; Ireland; Italy; Lithuania; Portugal; Spain; UK

No: Armenia; Bosnia and Herzegovina; Georgia; North Macedonia; Romania; Serbia; Switzerland

11. Which medicines can be supplied via e-pharmacies?



Non-prescription medicines: Austria; Belgium; France; Hungary; Ireland (see link to Irish regulations, as per The Pharmaceutical Society of Ireland (PSI) (pharmacy regulator): <https://bit.ly/2oQoC4H>); Italy; Lithuania; Spain

Both non-prescription and prescription medicines: Germany; Portugal; UK

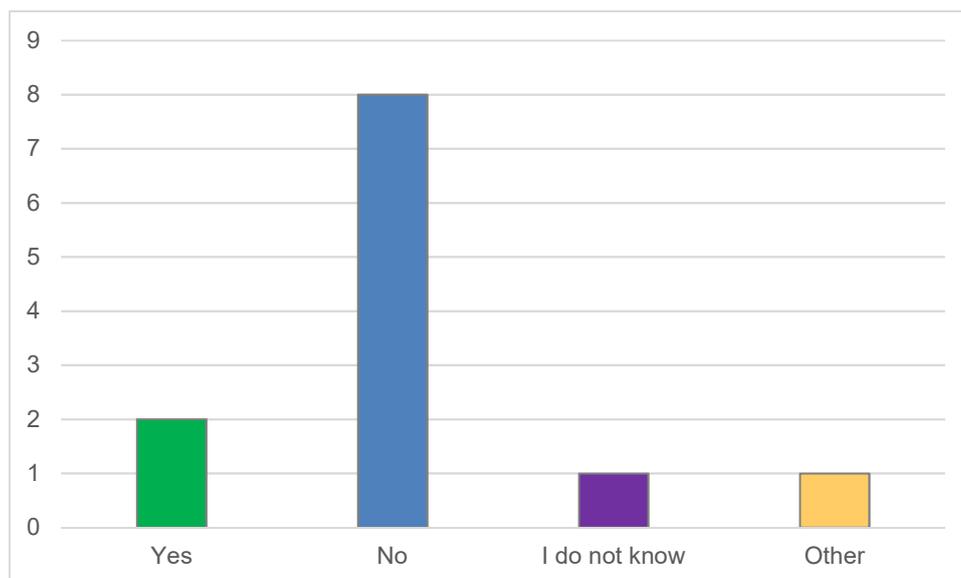
Food supplements: Austria; Belgium; Germany; Hungary; Italy; Lithuania

Other: Austria: medical devices.

Switzerland: in Switzerland “e-pharmacies” are only allowed if they have an authorisation as local pharmacies and in addition an authorisation for mail order (postal supply). All medicines can be supplied via e-pharmacies, but only if a medical prescription is on hand (mandatory prescription-only and non-prescription medicines).

Prescription medicines: -

12. Are medicines supplied via e-pharmacies subject to restrictions such as maximal pack size, restricted list of indications, oral forms only?



Yes: Lithuania; Spain

No: Austria; Belgium; France; Hungary; Ireland; Italy; Portugal; UK

I do not know: Germany

Other: Switzerland

Comments

Austria: non-prescription medicines only.

France: the same restrictions as those for “non-prescription status” apply to these medicines.

Germany: the same restrictions as those for “non-prescription status” should apply. However, it is not certain that this works in practice/in daily life.

Ireland: non-prescription medicines that are permitted for sale in conventional pharmacies or non-pharmacy outlets are permitted for sale in e-pharmacies. The same restrictions, if any, apply.

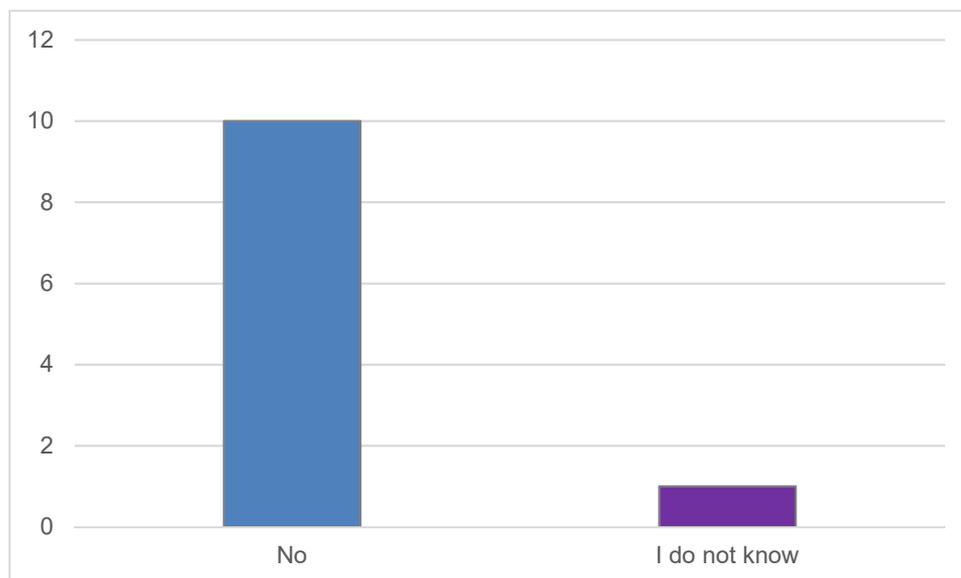
Lithuania: the therapy duration should be up to 1 month; medicinal products for children under 16 years of age are not dispensed (not for sale); medicinal products that can develop addiction or toxicomania through abuse (i.e. drugs containing precursors of the first category of narcotic and psychotropic substances, ethanol and its solutions, clonidine, antidepressants, antipsychotics, antihistamines) are not dispensed (not for sale) for children under 18 years of age; medicinal products containing narcotic and/or psychotropic substances included in the lists of controlled narcotic and psychotropic substances approved by the Minister of Health shall not be remotely dispensed (sold); no more than one package of non-prescription medicinal products containing precursors of the first category of narcotic and psychotropic substances may be purchased; non-prescription medicinal products containing a first-class narcotic and psychotropic drug precursor pseudoephedrine, administered at different times of the day, may be marketed at a rate of up to 720 mg per single course of treatment.

Spain: according to Article 10 of Royal Decree 870/2013, the responsible pharmacist should also assess the relevance or not of the dispensing of medications, especially in the case of requests for quantities that exceed those used in regular treatments, frequent or repeated requests, indicating the possibility of misuse or abuse of the drugs sold. Furthermore, according to Article 6, the Spanish Agency for Medicines and Health Products (AEMPS) will publish the list of medications for which it has established qualitative and quantitative limits for their potential misuse

Switzerland: see answer to question no. 11.

UK: medicines which are sold via online pharmacies must be sold in accordance with the conditions set out in their marketing authorisations. These same conditions will apply whether the medicine is sold/supplied in the pharmacy itself or via online pharmacy.

13. During the process of classification of a medicinal product are the particularities of internet pharmacies taken into consideration (e.g. no face-to-face patient counselling)?



No: Belgium; France; Germany; Hungary; Ireland; Italy; Lithuania; Portugal; Spain; UK

I do not know: Austria

Yes: -

Comments

Belgium: in general, the possibility to sell non-prescription products via an internet pharmacy is not taken into account when classifying a medicine. However, recently discussions have been ongoing to take this into consideration. In Belgium we have only OTC or POM classification, so the only possibility to limit internet sale is to put medicines on POM, which does not seem an acceptable solution either (extra cost for the patient for a doctor's visit; role of the pharmacist minimised).

14. Which national authority is in charge of authorising pharmacies to sell medications online?

Austria: Bundesamt für Sicherheit im Gesundheitswesen / Federal Office for Safety in Health Care.

Belgium: the Federal Agency of Medicines and Medicinal Products.

France: Ministry of Health.

Georgia: no specific regulations.

Hungary: Hungarian National Institute of Pharmacy and Nutrition.

Ireland: regulated by the Pharmacy Regulator (PSI) (<https://bit.ly/2Xnhit3>).

Italy: local competent authorities (regions and autonomous provinces).

Lithuania: the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania.

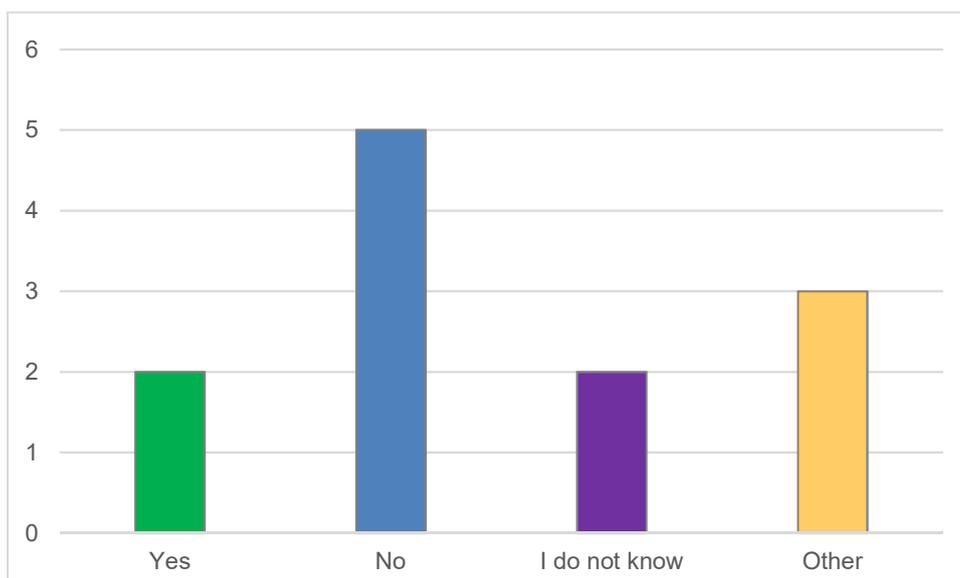
Portugal: e-pharmacies (always associated with local pharmacies and OTC outlets) must be registered with the national competent authority (INFARMED). In addition, websites of e-pharmacies must have a logo of certification (“EU common logo”) to inform the patient that it is a legal website and has been registered at INFARMED.

Spain: in Spain there is no authorisation procedure in itself, but according to Article 4 of RD 870/2013, a communication must be made prior to the start of the activity to the competent authorities of the autonomous community where the pharmacy is located. Information related to the pharmacy, the pharmacist or the website must be collected.

Switzerland: cantonal/local authorities.

UK: in the UK, it is the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA keeps a register of authorised online sellers of medicines. Online pharmacies must be registered with the MHRA in order to supply medicines for human use to the public and must display the Distance Selling Logo on each page of their website.

15. In addition to the patient information leaflet and, if applicable, an auxiliary label to be added on to the medication package, are internet pharmacies obliged to make additional medicine information services available to patients (e.g. toll-free phone number; information service provided through email, chat, social media)?



Yes: Austria; France

No: Belgium; Hungary; Italy; Portugal; Spain

I do not know: Germany; Ireland

Other: Lithuania; Switzerland; UK

Comments

Austria: the pharmacy has to provide their name, address, phone number, email-address and, if applicable, fax number on the homepage in order to make it possible for the patient to contact the pharmacy. The patient has to register before his/her initial purchase and he/she has the right to receive advice from a pharmacist toll-free via phone. If advice has been given this has to be documented by the pharmacy.

France: specific rules exist, you can find them on the Ministry of Health website: <https://bit.ly/2QdRizZ>

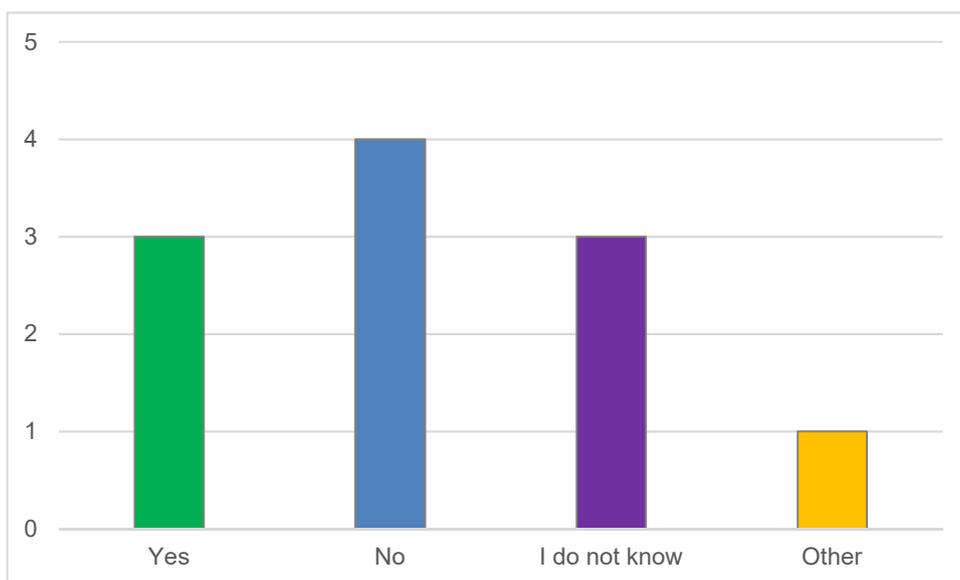
Germany: the supervision of movement of pharmaceuticals (including internet pharmacies) is the responsibility of the federal states and not of the Federal Institute for Drugs and Medical Devices (BfArM).

Lithuania: if pharmacies offer the sale of medicinal products at a distance, the pharmacy staff shall provide pharmaceutical services to the general public by means of communication. If a pharmacy offers to sell over-the-counter medicinal products to the general public by distance sale, the pharmaceutical service must be provided prior to the distance sale of the medicine using other means of distance communication. The pharmacy must ensure that the patient is provided with information about the pharmacy practitioner providing the pharmaceutical service, including his/her name and professional qualifications.

Switzerland: e-pharmacies must be available for requests and instructions if needed by the patient (same service as a local pharmacy).

UK: the MHRA's Blue Guide (<https://bit.ly/3dqSJUx>) provides guidance on the advertising and promotion of medicines and states that pharmacy websites should not allow a patient to choose a POM and its quantity before there has been an appropriate consultation with a prescriber.

16. Are there any specific inspection/licensing schemes for e-pharmacies in place?



Yes: Austria; France; UK
 No: Hungary; Italy; Lithuania; Portugal
 I do not know: Belgium; Germany; Spain
 Other: Ireland

Comments

Austria: the Federal Office has to inspect the online pharmacies periodically but at least every five years. Intervals might be smaller depending on the results of performed inspections.

France: the setting up of an e-pharmacy is subject to an authorisation granted by the competent regional authority.

Ireland: it is regulated by PSI.

Italy: e-pharmacies are inspected periodically in conjunction with the inspection of the pharmacy/non-pharmacy outlet they belong to.

Portugal: pharmacies and OTC outlets have to keep all the documents and data related to the supply of medicines via their website (e-pharmacies) and these data must be available for inspection by the national competent authority.

Spain: this is within the scope of the autonomous communities authorities responsible for pharmaceutical inspection. The AEMPS participates in this through the Technical Inspection Committee, i.e. a coordinating body in the field of inspection and control of medicines, medical devices, cosmetics and personal hygiene products, and in charge of guaranteeing the homogeneity of criteria and actions of the Inspection and Control Services of the AEMPS and of the competent bodies of the Autonomous Communities (CCAA).

UK: e-pharmacies are licensed and inspected in the same way as any other pharmacy.