NATIONAL REQUIREMENTS FOR NON-PRESCRIPTION MEDICINES AND RECLASSIFICATION OF MEDICINES

COMMITTEE OF EXPERTS CD-P-PH/PHO

SURVEY RESULTS

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Survey results

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.

The Committee of Experts on the Classification of Medicines as Regards their Supply (CD-P-PH/PHO) issues twice a year recommendations on the classification of medicines (prescription and non-prescription status) to health authorities of Council of Europe member states parties to the European Pharmacopoeia Convention, with a view to harmonising the legal status of medicines across Europe.

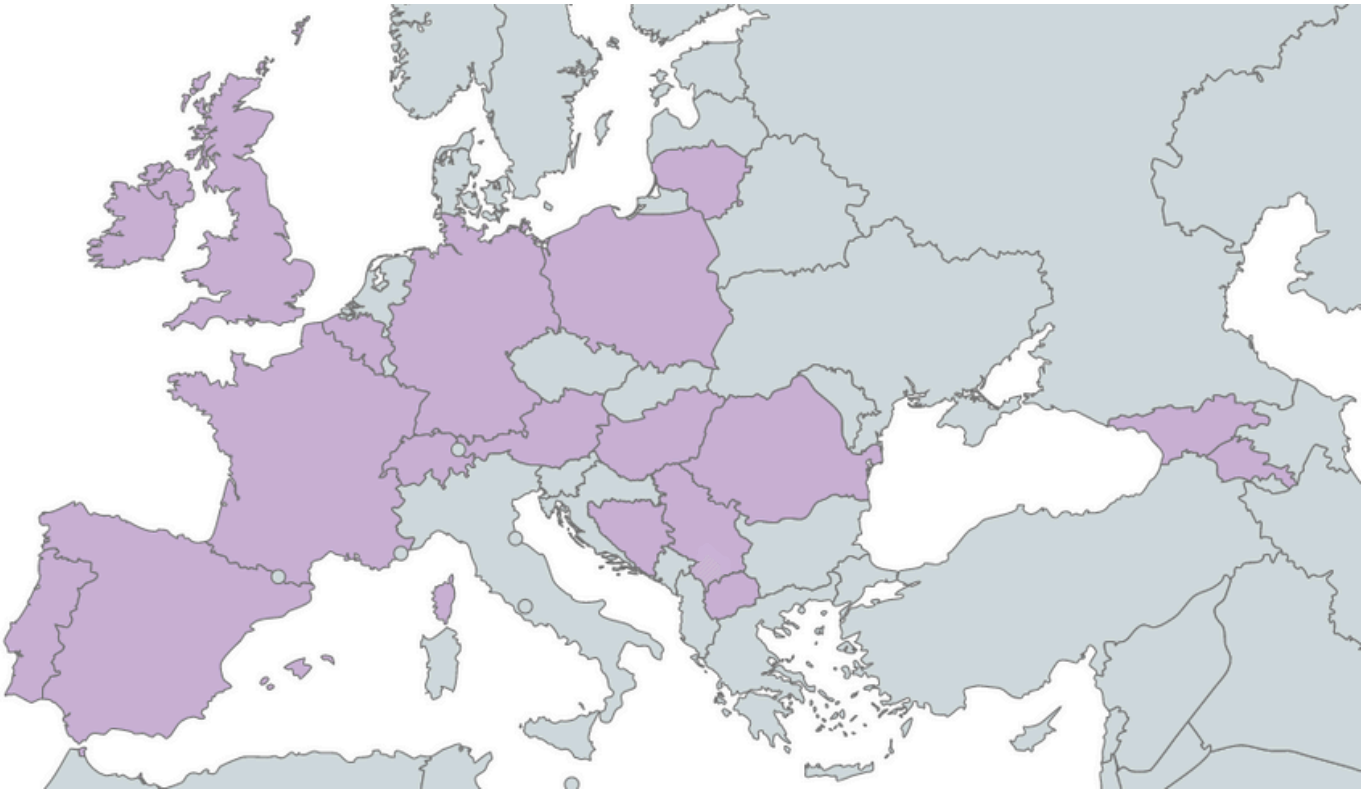
This report presents the main outcomes of a survey that the CD-P-PH/PHO performed in 2019-2021 among the experts participating in the CD-P-PH/PHO's work.

AIM: To gather information about national requirements for non-prescription medicines and reclassification of medicines in the Council of Europe member states.

RESPONSE RATE: 17 out of 24 delegates completed the questionnaire (70%).

DATE: The responses to this questionnaire were provided in 2019-2021.

MEMBER STATES: Armenia, Austria, Belgium, Bosnia and Herzegovina, France, Georgia, Germany, Ireland, Lithuania, North Macedonia, Poland, Portugal, Romania, Serbia, Spain, Switzerland, United Kingdom.

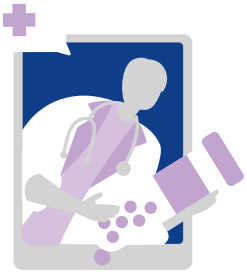


Disclaimer

Part 1

Non-prescription medicines and reclassification from prescription to non-prescription status

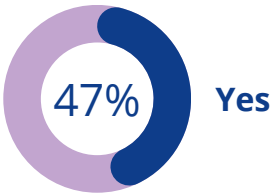
What are the national requirements for non-prescription medicines in your country?



National requirements for non-prescription status are different between the countries; however, some points are common, such as packaging size, maximum single dose or maximum daily dose. In addition, the criteria of the January 2006 European Commission "Guideline on changing the classification for the supply of a medicinal product for human use" are included in the national requirements for non-prescription status of some countries. This guidance allows a better understanding of non-prescription status at national level and provides useful information to countries for national "switches" (i.e. change of the legal status of a medicine from prescription to non-prescription and vice-versa) and revisions of national requirements.

Are there sub-classifications of non-prescription medicines in your country?

According to the responses, 47% of the countries have sub-classifications of non-prescription medicines (e.g. pharmacy-only, general sales list, pharmacist-only); however, the definitions and conditions of the sub-classifications are not the same across these countries.



If yes, what are the national requirements for the available sub-classifications?

According to the information provided, there are similarities and differences between national definitions of the sub-classifications.

Some countries have sub-classifications based on site of supply (pharmacy-only medications and general sale products) and others based on pharmacist's supervision (e.g. pharmacist-only medications).

In some cases the name used for sub-classification is the same but the definition is different.

Sub-classifications based on site of supply. Countries: Austria, Germany, North Macedonia, Portugal

Medicines not subject to medical prescription available only at the pharmacy; they are usually called pharmacy-only medicines.

Medicines not subject to medical prescription available outside of the pharmacy; they are usually called general sale products.

Source data

Sub-classifications based on pharmacist's supervision. Countries: France, Ireland

Medicines not subject to medical prescription available only under pharmacist's supervision; they are usually called pharmacist-only or pharmacy-only medicines.

Medicines not subject to medical prescription available without pharmacist's supervision (in pharmacies or outside of pharmacies); they are usually called general sale products.

Sub-classifications based on specialist or pharmacist's advice. Country: Switzerland

Medicines not subject to medical prescription available only under specialist's or pharmacist's advice (which means that a medication can also be supplied in specialist stores which are not pharmacies); these are called specialist-only.

Medicines not falling under specialist/pharmacist's advice; these are called general sale products.

Sub-classifications based on supervision of pharmacist and site of supply. Country: United Kingdom

Medicines not subject to medical prescription may be sold/supplied in pharmacies by or under supervision of a pharmacist; they are called pharmacy medicines (P).

Medicines not subject to medical prescription may be sold in other retail outlets; they are called general sales list medicines (GSL).

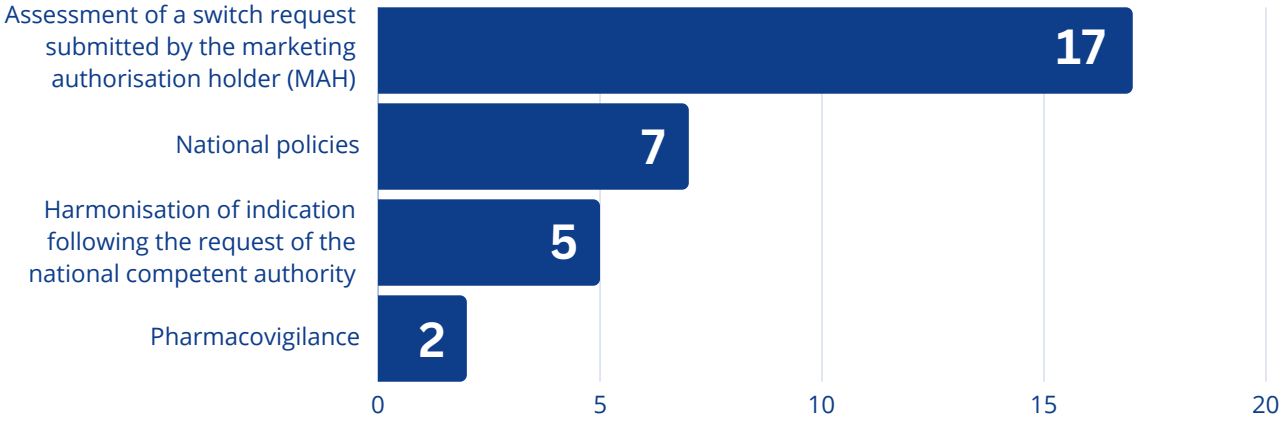
In Ireland and Switzerland, prescription-only medicines can be available without prescription if supplied by a pharmacist under certain conditions, but these medicines are not a sub-classification of non-prescription status.

Regarding the countries with sub-classifications of non-prescription medicines, it is important to point out that in 7 of these countries (87.5%) the medicines can be supplied outside of pharmacies.

From the information provided, 9 countries do not have sub-classifications; however, in 6 of these countries (66.6%) medicines are not supplied outside of pharmacies and this restriction could explain why sub-classifications are not available. This situation occurs in Armenia, Belgium, Bosnia and Herzegovina, Romania, Serbia and Spain.

Georgia, Lithuania and Poland do not have sub-classifications; nevertheless, in Georgia and Lithuania, non-prescription medicines can also be supplied outside of pharmacies, whereas in Poland there is a list of substances that can be sold in general sale (e.g. in supermarkets).

What are the reasons for the reclassification from prescription to non-prescription status?



All 17 of the countries answering the survey perform reclassifications for switch requests submitted by the MAH.

Which active substances were switched from prescription to non-prescription status in the time-frame 1 January 2014 - 31 January 2019?

In the above time-frame 11 active substances (not single products) were switched from prescription to non-prescription status (or a sub-classification of non-prescription status, if applicable) in at least three countries:

Ulipristal – ATC code: G03AD02	
Belgium	7 countries
Bosnia and Herzegovina	
France	
Germany	
Portugal	
Switzerland	
United Kingdom	

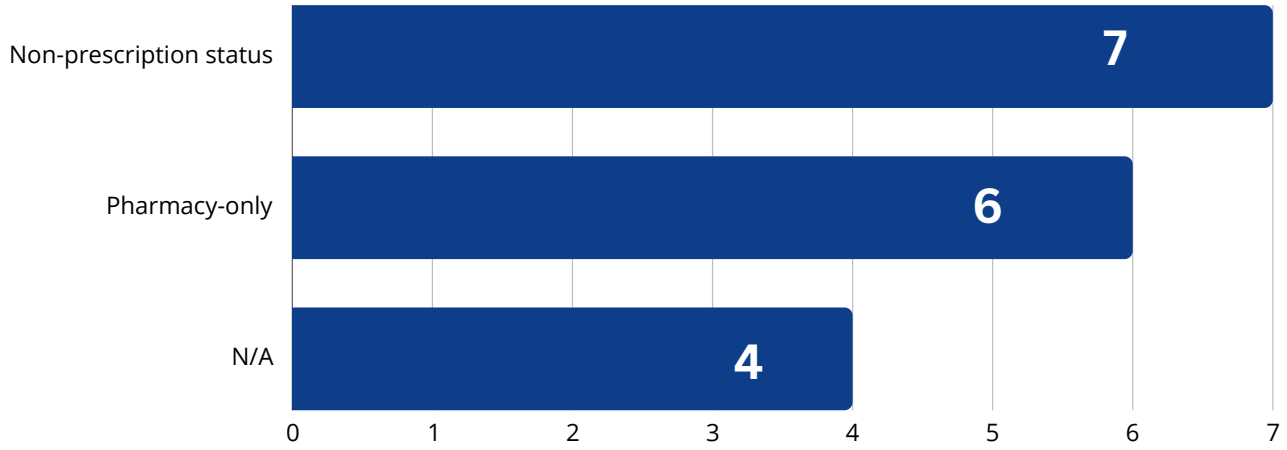
Source data

Fluticasone – ATC code: R01AD08	
Belgium	6 countries
Germany	
Lithuania	
Portugal	
Serbia	
United Kingdom	
Amorolfine – ATC code: D01AE16	
Poland	3 countries
Portugal	
United Kingdom	
Clotrimazole – ATC code: G01AF02	
Bosnia and Herzegovina	3 countries
France	
Poland	
Dexketoprofen – ATC code: M01AE17	
Lithuania	3 countries
Poland	
Portugal	
Diosmin – ATC code: C05CA03	
Armenia	3 countries
Bosnia and Herzegovina	
Romania	
Glucosamine – ATC code: M01AX05	
Lithuania	3 countries
Portugal	
United Kingdom	

Source data

Ibuprofen – ATC code: M01AE01	
Bosnia and Herzegovina	3 countries
Germany	
Portugal	
Ketotifen – ATC code: S01GX08	
Germany	3 countries
Poland	
Portugal	
Mometasone– ATC code: R01AD09	
Belgium	3 countries
Germany	
United Kingdom	
Triamcinolone– ATC code: R01AD11	
Belgium	3 countries
Ireland	
Portugal	

In the case of EU centrally authorised “switches” from prescription-only to non-prescription status, what are the available classification or sub-classification options?



For the countries with sub-classifications available, centrally authorised medicines that are switched to non-prescription status are normally classified “pharmacy-only”.

In 4 countries, where there are no sub-categories of non-prescription medicines, medicines are not supplied outside of pharmacies. Therefore, centrally authorised medicines that are switched to non-prescription status are only available in pharmacies.

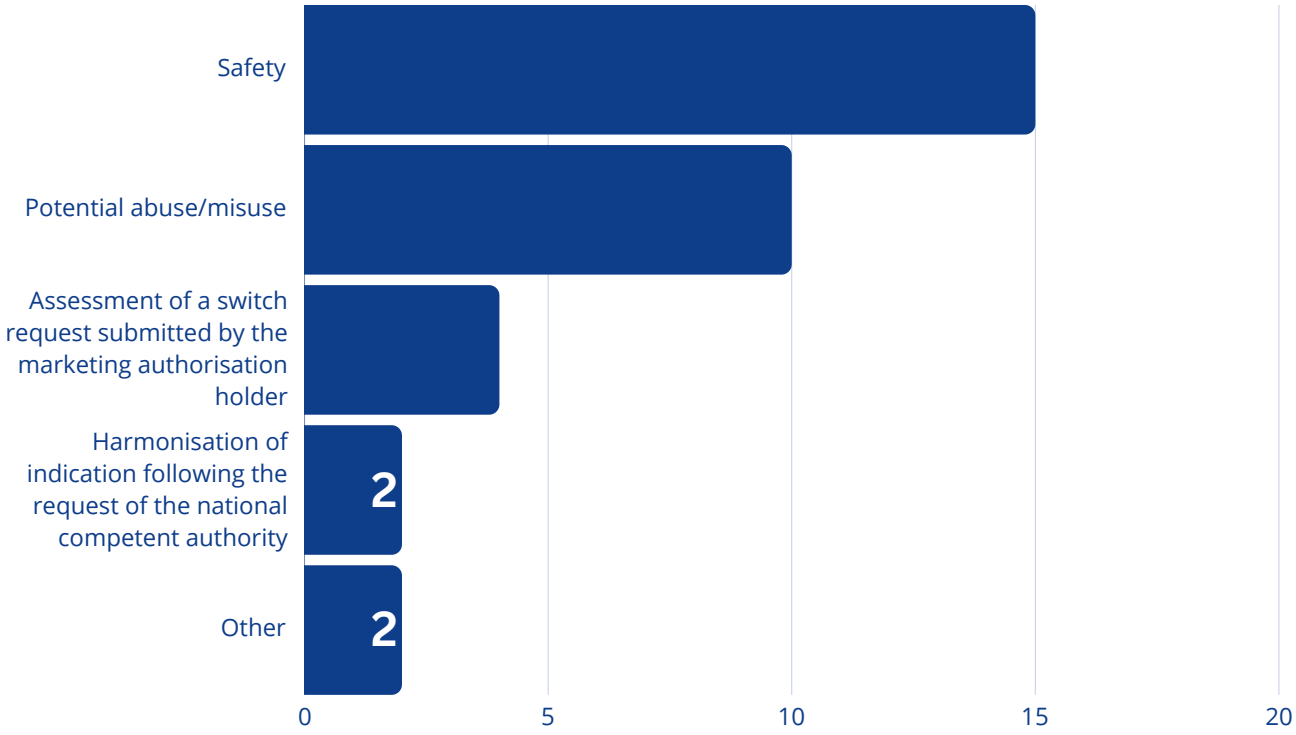
Centrally authorised products are not available in Armenia, Bosnia and Herzegovina, Georgia and Switzerland (N/A in the graph).

Source data

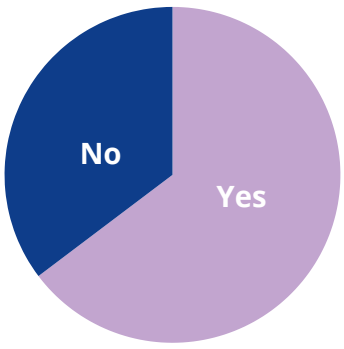
Part 2

Reclassification from non-prescription to prescription-only status

What are the main reasons for the reclassification from non-prescription to prescription-only status?



In the time-frame 1 January 2014 - 31 January 2019, have non-prescription medicines been reclassified from non-prescription to prescription status?



Yes: Armenia, Belgium, Bosnia and Herzegovina, France, Georgia, Germany, Poland, Portugal, Serbia, Spain, United Kingdom (11 countries, corresponding to 64.7%).

No: Austria, Ireland, Lithuania, North Macedonia, Romania, Switzerland (6 countries, corresponding to 35.3%).

Source data

Which active substances were reclassified from non-prescription to prescription-only status in the time-frame 1 January 2014 - 31 January 2019?

Country	INN and ATC code	Reasons for reclassification from non-prescription to prescription-only status
Armenia	Desloratadine (ATC code: R06AX27) - Oral solution 0.5 mg/mL (150 mL glass vial)	Safety reasons
	Ketoprofen for topical use (ATC code: M02AA10)	Safety reasons
	Silver sulfadiazine (ATC code: D06BA01) - Ointment and cream 10 mg/g	Safety reasons
Belgium	Domperidone (ATC code: A03FA03) - Tablets 10 mg	Safety reasons
	Ethylmorphine (ATC code: R05DA01) - Syrup 10 mg/15 mL	Safety and abuse reasons
	Metoclopramide (ATC code: A03FA01) - Tablets 10 mg	Safety reasons
Bosnia and Herzegovina	Domperidone (ATC code: A03FA03) - Tablets 10 mg	Reclassification request submitted by the MAH based on EMA (PRAC) recommendations
	Paracetamol (ATC code: N02BE01) - Tablets 500 mg (500 tablets per pack - hospital use)	Request of the national competent authority
France	Alimemazine (ATC code: N05CM) - Syrup	Safety profile and indication in insomnia
	Dextromethorphan, ethylmorphine, noscapine (ATC codes: R05DA, R05DA04, R05DA09, R05DA20, N02AJ06)	Potential abuse (young people)
	Malathion (ATC code: P03AX03)	Potential misuse and safety profile
Georgia	Codeine-containing medicines (combinations) (various ATC codes)	Reclassified as prescription-only medicines under special control (Group I)

Source data

Germany	Cannabidiol (ATC code: N02BG10)	Indications need the intervention of a physician and possible adverse reactions
	Doxylamine (ATC code: N05CM21) indicated for the treatment of sleep disorders in children up to 18 years of age	Diagnosis and treatment of sleep disorders in children need the intervention of a physician
	Quinine (ATC code: M09AA02)	Possible serious adverse reactions and indications need the intervention of a physician
	Nitrous oxide (ATC code: N01AX19) - Inhalation use	Misuse and outcome of Periodic Safety Update Single Assessment in 2018
	Succimer (DMSA) except in kits for radioactive medications	Use outside the established indications in alternative medicine and possible serious adverse reactions
Portugal	Camphor (27 mg) + Eucalyptol (65 mg) + Menthol (9 mg) suppository for adults and Camphor (13 mg) + Eucalyptol (31 mg) + Menthol (4 mg) - Suppository for children (no ATC code available)	Reclassification during MA renewal, for safety reasons: these medicinal products are very old; the periodic safety update report (PSUR) demonstrates a lack of information on the use of these products via this administration route and safety information is based on other routes of administration (topical, inhalation use and oral use – effusions)
	Camphor (25 mg/g) + Eucalyptol (100 mg/g) - Cutaneous use (ointment) for children (no ATC code available)	Reclassification during MA renewal, for safety reasons: this medicinal product is very old and the paediatric use of this combination product, regardless of the route of administration, is not recommended, taking into account the special vulnerability of children to these products by increased skin absorption and the severity of some adverse effects in children, especially on the central nervous system, respiratory tract and skin
	Paracetamol (ATC code: N02BE01) - Suppository 1000 mg	Reclassification during MA renewal, after national recommendations for paracetamol-related hepatotoxicity: 1000 mg should be prescription-only and maximum daily dose should be 3 g/day
Serbia	Domperidone (ATC code: A03FA03) - Tablets 10-30 mg	Safety reasons

Switzerland	No reclassification from non-prescription to prescription-only status	N/A
United Kingdom	Domperidone (ATC code: A03FA03)	Increased risk of potentially life-threatening effects on the heart, no longer to be used for heartburn, bloating or stomach discomfort
	Diclofenac (ATC code: M01AB05)	Small increased risk of cardiovascular side effects (myocardial infarction and stroke), medical assessment required to determine if product is suitable

It is interesting to note that one active substance was reclassified from non-prescription to prescription-only status in more than one country: Domperidone (ATC code: A03FA03). This active substance was reclassified in Belgium, Bosnia and Herzegovina, Serbia and the United Kingdom.

The Committee of Experts on the Classification of Medicines as Regards their Supply (CD-P-PH/PHO) reviews the national legal supply status of medicinal products for human use and issues recommendations on the classification of medicines to health authorities of the Council of Europe member states parties to the European Pharmacopoeia Convention with a view to harmonising the legal status of medicines in Europe.

Acknowledgments:

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