Committee of Experts on the Classification of Medicines as Regards their Supply (CD-P-PH/PHO)

NATIONAL REQUIREMENTS FOR NON-PRESCRIPTION MEDICINES AND RECLASSIFICATION OF MEDICINES

Survey results

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

AIM of the SURVEY: To gather information about national requirements for non-prescription medicines and reclassification of medicines.

RESPONSE RATE: 17 out of 24 delegates completed the questionnaire, i.e. RR: 70%

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

QUESTIONS and ANSWERS

Q1. Countries: Armenia, Austria, Belgium, Bosnia and Herzegovina, France, Georgia, Germany, Ireland, Lithuania, North Macedonia, Poland, Portugal, Romania, Serbia, Spain, Switzerland, United Kingdom.

PART I - Questions related to non-prescription medicines and reclassification from prescription to non-prescription status

Q2. What are the national requirements for non-prescription medicines in your country?

Armenia: According to the Law on Medicines of the Republic of Armenia (Article 16 parts 24 and 25) as well as the Order of the Ministry of Health, a decision on the legal status of supply is made during the assessment of the marketing authorisation (MA) application of the medicinal product. In the assessment of a medicinal product's suitability for use without prescription, nature of the active substance, indications, maximum single dose, maximum daily dose, pharmaceutical form, packaging, labelling and package size in relation to the recommended duration of treatment are considered. During the assessment of the application, considering direct or indirect danger caused by use of the medicine without medical supervision, even when used correctly, the following factors should be addressed: 1. direct danger/safety profile; 2. indirect danger/safety profile; 3. self-assessment; 4. risk and consequences of incorrect use; 5. patient information.

Austria: Medicinal products not subject to prescription are those that do not meet the criteria listed in Article 71 of the Community Code 2001/83/EC.

Belgium: To be accepted as a non-prescription medicine, the medicine has to fulfil the following requirements: 1. the indications have to be clear and acceptable as non-prescription; 2. the treated disease or symptoms are easily recognisable by a pharmacist and by the public; 3. there is no risk of an incorrect diagnosis; 4. the medicine is not very toxic; 5. mention of the maximum duration of treatment is desirable; 6. pack size in accordance with the maximum period of treatment; 7. accidental and intentional intoxication, misuse and abuse have to be considered before an non-prescription status is granted. The labelling has to fulfil the European requirements of the non-prescription product labelling (instructions on how to use). In the blue box, the classification status must be mentioned.

Bosnia and Herzegovina: 1. low overall toxicity; 2. no genotoxic or carcinogenic properties, or significant effect on reproductive health; 3. low risk of serious adverse reactions and unexpected serious adverse reactions; 4. no interactions with the most commonly used medicines; 5. contraindications, interactions, warnings and precautions should be understandable to the patient; 6. the use of the medicine should not lead to addiction, etc.

France: Please refer to "A guideline on changing the classification for the supply of a medicinal product for human use" (European Community Volume 2C: Guidelines). We refer to Art. 71 of the 2001/83/EC Directive,

which is transposed into the national regulation. We also have an old French notice to applicants for non-prescription medicinal products, but we cannot refer to it as it must be updated.

Georgia: Non-prescription medicines may be dispensed by an “authorised pharmacy”, which also dispenses medicinal products under special control (Group I medicines); by a “pharmacy - retailer”, which also dispenses medicines of Group II (prescription-only medicines, other than under special control); and “non-specialised retailers”, which may dispense only non-prescription medicines (Group III).

Germany: The criteria outlined in Art. 71(1) of Directive 2001/83/EC are included in our national Medicinal Product Act, excluding the last paragraph regarding parenteral application. In addition please refer to “A guideline on changing the classification for the supply of a medicinal product for human use” of the EC dated 1/2006.

Ireland: Medicinal products not subject to prescription must demonstrate that they do not fulfil the criteria outlined in Art. 71 of Directive 2001/83/EC. See HPRA Guide to Reclassification: https://bit.ly/4anhxtO The HPRA Guide to Reclassification (Switching) of Legal Supply Status of Human Medicinal Products provides information in line with the legislation and HMA Best Practice Guide. The guide provides information on reclassification from prescription to non-prescription, pharmacy-only, and to non-prescription, general sale. It clarifies the legal status for centralised products, and the limitations at national level, which include the fact that centralised products deemed non-prescription are confined to pharmacy-only in Ireland, and are not permitted on general sale.

Lithuania: According to Article 10. Criteria for Classification of Medicinal Products of the Republic of Lithuania Law on Pharmacy:

1. Medicinal products shall be classified as those subject to medicinal prescription and those not subject to medicinal prescription.

2. Assigned to medicinal products subject to medicinal prescription shall be those medicinal products which meet the following criteria: 1) they are likely to present a danger either directly or indirectly, if utilised without medical supervision; 2) they are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health; 3) they contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation; 4) they are normally prescribed by a doctor to be administered parenterally; 5) the medicinal products, because of their pharmaceutical characteristics or novelty or in the interests of public health, are reserved for treatments which can only be followed in a hospital environment; 6) the medicinal products are used in the treatment of conditions which must be diagnosed in a hospital environment or in institutions with adequate diagnostic facilities (although administration and follow-up may be carried out elsewhere); 7) the medicinal products are intended for outpatients but their use may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment.

3. The sub-category of medicinal products subject to special medical prescription shall be provided for in the group of medicinal products subject to medical prescription. Attributed to the sub-category shall be medicinal products corresponding to at least one of the following criteria: 1) the medicinal product contains a substance classified as a narcotic or a psychotropic substance entered in List II of Narcotic and Psychotropic Substances certified by the Minister of Health (narcotic and psychotropic substances permitted to be used for medicinal purposes); 2) if incorrectly used, the medicinal product is likely to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes, 3) the medicinal product contains a substance which, by reason of its novelty or properties, could be considered, as a precautionary measure, as belonging to the group envisaged in subparagraph 2 of paragraph 3 of this Article.

4. Medicinal products not corresponding to the criteria laid down in paragraphs 2 and/or 3 of this Article shall be assigned to the sub-category of medicinal products not subject to subscription.

North Macedonia: According to the national requirements, non-prescription medicines are those that have a wide range of therapeutic indications, of a low toxicity, with small overdose possibility, minimal interactions and with indications well known to patients and appropriate to be used for self-medication. Both Pharmacy-only and general sales list (GSL) medicines must fulfil the above-mentioned criteria, but GSL is a small list which contains medicines belonging to non-prescription analgesics, antipyretics as well as antiseptics with the lowest dose and smallest packaging size. The GSL medicines are not so popular in the country because the population is used to obtaining medicines from the pharmacy.

Poland: The national requirements on medicinal product classification are defined in the Regulation of the Minister of Health of 14.11.2008 on legal category supply of medicinal products. The national requirements comply with Articles 71-72 of Directive 2001/83/EC. Non-prescription medicines are those that do not meet the criteria listed in Article 71 of Directive 2001/83/EC.

Portugal: National requirements for non-prescription medicines are different according to sub-classification (see question 4).

Romania: The following elements should be evaluated: 1) direct danger/direct safety profile; 2) self-evaluation; 3) risk and consequences of misuse; 4) information for the patient; 5) packaging size and packaging type; 6) non-clinical and/or clinical evaluation; 7) non-clinical and/or clinical safety.

Serbia: National requirements for non-prescription medicines are defined in articles 52-54 of the Law on Medicines and Medical Devices ("The Official Gazette of the Republic of Serbia", 30/2010; 107/2012-other law and 113/2017-other law). These articles are in accordance with Articles 70-72 of Directive 2001/83/EC. In addition, if there is more than one medicine (from the same manufacturer or MA holder) with the same INN, same or different pharmaceutical form, strength and pack size, with different legal categories, those medicines must have different names.

Spain: In accordance with Art. 24 of Royal Decree 1345/2007, the Spanish Agency of Medicines and Medical Devices will establish the conditions of prescription and supply of medicinal products, classifying them into two different categories: medicines subject to medical prescription and medicines not subject to medical prescription.

According to the criteria outlined in Art. 71 of Directive 2001/83/EC, medicinal products shall be subject to medical prescription where they: 1) are likely to present a danger either directly or indirectly, even when used correctly, if utilised without medical supervision; 2) are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health; 3) contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation; 4) are normally prescribed by a doctor to be administered parenterally.

The decision on the legal status is made during the assessment of the MA application for the medicinal product. The criteria established in the document "A guideline on changing the classification for the supply of a medicinal product for human use" (European Community Volume 2C: Guidelines) are taken into consideration.

Switzerland: A medicine can be classified as non-prescription when it does not fall under criteria of prescription.

Prescription criteria:

> List II criteria: a) recommended against diseases the treatment of which requires medical diagnosis or supervision; b) it is likely to present a direct or indirect health risk when used as intended without medical diagnosis or supervision; c) it is frequently not used as intended and is likely to present a direct or indirect health risk; d) it contains active substances or preparations of active substances the effects and undesirable effects of which require further research; e) it is intended for parenteral use; f) its supply requires the advice of a medical professional.
>
> List I criteria: a) the duration of the therapy is limited and, for reasons of safety, may not be extended without a medical prescription; b) its use without medical diagnosis and supervision may cause serious damage; c) its incorrect use could significantly impair the subsequent treatment of serious diseases.

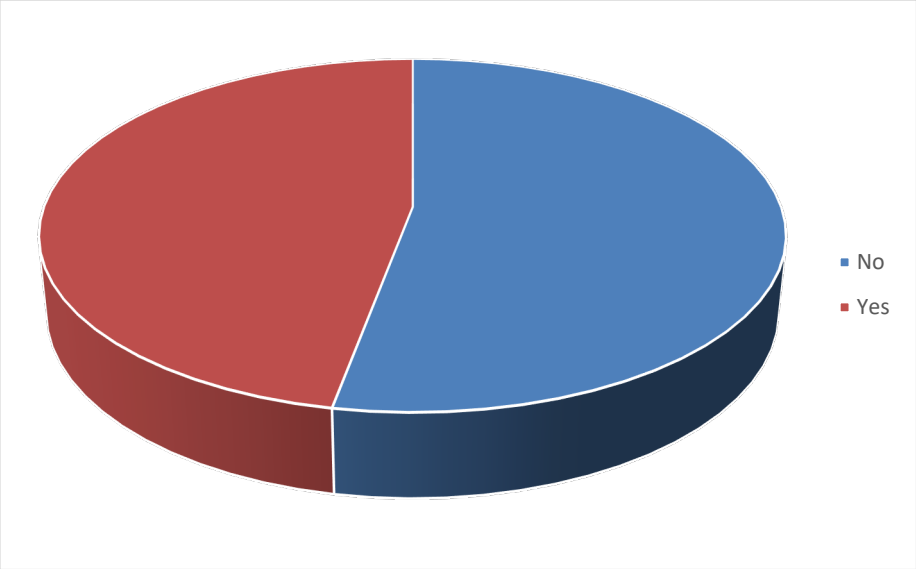
United Kingdom: Under the Human Medicines Regulations 2012, there are 2 categories of non-prescription (OTC) medicinal product as follows: P - pharmacy medicines (may be sold/supplied in pharmacies by or under supervision of a pharmacist) and GSL - general sales list medicines, which may be sold in other retail outlets. To be classified as "P", it must be demonstrated that the prescription-only criteria for the particular product are NOT met; to be "GSL", it must be demonstrated that the prescription-only criteria are NOT met and the GSL criterion IS met. Further details may be found on the MHRA website at the following link: https://bit.ly/2Gxvp8l

The medicines classification criteria are laid down in the Human Medicines Regulations 2012, regulations 62(3) and 62(5). Further details can be found in the MHRA guideline "MHRA guidance on the reclassification of medicines in the UK".

Discussion: national requirements 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. The 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.

Q3. Are there sub-classifications of non-prescription medicines in your country (e.g. pharmacy-only, general sales list, pharmacist-only)? If yes, what are the national requirements for the available sub-classifications?

According to the responses, 47% of the countries have sub-classifications of non-prescription medicines; however, the definitions and conditions of the sub-classifications are not the same across these countries.



Sub-classifications available in member states and national requirements for sub-classifications (if applicable):

Country	Availability of sub-classifications of non-prescription medicines	Sub-classifications of non-prescription medicines	Medicines supply outside of pharmacies	Requirements for sub-classifications
Armenia	No	No sub-classifications available	No	Not applicable
Austria	Yes	Sub-category for sale outside pharmacies in "drogueries". **Classification based on site of supply**	Yes	Medicinal products which, based on the experience of everyday life, do not raise a health risk for humans and animals even when not used as intended.
Belgium	No	No sub-classifications available	No	Not applicable
Bosnia and Herzegovina	No	No sub-classifications available	No	Not applicable
France	Yes	Two subcategories: pharmacy-only and pharmacist-only (both to be sold in community pharmacies only) **Classification based on supervision of pharmacist**	No	Pharmaceutical monopoly with sub-classifications of non-prescription medicines are available. In France, medicinal products can be sold only in pharmacies, even the non-prescription ones. For the non-prescription medicines, there are 2 subcategories: - Medicinal products that can be chosen directly by the patient in the pharmacy (over the counter); they are listed by the ANSM (short list) on a case-by-case basis, upon a

				MAH specific request; they can be used without the help or advice of a healthcare professional, they don't present major risks, the pack size and the leaflet are appropriate for self-medication ("pharmacy-only") - All the other non-prescription medicinal products are presented behind the counter; they can be sold without prescription but not without a pharmacist's advice ("pharmacist-only").
Germany	Yes	In accordance with response to question 4, there are two subcategories: Ordinance on Pharmacy-Only Medicinal Products and Medicinal Products Sold outside Pharmacies. **Classification based on site of supply**	Yes. In accordance with response to question 4	The national requirements are comprehensive and are laid down in the "Ordinance on Pharmacy-Only Medicinal Products and Medicinal Products Sold outside Pharmacies". Some requirements are also laid down in the German Medicines Act.
Georgia	No	No sub-classifications available	Yes	Not applicable
Ireland	Yes	Two subcategories: pharmacy-only and general sale products **Classification based on supervision of pharmacist**	Yes (survey new trends as regards the supply modes of medicines)	Dossier requirements for OTC and GSL applications are on page 10-16 of the guideline: Pharmacy-only status: medicinal products that are available under the supervision of a pharmacist. General sale products that, following review of the nature and intended use of the product, can, with reasonable safety, be sold without the supervision of a pharmacist. In some instances, products which normally come under prescription control may be classified for supply without a prescription with certain restrictions e.g. a maximum single dose (MD), a maximum daily dose (MDD), a specified strength or pharmaceutical form, limited pack size or indications for use. Non-prescription general sale medicines are permitted to be sold in the open areas of pharmacies and in non-pharmacy outlets provided they meet the criteria outlined in the above guide. The principal criterion being that they can be sold/supplied without the intervention of a pharmacist. The pack size is often smaller than a non-prescription, pharmacy-only medicine. An example is paracetamol where the pack size limit in general sale is 12, whereas in pharmacies it is 24, with pack sizes above 24 subject to prescription.
Lithuania	No	No sub-classifications available	Yes - although the dispensing of over-the-counter medicines in retail establishments is permitted in Lithuania, we do not have subcategories for non-prescription products.	Not applicable
North Macedonia	Yes	Two subcategories: pharmacy-only and GSL. **Classification based on site of supply**	Yes	Smallest package, oral use. According to the national requirements, non-prescription medicines are those that have a wide range of therapeutic indications, of a low toxicity, with small overdose possibility, minimal interactions and with indications well known to patients and appropriate to be used for self-medication. Both pharmacy-only and GSL must fulfil the above-mentioned criteria but GSL is a small list which contains medicines belonging to non-prescription analgesics, antipyretics as well as antiseptics with the lowest dose and smallest package size. The GSL medicines are not so popular in the

				country because the population is used to obtaining medicines from the pharmacy. **At the moment the new draft Law on medicines has been prepared and the part regarding classification of medicines fully complies with Directive 2001/83/EC.**
Poland	No	No sub-classifications available	Yes (a list of substances that can be sold in general sale (e.g. in supermarkets))	There are no sub-classifications for non-prescription medicines in Poland. There is only one supply category for non-prescription medicine – OTC. However, there is a list of substances that can be sold in general sale (e.g. in supermarkets)).
Portugal	Yes	Two subcategories of non-prescription medicine: pharmacy-only and general sale products **Classification based on site of supply**	Yes	Non-prescription status is based on: a) a self-medication indications list with 40 self-medication indications (digestive, respiratory, cutaneous and general use); b) given that, for the same active substance, strength, pharmaceutical form and therapeutic indications there were products classified as non-prescription, an assessment was initiated to assure the same prescription status for all medicines; c) analysis case by case of proposal from MA holder. Pharmacy-only status is based on: a) list of active substance supply conditions included on pharmacy-only list after analysis and definition by a Technical group (the baseline for the list was active substances classified as non-prescription in at least one of the considered member states (SE, DK, UK); b) analysis case by case of proposal from MA holder; c) first medicinal product with active substance not non-prescription in Portugal should be classified as pharmacy-only; d) switch of centralised medicinal product from prescription-only (POM) medicine to non-prescription medicine should be pharmacy-only.
Romania	No	No sub-classifications available	No	Not applicable
Serbia	No	No sub-classifications available	No	Not applicable
Spain	No	No sub-classifications available	No	Not applicable
Switzerland	Yes	Two subcategories: supply after specialist advice and general sale	Yes	Advice from a specialist (pharmacist or specialist) vs no advice needed (GSL).
United Kingdom	Yes	Two subcategories: P and GSL. P medicines (may be sold/supplied in pharmacies by or under supervision of a pharmacist) and GSL medicines, which may be sold in other retail outlets. **Classification based on supervision of pharmacist and site of supply**	Yes. In accordance with response to question 2	For P medicines, it must be demonstrated that the POM criteria do NOT apply. For full details, including definition of the POM criteria, see MHRA website at: https://bit.ly/2Gxvp8l For GSL medicines, it must be demonstrated that POM criteria are not met and the GSL criterion is met (i.e. that the medicine may with reasonable safety be sold/supplied otherwise by or under supervision of a pharmacist). For full details, including definition of "with reasonable safety", see MHRA website at: https://bit.ly/2Gxvp8l The medicines classification criteria are laid down in the Human Medicines Regulations 2012, Regulations 62(3) and 62(5). Further details can be found in the MHRA guideline "How to Change the Legal Classification of a Medicine in the UK".

Discussion

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

Some countries have classification based on site of supply and others based on pharmacist's supervision. In some cases the name used for sub-classification is the same, but the definition is different.

b) In general, the sub-classifications available are:

1. Based on site of supply. Countries: Austria, Germany, North Macedonia, Portugal

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

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

2. Based on pharmacist´s supervision. Countries: France, Ireland

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

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

3. Based on specialist or pharmacist advice. Country: Switzerland

3.1 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.

3.2 Medicines not falling under specialist/pharmacist advice; these are called general sale.

4. Based on supervision of pharmacist and site of supply. Country: United Kingdom

4.1 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).

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

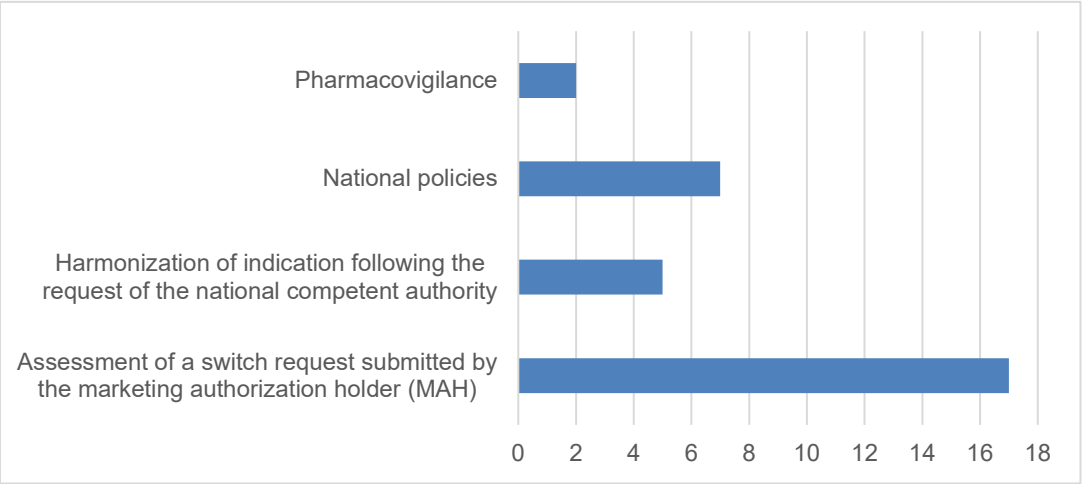
In Ireland and Switzerland, prescription-only medicines can be available without prescription if supplied by a pharmacist under certain conditions, but these medicines are not a sub-classification of non-prescription status.

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.

Poland, Georgia and Lithuania 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).

Q4. What are the reasons for the reclassification from prescription to non-prescription status? *More than one answer possible.*



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

Country	Reasons for reclassification other than switch request submitted by the MAH
Belgium	None
Bosnia and Herzegovina	
France	
Germany	
Lithuania	
North Macedonia	
Romania	
Poland	
Spain	
United Kingdom	
Georgia	National policies
Ireland	
Austria	National policies Harmonisation of indication at the request of the national competent authority
Portugal	
Switzerland	
Armenia	National policies Harmonisation of indication at the request of the national competent authority Pharmacovigilance
Serbia	

Q5. Which active substances (not single products) were switched from prescription to non-prescription status in the time-frame 1 January 2014 - 31 January 2019 (date of granting of new marketing authorisation)?

The table below shows 118 active substances mentioned by the countries where switches to non-prescription status have occurred between 1 January 2014 and 31 January 2019:

INN and ATC code
Acetylcysteine (ATC code: R05CB01)
Acetylsalicylic acid (ATC code: N02BA01)
Acetylsalicylic acid, magnesium hydroxide (ATC code: B01AC30)
Aciclovir (ATC code: D06BB03)
Aciclovir (ATC code: J05AB01)
Acrivastine (ATC code: R06AX18)
Ambroxol hydrochloride (ATC code: R05CB06)
Amorolfine(ATC code: D01AE16)
Antazoline and naphazoline (ATC code: S01GA51)
Azelastine (ATC code: R01AC03)
Beclometasone (ATC code: R01AD01)
Benzydamine hydrochloride (no ATC code mentioned)
Budesonide (ATC code: R01AD05)
Butamirate (ATC code: R05DB13) 50 mg
Butylscopolamine + paracetamol (ATC code: A03DB04)
Caffeine and dimenhydrinate (no ATC code mentioned)
Calcipotriol (ATC code: D05AX02)
Calcitriol (ATC code: A11CC04)
Calcium dobesilate (ATC code: C05BX01)
Camomilla flos estratto fluido and lidocaine (ATC code: A01AD11) 20 mg/g + 185 mg/g
Carbocisteine (ATC code: R05CB03)
Carmellose sodium (no ATC code mentioned)
Cetirizine (ATC code: R06AE07)
Ciclopirox (ATC code: D01AE14)
Clotrimazole (ATC code: D01AC01)
Clotrimazole (ATC code: G01AF02)
Crataegus oxyacantha tincture and Passiflora incarnata extract (no ATC code mentioned)
Desloratadine (ATC code: R06AX27)
Dexketoprofen (ATC code: M01AE17)
Dextromethorphan and guaifenesin (no ATC code mentioned)
Dichlorobenzyl alcohol and amylmetacresol (no ATC code mentioned)
Diclofenac Diethylamine (no ATC code mentioned)
Diclofenac diethylammonium (no ATC code mentioned)
Diclofenac epolamine (no ATC code mentioned)
Diosmin (ATC code: C05CA03)
Diphenhydramine (ATC code: R06AA02)
Docosanol (ATC code: D06BB11)
Doxylamine (ATC code: R06AA09)
Erdosteine (ATC code: R05CB15)
Esomeprazole (ATC code: A02BC05)
Fenspiride (ATC code: R03DX03)
Fenticonazole (ATC code: G01AF12)
Fexofenadine (ATC code: R06AX26) 120 mg
Flurbiprofen (ATC code: R02AX01)
Fluticasone Propionate (no ATC code mentioned)
Fluticasone (ATC code: R01AD08)
Folic acid + cyanocobalamin + iodine (ATC code: B03BB51)
Folic acid (ATC code: B03BB01)
Fusidic acid (ATC code: D06AX01)
Glucosamine (ATC code: M01AX05)

Guaifenesin and phenylephrine (no ATC code mentioned)
Hedera helix (no ATC code mentioned)
Hydrocortisone (ATC code: D07AA02)
Hydroxocobalamin, combinations (ATC code: B03BA53)
Hyoscine butylbromide (ATC code: A03BB01)
Ibuprofen (ATC code: M01AE01)
Ibuprofen (ATC code: M02AA13)
Ibuprofen + Levomenthol (no ATC code mentioned)
Ibuprofen + paracetamol (ATC code: M01AE51)
Ibuprofen + pseudoephedrine (ATC code: R05X)
Inosine pranobex (ATC code: J05AX05)
Kagocel (no ATC code mentioned)
Ketoprofen (ATC code: M01AE03)
Ketotifen (ATC code: S01GX08)
Lactulose (ATC code: A06AD11)
Lansoprazole (ATC code: A02BC03)
Levocetirizine (ATC code: R06AE09)
Levodropropizine (ATC code: R05DB27)
Levonorgestrel (ATC code: G03AD01)
Lidocaine + prilocaine (ATC code: N01BB20)
Loratadine (ATC code: R06AX13)
Magnesium aspartate + potassium aspartate (ATC code: A13A)
Mebeverine (ATC code: A03AA04)
Miconazole (ATC code: D01AC02)
Minoxidil (no ATC code mentioned)
Mometasone (ATC code: R01AD09)
Mucopolysaccharide Polysulfate + Salicylic Acid (no ATC code mentioned)
Naloxone (ATC code: V03AB15)
Naproxen (no ATC code mentioned)
Nystatin (ATC code: A07AA02)
Nystatin (ATC code: D01AA01)
Nystatin (ATC code: G01AA01)
Olopatadine (ATC code: S01GX09)
Omeprazole (ATC code: A02BC01)
Orlistat (ATC code: A08AB01)
Oxymetazoline (no ATC code mentioned)
Paracetamol (no ATC code mentioned)
Paracetamol + diphenhydramine (ATC code: N02BE51)
Paracetamol + pseudoephedrine (ATC code: N02BE51)
Paracetamol, chlorphenamine and phenylephrine (no ATC code mentioned)
Penciclovir (no ATC code mentioned)
Pentanedioic acid (pentanedioic acid imidazolyl ethanamide) (ATC code: J05AX21)
Phloroglucinol + simeticone (ATC code: A03AX)
Piketoprofen (ATC code: M02AA28)
Piroxicam (no ATC code mentioned)
Proguanil Hydrochloride, Atovaquone (no ATC code mentioned)
Pseudoephedrine + triprolidine (ATC code: R01BA52)
Pyrantel (ATC code: P02CC01)
Racecadotril (ATC code: A07XA04)
Rhamnus purshiana extract and Fucus vesiculosus extract (no ATC code mentioned)
Rosmarinus officinalis oil (no ATC code mentioned)

A-macrogol (macrogol 3350), sodium sulfate, sodium chloride, potassium chloride; sachet B-ascorbic acid, sodium ascorbate (ATC code: A06AD65)
Salicylic acid + fluorouracil (ATC code: D11AF)
Serenoae repentis extractum (Latin name Sabalis serrulatae fructus) (ATC code: G04CX02)
Sildenafil (ATC code: G04BE03)
Silver sulfadiazine (ATC code: D06BA01)
Sodium selenate (ATC code: A12CE01)
Sulbutiamine (ATC code: A11DA02)
Sumatriptan (ATC code: N02CC01)
Tolfenamic acid (ATC code: M01AG02)
Triamcinolone (ATC code: R01AD11)
Trimebutine (ATC code: A03AA05)
Ulipristal (ATC code: G03AD02)
Valerian extract (no ATC code mentioned)
Xylometazoline hydrochloride, Ipratropium bromide (no ATC code mentioned)
Zolmitriptan (ATC code: N02CC03)

Eleven actives substances were switched in at least three countries:

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

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	

Ibuprofen – ATC code: M01AE01	
Bosnia and Herzegovina	3 countries
Germany	
Portugal	

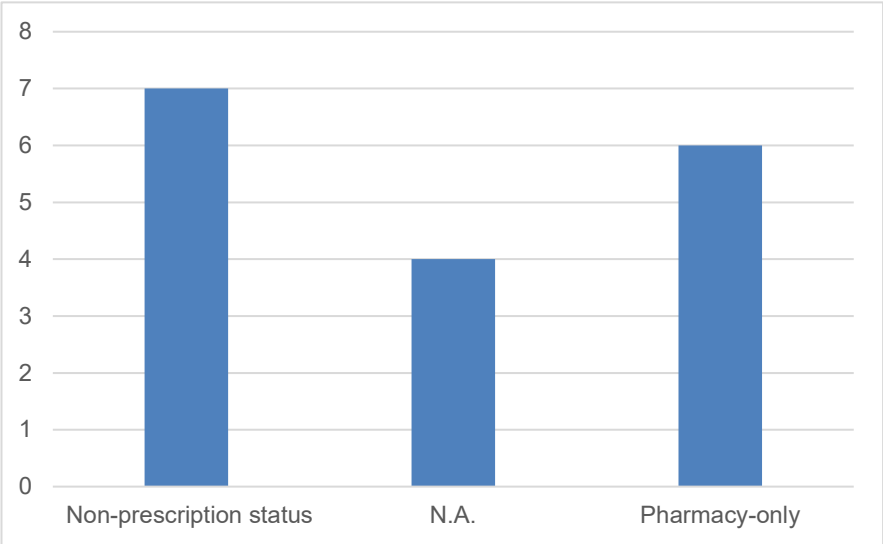
Ketotifen – ATC code: S01GX08	
Germany	3 countries
Poland	
Portugal	

Mometasone – ATC code: R01AD09	
Belgium	3 countries
Germany	
United Kingdom	

Triamcinolone – ATC code: R01AD11	
Belgium	3 countries
Ireland	
Portugal	

A table with more details regarding question 5 is available in **Annex 1**.

Q6. In the case of EU centrally authorised switches from prescription-only to non-prescription status, what are the available classification or sub-classification options?



Non-prescription: Belgium, France, Lithuania, Poland (except contraceptives e.g. ellaOne; according to the Polish Pharmaceutical Law all contraceptives are prescription-only medicines), Romania, Serbia, Spain (7 countries, corresponding to 41.2%).

Pharmacy-only: Austria (pharmacy-only in case of Ulipristal), Germany, Ireland (GSL does not apply to centrally authorised products), North Macedonia, Portugal (since 2013), United Kingdom (also see question no. 8) (6 countries corresponding to 35.3%).

N.A.: Armenia, Bosnia and Herzegovina, Georgia, Switzerland (4 countries, corresponding to 23.5%).

Comments:

France: centrally authorised medicinal products follow the same classification as national ones, if they switch to non-prescription they can be either “over the counter” (“pharmacy-only”) or “behind the counter” (“pharmacist-only”). The sub-category “over the counter” is assessed on a case-by-case basis, upon MAH application, as explained above.

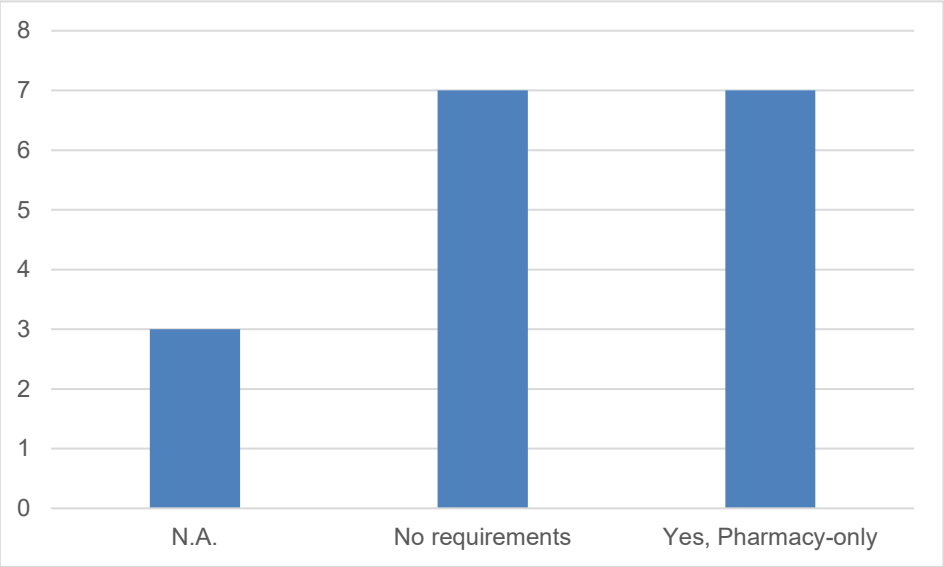
Summary

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 subcategories 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.

Q7. Do EU centrally authorised switches have special requirements at national level for classification and/or supply (e.g. in some countries centrally authorised switches are automatically classified as pharmacy-only medicines)? If yes, please provide a brief overview of the requirements.



Pharmacy-only: Austria, Germany, Ireland, North Macedonia, Portugal, Romania, United Kingdom (7 countries, corresponding to 41.2%).

No requirements: Belgium, France, Georgia, Lithuania, Serbia, Spain, Poland (7 countries, corresponding to 41.2%).

N.A.: Armenia, Bosnia and Herzegovina, Switzerland (3 countries, corresponding to 17.6%).

Comments:

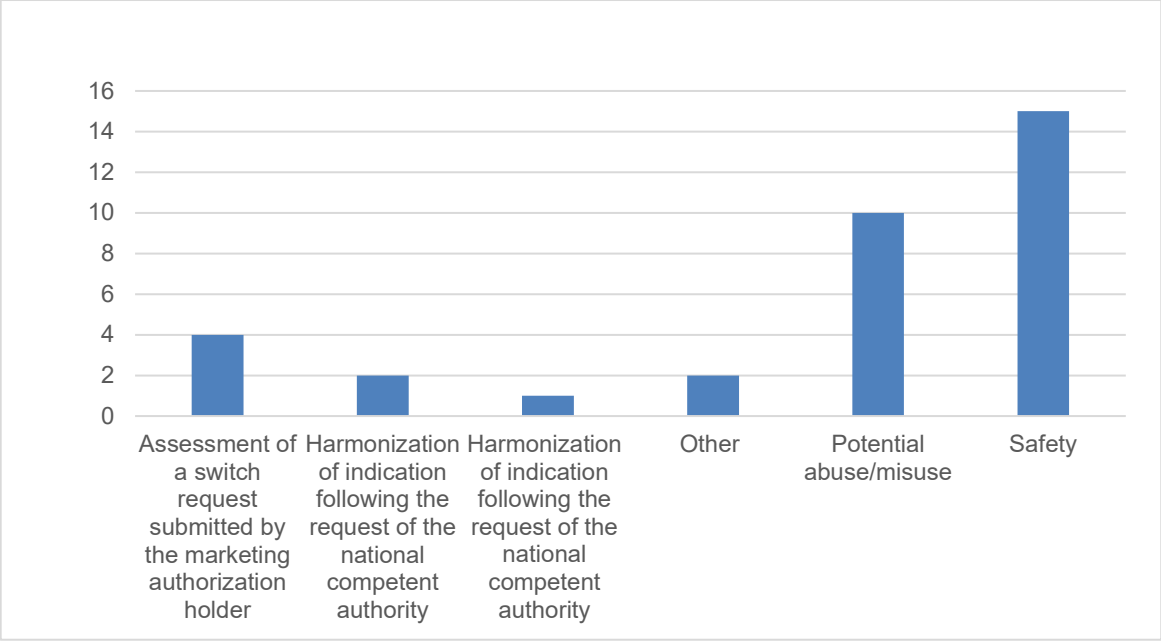
Lithuania: No special requirements, we have had retail sales (through non-pharmacy outlets) since 1 January 2019.

Portugal: Since 2013 centralised medicinal products after switch from prescription-only to non-prescription status should be pharmacy-only (e.g. ellaOne). Before 2013 centralised medicinal products after switch from prescription-only to non-prescription status were classified as non-prescription (e.g. alli).

United Kingdom: The product will automatically have P (pharmacy) status, unless: 1) MAH applies for GSL status (national conditions must be met); 2) There is an analogous GSL product already authorised in the UK. For definition of an “analogous product”, please see MHRA website: https://bit.ly/2Gxvp8l

PART II - Questions related to reclassification from non-prescription to prescription-only status

Q1. What are the main reasons for the reclassification from non-prescription to prescription-only status?



Safety: Armenia, Austria, Belgium, France, Georgia, Germany, Ireland, Lithuania, North Macedonia, Portugal, Romania, Serbia, Spain, Switzerland, United Kingdom (15 countries).

Potential abuse/misuse: Armenia, Austria, France, Georgia, Germany, Lithuania, Poland, Romania, Serbia, Switzerland (10 countries).

Assessment of a switch request submitted by the MAH: Armenia, Germany (but in rare cases), Poland, Switzerland (4 countries).

Harmonisation of indication at the request of the national competent authority: Armenia, Bosnia and Herzegovina, Switzerland (3 countries).

Other: Portugal, Switzerland (2 countries).

Comments:

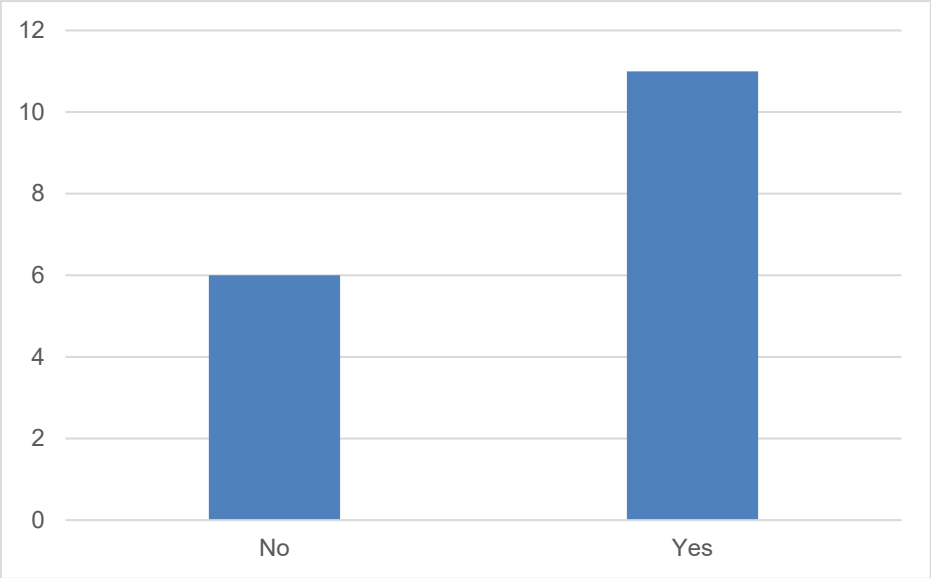
North Macedonia: Recently, no medicine has been switched from non-prescription to PRESCRIPTION-ONLY, but safety concerns would certainly be the main reason for such switches.

Portugal: See answer provided to question no. 3.

Switzerland: Legislation change.

Belgium: Most of the time, reclassification to prescription-only is for safety reasons. Few cases are for reasons of abuse (e.g. codeine in syrup). I have no memory of switches at the request of the MAH. If a decision to reclassify was taken for one medicinal product, reclassification will also be requested for other medicinal products with the same active substance/indications/formulation.

Q2. 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%).

Comments:

Armenia: Safety reasons.

Poland: Recently we have only had switches from non-prescription to prescription status for medicines with ATC R01BA52 – pseudoephedrine, combinations. The switches were made at the request of the MAH and were connected with the new Regulation of the Minister of Health of 16.12.2016, which sets the limit for pseudoephedrine content in non-prescription medicines. Medicines containing pseudoephedrine in composition, e.g. with antihistamines, can be classified as prescription medicines or non-prescription medicines depending on the amount of pseudoephedrine.

Ireland: reclassifications from non-prescription to prescription are invariably a result of significant safety issues, usually discussed at PRAC.

Q3. Which active substances were switched 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

Belgium	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: R05DA04, N02AJ06, R05DA09, R05DA, R05DA20)	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)
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 the 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	Diclofenac (ATC code: M01AB05)	Small increased risk of cardiovascular side effects (myocardial infarction and stroke), medical assessment required to determine if product is suitable
	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

Comment: 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.

Annex 1 - Information regarding reclassifications from prescription to non-prescription status until January 2019 (Question 5)

	INN/ATC Code	Reason for reclassification	Date of switch
Armenia	Acetylsalicylic acid, magnesium hydroxide (ATC code: B01AC30)	Tablets, 75 mg + 15.2 mg; (96/4x24/) in blister. No reason for switch mentioned.	2015
	Diosmin (ATC code: C05CA03)	Tablets, 600 mg; (15/1x15/), (18/1x18/), (30/2x15/) (60/4x15/) in blister. No reason for switch mentioned.	2015
	Kagocel (no ATC code mentioned)	Tablets, 12 mg; (10/1x10/) in blister, (20/2x10/) in blister, (30/3x10/) in blister. No reason for switch mentioned.	2016
	Pentanedioic acid (pentanedioic acid imidazolyl ethanamide) (ATC code: J05AX21)	Capsules, 90 mg; (7/1x7/), in blister. No reason for switch mentioned.	2017
	Lactulose (ATC code: A06AD11)	Solution oral, 670 mg/mL; 100 mL, 200 mL, 250 mL and 500 mL. No reason for switch mentioned.	2018
	Serenoae repentis extractum (Latin name: Sabalis serrulatae fructus) (ATC code: G04CX02)	Capsules, 320 mg; (30/2x15/) in blister.	2018
	Sulbutiamine (ATC code: A11DA02)	Tablets, 200 mg; (20/2x10/) in blister.	2019
	Sachet A-macrogol (macrogol 3350), sodium sulfate, sodium chloride, potassium chloride; sachet B-ascorbic acid, sodium ascorbate (ATC code: A06AD65)	Powder for oral solution, sachet A-100 g + 7.5 g + 2.691 g + 1.015g; sachet B 4.7 g + 5.9 g; (4/(2) sachet A (111.896 g) + (2) sachet B (10.6 g)/).	No date mentioned
Belgium	Levocetirizine (ATC code: R06AE09)	POM to non-prescription switch at request of the MAH. Conditions: 5 mg.	2014
	Omeprazole (ATC code: A02BC01)	POM to non-prescription switch at request of the MAH. Conditions: 10 mg, 20 mg.	2014
	Ulipristal (ATC code: G03AD02)	POM to non-prescription switch at request of the MAH. Conditions: 30 mg.	2015
	Mometasone (ATC code: R01AD09)	POM to non-prescription switch at request of the MAH. Conditions: 50 µg/dose.	2016
	Triamcinolone (ATC code: R01AD11)	POM to non-prescription switch at request of the MAH. Conditions: 55 µg/dose.	2016
	Fluticasone (ATC code: R01AD08)	POM to non-prescription switch at request of the MAH. Conditions: 550 µg/dose.	2017
Bosnia and Herzegovina	Loratadine (ATC code: R06AX13)	POM to non-prescription switch at request of the MAH. Conditions: 10 mg.	2014
	Butamirate (ATC code: R05DB13), 50 mg	POM to non-prescription switch at request of the MAH.	2015
	Fexofenadine (ATC code: R06AX26), 120 mg	POM to non-prescription switch at request of the MAH.	2015

Bosnia and Herzegovina	Ibuprofen (ATC code: M01AE01)	POM to non-prescription switch at request of the MAH. Conditions: 400 mg.	2015
	Nystatin (ATC code: A07AA02)	POM to non-prescription switch at request of the MAH. Conditions: 100 000 IU.	2015
	Nystatin (ATC code: D01AA01)	POM to non-prescription switch at request of the MAH. Conditions: 100 000 IU/g.	2015
	Nystatin (ATC code: G01AA01)	POM to non-prescription switch at request of the MAH. Conditions: 100 000 IU.	2015
	Ulipristal (ATC code: G03AD02)	POM to non-prescription switches at request of the MAH.	2015
	Camomilla flos estratto fluido and lidocaine (ATC code: A01AD11), 20 mg/g+185 mg/g	POM to non-prescription switch at request of the MAH.	2016
	Clotrimazole (ATC code: D01AC01)	POM to non-prescription switch at request of the MAH. Conditions: 10 mg/g.	2016
	Clotrimazole (ATC code: G01AF02)	POM to non-prescription switch at request of the MAH. Conditions: 200 mg.	2016
	Miconazole (ATC code: D01AC02)	POM to non-prescription switch at request of the MAH. Conditions: 20 mg/g.	2017
	Silver sulfadiazine (ATC code: D06BA01)	POM to non-prescription switch at request of the MAH. Conditions: 10 mg/g.	2017
	Diosmin (ATC code: C05CA03)	POM to non-prescription switch at request of the MAH. Conditions: 600 mg.	2018
France	Ulipristal (ATC code: G03AD02)	POM to non-prescription switch at request of the MAH. Conditions: oral use + maximal dose per unit: 30 mg + maximal total quantity supplied: 30 mg, public health grounds (indication).	2015
	Ibuprofen (ATC code: M02AA13)	POM to non-prescription switch at request of the MAH. Conditions: patch + maximal dose per unit: 200 mg + maximal total quantity supplied: 1 g.	2018
	Naloxone (ATC code: V03AB15)	POM to non-prescription switch at request of the MAH. Conditions: intramuscular use + maximal dose per unit: 0.364 mg + maximal total quantity supplied: 3.64 mg, public health grounds (indication).	2018
	Clotrimazole (ATC code: G01AF02)	POM to non-prescription switch at request of the MAH. Conditions: vaginal use + maximal dose per unit: 500 mg + maximal total quantity supplied: 1.2 g, MAH request.	2015
	Naloxone (ATC code: V03AB15)	POM to non-prescription switch at request of the MAH. Conditions: nasal use + maximal dose per unit: 3.6 mg + maximal total quantity supplied: 7.2 mg, public health grounds (indication).	2015
Georgia	Huge number of medicines (nasal dosage forms, some ophthalmology medicines, dermatological medicines, most of oral NSAIDs) were reclassified to non-prescription medicines	Reason: rebuild and revive prescription system, which was abolished in 90s after the fall of the Union of Soviet Socialist Republics.	2014
Germany	Esomeprazole (ATC code: A02BC05)	Conditions: for the treatment of heartburn and acid reflux, maximal dose per unit: 20 mg, maximal daily dose 20 mg, maximal total quantity supplied 280 mg, maximal application duration 14 days. No reason for switch mentioned.	2015

Germany	Flurbiprofen (ATC code: R02AX01)	Conditions: oropharyngeal use, short time treatment, maximal daily dose 50 mg. No reason for switch mentioned.	2015
	Fluticasone (ATC code: R01AD08)	Conditions: intranasal use, daily dose 200 µg, adults only. No reason for switch mentioned.	2015
	Racecadotril (ATC code: A07XA04)	Conditions: in solid preparations for the symptomatic treatment of acute diarrhoea, 30 mg per dosage form and 540 mg per package, for children from the age of 12 with oral rehydration. No reason for switch mentioned.	2013
	Ketotifen (ATC code: S01GX08)	Conditions: ophthalmic use, maximal concentration 0.025%. No reason for switch mentioned.	2015
	Beclometasone (ATC code: R01AD)	Conditions: intranasal use, maximal daily dose 400 µg, adults only. No reason for switch mentioned.	2016
	Mometasone (ATC code: R01AD09)	Conditions: intranasal use, maximal daily dose 200 µg, adults only. No reason for switch mentioned.	2016
	Aciclovir (ATC code: D06BB03)	Conditions: in preparations as a cream in combination with 1% hydrocortisone for the treatment of herpes for adults and children aged 12 and over in pack sizes of up to 2 g and with an active substance content of up to 100 mg aciclovir per divided medicinal form. No reason for switch mentioned.	2017
	Ibuprofen (ATC code: M01AE01)	Conditions: indicated for external use as a patch without the addition of further medicinally active ingredients in an active ingredient quantity of up to 200 mg ibuprofen per divided dosage form; ibuprofen for oral use (in maximum single dose of 400 mg and in a maximum daily dose of 1200 mg) in combination with caffeine (in maximum single dose of 100 mg and in a maximum daily dose of 300 mg), indicated for the treatment of acute moderately severe pain in adults. No reason for switch mentioned.	2017
	Sodium selenate (ATC code: A12CE01)	Conditions: for internal use of maximal daily dose of 70 µg. No reason for switch mentioned.	2017
	Levonorgestrel (ATC code:G03AD01)	Conditions: oral use for emergency contraception, max 1.5 mg per dosage form. No reason for switch mentioned.	2015
	Ulipristal (ATC code: G03AD02)	Conditions: only ellaOne® for emergency contraception. No reason for switch mentioned.	2015
Ireland* **	Calcipotriol (ATC: D05AX02)	No reason for switch mentioned.	Not mentioned
	Hyoscine butylbromide (ATC: A03BB01)	No reason for switch mentioned.	Not mentioned

Ireland* **	Lactulose (ATC code: A06AD11)	No reason for switch mentioned.	Not mentioned
	Ibuprofen + paracetamol (ATC code: M01AE51)	No reason for switch mentioned.	Not mentioned
	Sumatriptan (ATC: N02CC01)	No reason for switch mentioned.	Not mentioned
	Triamcinolone (ATC code: R01AD11)	No reason for switch mentioned.	Not mentioned
Lithuania	Dexketoprofen (ATC code: M01AE17)	POM to non-prescription switch at request of the MAH. Conditions: 25 mg film-coated tablets N10.	2015
	Glucosamine (ATC code: M01AX05)	POM to non-prescription switch at request of the MAH. Conditions: 1.5 g powder for oral solution.	2017
	Fluticasone (ATC code: R01AD08)	POM to non-prescription switch at request of the MAH. Conditions: 50 micrograms/actuation nasal spray, suspension.	2018
Poland	Inosine pranobex (ATC code: J05AX05)	All switches at the request of the MAH.	2014
	Lansoprazole (ATC code: A02BC03)	All switches at the request of the MAH.	2014
	Tolfenamic acid (ATC code: M01AG02)	All switches at the request of the MAH.	2014
	Calcium dobesilate (ATC code: C05BX01)	All switches at the request of the MAH.	2014
	Desloratadine (ATC code: R06AX27)	All switches at the request of the MAH.	2014
	Fenspiride (ATC code: R03DX03)	All switches at the request of the MAH.	2014
	Calcitriol (ATC code: A11CC04)	All switches at the request of the MAH.	2015
	Dexketoprofen (ATC code: M01AE17)	All switches at the request of the MAH.	2015
	Trimebutine (ATC code: A03AA05)	All switches at the request of the MAH.	2015
	Levodropropizine (ATC code: R05DB27)	All switches at the request of the MAH.	2016
	Sildenafil (ATC code: G04BE03)	All switches at the request of the MAH.	2016
	Antazoline and naphazoline (ATC code: S01GA51)	All switches at the request of the MAH.	2016
	Ciclopirox (ATC code: D01AE14)	All switches at the request of the MAH.	2016
	Ketotifen (ATC code: S01GX08)	All switches at the request of the MAH.	2016

Poland	Pyrantel (ATC code: P02CC01)	All switches at the request of the MAH.	2016
	Aciclovir (ATC code: J05AB01)	All switches at the request of the MAH.	2017
	Amorolfine (ATC code: D01AE16)	All switches at the request of the MAH.	2017
	Fenticonazole (ATC code: G01AF12)	All switches at the request of the MAH.	2017
	Ketoprofen (ATC code: M01AE03)	All switches at the request of the MAH.	2017
	Clotrimazole (ATC code: G01AF02)	All switches at the request of the MAH.	2018
	Erdosteine (ATC code: R05CB15)	All switches at the request of the MAH.	2018
	Carbocisteine (ATC code: R05CB03)	All switches at the request of the MAH.	2019
	Mebeverine (ATC code: A03AA04)	All switches at the request of the MAH.	2019
	Olopatadine (ATC code: S01GX09)	All switches at the request of the MAH.	2019
Portugal	Amorolfine (ATC code: D01AE16)	Pharmacy-only. New MA. Conditions: cutaneous use	2015
	Fluticasone (ATC code: R01AD08)	Pharmacy-only. New MA. Conditions: nasal use	2015
	Fusidic acid (ATC: D06AX01)	Switched to pharmacy-only. Conditions: cutaneous use. No reason for switch mentioned.	2015
	Hydrocortisone (ATC code: D07AA02)	Switched to pharmacy-only. Conditions: cutaneous use. No reason for switch mentioned.	2015
	Lidocaine + prilocaine (ATC code: N01BB20)	Switched to pharmacy-only. Conditions: cutaneous use. No reason for switch mentioned.	2015
	Piketoprofen (ATC code: M02AA28)	Switched to pharmacy-only. Conditions: cutaneous use. No reason for switch mentioned.	2015
	Salicylic acid + fluorouracil (ATC code: D11AF)	Switched to pharmacy-only. Conditions: cutaneous use. No reason for switch mentioned.	2015
	Ulipristal (ATC code: G03AD02)	Switched to pharmacy-only. Conditions: oral use. No reason for switch mentioned.	2015
	Acetylsalicylic acid (ATC code: N02BA01)	Pharmacy-only. New MA. Conditions: 1000 mg, oral use	2016
	Butylscopolamine + paracetamol (ATC code: A03DB04)	Switched to pharmacy-only. Conditions: oral use. No reason for switch mentioned.	2016
	Ibuprofen (ATC: M01AE01)	Switched to pharmacy-only. Conditions: oral use, 400 mg. No reason for switch mentioned.	2016

Portugal	Phloroglucinol + simeticone (ATC code: A03AX)	Pharmacy-only. New MA. Conditions: oral use.	2016
	Budesonide (ATC code: R01AD05)	Pharmacy-only. New MA. Conditions: nasal use.	2017
	Cetirizine (ATC code: R06AE07)	Switched to non-prescription status. Note: there have been other switches to non-prescription, but for harmonisation of classification - for the same active substance, strength, pharmaceutical form and therapeutic indications there were products classified as non-prescription in Portugal (e.g. Aciclovir for cutaneous use, omeprazole oral use).	2017
	Glucosamine (ATC code: M01AX05)	Switched to non-prescription status. Note: there have been other switches to non-prescription, but for harmonisation of classification - for the same active substance, strength, pharmaceutical form and therapeutic indications there were products classified as non-prescription in Portugal (ex: Aciclovir for cutaneous use, omeprazole oral use).	2017
	Ibuprofen + pseudoephedrine (ATC code: R05X)	Pharmacy-only. New MA. Conditions: oral use.	2017
	Ketotifen (ATC code: S01GX08)	Switched to pharmacy-only. Conditions: ocular use. No reason for switch mentioned.	2017
	Magnesium aspartate + potassium aspartate, (ATC code: A13A)	Switched to pharmacy-only. Conditions: oral use. No reason for switch mentioned.	2017
	Paracetamol + pseudoephedrine (ATC code: N02BE51)	Switched to pharmacy-only. Conditions: oral use. No reason for switch mentioned.	2017
	Dexketoprofen (ATC code: M01AE17)	Switched to pharmacy-only. Conditions: oral use. No reason for switch mentioned.	2018
	Diphenhydramine (ATC code: R06AA02)	Pharmacy-only. New MA. Conditions: oral use.	2018
	Folic acid + cyanocobalamin + iodine (ATC code: B03BB51)	Switched to pharmacy-only. Conditions: oral use.	2018
	Folic acid (ATC code: B03BB01)	Switched to pharmacy-only. Conditions: oral use. No reason for switch mentioned.	2018
	Ibuprofen + paracetamol (ATC code: M01AE51)	Pharmacy-only. New MA. Conditions: oral use.	2018
	Loratadine (ATC code: R06AX13)	Switched to pharmacy-only. Conditions: oral use, 10 mg. No reason for switch mentioned.	2018
	Paracetamol + diphenhydramine (ATC code: N02BE51)	Pharmacy-only. New MA. Conditions: oral use.	2018
	Pseudoephedrine + triprolidine (ATC code: R01BA52)	Switched to pharmacy-only. Conditions: oral use.	2018

Portugal	Triamcinolone (ATC code: R01AD11)	Switched to pharmacy-only. Conditions: nasal use.	2018
Romania	Ciclopirox (ATC code: D01AE14)	No reason for switch mentioned.	2015
	Fenticonazole (ATC code: G01AF12)	No reason for switch mentioned.	2015
	Diosmin (ATC code: C05CA03)	No reason for switch mentioned.	2017
	Erdosteine (ATC code: R05CB15)	No reason for switch mentioned.	2017
Serbia	Azelastine (ATC code: R01AC03)	Switched from POM to non-prescription status at the request of the MAH. During the requested time-frame, we did not have non-prescription switches for all products with specific active substances, but we did have non-prescription switches for single products. Conditions: daily dose: 0.56 mg azelastine hydrochloride (nasal spray).	2016
	Fluticasone (ATC code: R01AD08)	Switched from POM to non-prescription status and at the request of the MAH. During the requested time-frame, we did not have non-prescription switches for all products with specific active substances, but we did have non-prescription switches for single products. Conditions: two sprays into each nostril once a day.	2017
	Desloratadine (ATC code: R06AX27)	Switched from POM to non-prescription status at the request of the MAH. During the requested time-frame, we did not have non-prescription switches for all products with specific active substances, but we did have non-prescription switches for single products. Conditions: 5 mg.	2018
Spain	Benzydamine hydrochloride (no ATC code mentioned)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Acetylcysteine (ATC code: R05CB01)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Ambroxol hydrochloride (ATC code: R05CB06)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Antazoline and naphazoline (ATC code: S01GA51)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Caffeine and dimenhydrinate (no ATC code mentioned)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Carbocisteine (ATC code: R05CB03)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Carmellose sodium (no ATC code mentioned)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Crataegus oxyacantha tincture and Passiflora incarnata extract (no ATC code mentioned)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned

Spain	Dextromethorphan and guaifenesin (no ATC code mentioned)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Dichlorobenzyl alcohol and amylmetacresol (no ATC code mentioned)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Diclofenac epolamine (no ATC code mentioned)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Docosanol (ATC code: D06BB11)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Doxylamine (ATC code: R06AA09)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Guaifenesin and phenylephrine (no ATC code mentioned)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Hedera Helix (no ATC code mentioned)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Levonorgestrel (ATC code:G03AD01)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Omeprazole (ATC code: A02BC01)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Orlistat (no ATC code mentioned)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Oxymetazoline (no ATC code mentioned)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Paracetamol (no ATC code mentioned)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Paracetamol, chlorphenamine and phenylephrine (no ATC code mentioned)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Rhamnus purshiana extract and Fucus vesiculosus extract (no ATC code mentioned)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Rosmarinus officinalis oil (no ATC code mentioned)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned
	Valerian extract (no ATC code mentioned)	During the requested period 257 medicinal products with the legal status 'not subject to medical prescription' have been authorised.	Not mentioned

Switzerland	Ulipristal (ATC code: G03AD02)	List I > non-prescription (pharmacy-only), 1 x 30 mg MAH application.	2016
	Hydroxocobalamin, combinations (ATC code: B03BA53)	List II > non-prescription (specialist advice), 1 x 0.5 mg, MAH application.	2014/2015
United Kingdom▪▪	Zolmitriptan (ATC code: N02CC03)	POM to P. For acute relief of migraine attacks with or without aura for adults aged 18 to 65 years; 2.5 mg; orodispersible tablet.	2014
	Penciclovir (no ATC code mentioned)	P to GSL. For the treatment of herpes simplex virus infections of the lips and face (herpes labialis) in adults and children aged 12 years or more; 1 mg; cream.	2014
	Ulipristal (ATC code: G03AD02)	POM to P. For emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure; 30 mg; tablet.	2015
	Esomeprazole (ATC code: A02BC05)	P to GSL. For the short-term treatment of reflux symptoms (e.g. heartburn and acid regurgitation) in adults; 20 mg; gastro-resistant tablet.	2015
	Fluticasone (ATC code: R01AD08)	P to GSL. For the treatment of allergic rhinitis, in persons aged 18 years and over, for a maximum period of 1 month; 0.05%; nasal spray.	2015
	Diclofenac diethylamine (no ATC code mentioned)	POM to P. For the local symptomatic relief of pain and inflammation in: - trauma of the tendons, ligaments, muscles and joints, e.g. due to sprains, strains and bruises; - localised forms of soft tissue rheumatism. For the relief of pain of non-serious arthritic conditions; 180 g; gel.	2016
	Naproxen (no ATC code mentioned)	P to GSL. For the treatment of primary dysmenorrhoea in women aged 15 to 50 years; 250 mg; gastro-resistant tablet.	2016
	Ibuprofen (no ATC code mentioned)	POM to P. Children aged 7 to 12 years. Rheumatic or muscular pain, headache, dental pain, feverishness, symptoms of cold and influenza; 200 mg/mL; oral suspension.	2017
	Acrivastine (no ATC code mentioned)	POM to P. For the symptomatic relief of allergic rhinitis, including hay fever, and for chronic idiopathic urticaria. 8 mg; 48 capsules.	2017
	Acrivastine (ATC code: R06AX18)	P to GSL. For the symptomatic relief of allergic rhinitis, including hay fever, and for chronic idiopathic urticaria. 8 mg; 24 capsules.	2017
	Xylometazoline hydrochloride, Ipratropium bromide (no ATC code mentioned)	POM to P. Symptomatic treatment of nasal congestion and rhinorrhoea in connection with common colds; 0.5 mg/mL.	2017
	Proguanil hydrochloride, Atovaquone (no ATC code mentioned)	POM to P. Chemoprophylaxis of *Plasmodium falciparum* malaria in adults. 100 mg; film-coated tablets.	2017
	Mometasone (ATC Code: R01AD09)	POM to P. For use in adults to treat the symptoms of seasonal or perennial allergic rhinitis. 0.5 milligrams per gram; nasal spray, suspension.	2017

United Kingdom▪▪	Docosanol (ATC code: D06BB11)	P to GSL. Treatment of early stages (prodrome or erythema phase) of recurrent labial herpes simplex infection (cold sores) in immunocompetent patients. 100 mg/g.	2017
	Calcipotriol (ATC: D05AX02)	POM to P. For the treatment of mild to moderate plaque psoriasis which has been previously diagnosed by a doctor in adults aged 18 years and over; 50 µg/g; cream.	2017
	Glucosamine (ATC code: M01AX05)	POM to P. For relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor. 750 mg, 180 tablets.	2017
	Glucosamine (ATC code: M01AX05)	POM to P. For relief of symptoms in mild to moderate osteoarthritis of the knee as diagnosed by a doctor. 1500 mg, 90 tablets.	2017
	Sildenafil (ATC code: G04BE03)	POM to P. For the treatment of adult men with erectile dysfunction. 50 mg, 8 tablets.	2017
	Mucopolysaccharide polysulfate + Salicylic acid (no ATC code mentioned)	P to GSL. For the relief of muscular pain and stiffness, sprains and strains for not more than 7 days in adults and children aged 12 years and over. 0.2 + 2.0 percent weight in weight, cream.	2017
	Ibuprofen (no ATC code mentioned)	POM to P. For short-term symptomatic treatment of local pain in acute muscular strains, or strains in benign traumas close to the joint of the upper or lower limb for not more than 5 days in adults & adolescents aged 16 years and over. 200 mg; plaster.	2017
	Ibuprofen + Levomenthol (no ATC code mentioned)	P to GSL. For relief of rheumatic pain and muscular aches, pains and swellings such as strains sprains and sports injury for not more than 14 days in adults and children aged 12 & over. 5.0 + 3.0 percent weight in weight; gel.	2018
	Ibuprofen (no ATC code mentioned)	POM to P. For relief of migraine, backache, dental pain, neuralgia, period pain, muscular pain, pain of non-serious arthritic conditions, fever, and cold and flu symptoms in adults and children aged 12 years and over for not more than 10 days for adults (18 years & over) and not more than 3 days for children and adolescents aged 12 to 18 years. 200 mg/5 mL; suspension.	2018
	Piroxicam (no ATC code mentioned)	POM to P. For the local symptomatic relief of pain and stiffness accompanying non-serious arthritic conditions and pain or swelling accompanying sprains, strains and sports injuries in adults aged 18 years of age and over, for not more than 14 days. 0.5 percent weight in weight; gel.	2018
	Amorolfine (ATC code: D01AE16)	P to GSL. For treatment of mild cases of distal and lateral subungual onchomycoses caused by dermatophytes, yeasts and moulds; in adults aged 18 years and over; treatment is limited to 2 nails. 5 percent weight in volume, nail lacquer.	2018

United Kingdom▪▪	Diclofenac diethylammonium (no ATC code mentioned)	P to GSL. Additional GSL pack size. For use in adults and children aged 14 years and over for the local symptomatic relief of pain and inflammation in trauma of the ligaments, muscles and joints (e.g. due to sprains, strains and bruises); localised forms of soft tissue rheumatism; for up to 7 days; 1.16 percent weight in weight, gel.	2018
	Minoxidil (no ATC code mentioned)	P to GSL. For the treatment of alopecia androgenetica (also known as female pattern hair loss) in women between 18 and 65 years of age. 5 percent weight in weight; cutaneous foam.	2018
	Fluticasone propionate (no ATC code mentioned)	POM to P. Adults 18 years of age and over. For treatment and prevention of allergic rhinitis, including hay fever and that caused by other airborne allergens such as house dust mite and animal dander. For symptomatic relief of sneezing, itchy and runny nose, itchy and watery eyes, nasal congestion and associated sinus discomfort. 0.05 percent weight in weight; nasal spray, suspension.	2018

*** A list of all currently available non-prescription pharmacy-only medicines, including ATC code, is available here: https://bit.ly/2vnpMnX A list of all currently available non-prescription general sale medicines including ATC code, is available here: https://bit.ly/2PyBCoK

▪▪ This list was obtained via the link “Approved Reclassifications” (https://bit.ly/2Gxvp8l) and shows only the active substances switched between 2014 and 2019. It is important to note that reclassifications apply to a particular product, not to the active substance. In addition, it may not necessarily mean that this is the first time that medicines containing these active substances have been reclassified; it might just be a widening of the conditions under which a substance can be reclassified and made available as a non-prescription medicine (e.g. Ibuprofen). No reasons for reclassification are reported.