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DRUID
Driving under the Influence of Drugs, Alcohol and Medicines
Integrated Project 1.6. Sustainable Development, Global Change and Ecosystem 1.6.2: Sustainable Surface Transport

6th Framework Programme
Deliverable 4.3.1

Establishment of framework for classification/categorisation and labelling of medicinal drugs and driving

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List of Abbreviations

ADR: Adverse Drug Reaction

ADHD: Attention deficit/hyperactivity disorder

AFSSAPS: Agence Française de Sécurité Sanitaire des Produits de Santé (French Health Products Safety Agency)

ATC: Anatomical Therapeutic Chemical classification system

CHMP: Committee for Medicinal Products for Human Use

DRUID: Driving Under the Influence of Drugs, Alcohol and Medicines

EC: European Commission

EMA: European Medicines Agency

eMC: Electronic Medicines Compendium

EU: European Union

HCP: Health Care Professional

ICADTS: International Council on Alcohol, Drugs and Traffic Safety

IMB: Irish Medicines Board

MHRA: Medicines and Healthcare products Regulatory Agency

PIL: Patient Information Leaflet

SmPC: Summary of Product Characteristics

WP: Work Package

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Executive Summary

The establishment of criteria for a European categorisation will have to serve most of the needs of all parties involved: health professionals, drug regulatory agencies, drug manufacturers and patients. Clear warnings and symbols are needed so patients use their medicines in the most optimal (and safest) way possible

The DRUID WP4 expert group established and agreed that, according to its influence on the ability to drive, a medicine could, regarding to driving, be categorized as followed:

- category 0 (no or negligible influence on fitness to drive),
- category I (minor influence on fitness to drive),
- category II (moderate influence on fitness to drive),
- and category III (severe influence on fitness to drive).

The DRUID methodology on categorisation/labelling on medicines and driving.

In summary, categorisation of a medicine on driving includes several steps of evaluation after taken into account the conditions of use of the medicine on the European Union market:

1. Pharmacodynamic and pharmacokinetic data
2. Pharmacovigilance data (including prevalence of unwanted effects reported in the SmPC)
3. Experimental and epidemiological data
4. Additional data derived from the Patient Information Leaflet (PIL) and existing categorisation systems
5. Synthesis

Básically conditions of use of the medicine, pharmacodynamics, pharmacokinetic data, and pharmacovigilance data (including prevalence of unwanted effects) were derived from the SmPC, while section 3 was based on a scientific literature serach. Additional data step consisted of reviewing section 4.7 of the SmPC “Effects on ability to drive and use machines” and the PIL section on “driving and using machines” as well as reviewing the previous categorisations (if available) of the medicine in Belgium, France, Spain as well as to the ICADTS list.

After evaluating all the available data, a provisional category was assigned to each active substance. The provisional category was proposed and discussed during WP4 meetings where a final and definitive category was assigned and approved by all WP4 partners.

A mechanism for modifying the classification, based on new evidence.

The existing methodology on DRUID categorisation on medicines and driving, allows to, if new evidences emerges, re-categorise the medicine or confirm the previous categorisaton following again the same 5 step process.

Classification/categorisation, labelling and patient oriented information for the relevant therapeutic groups of medicines available in the European Union market.

The aim of WP4 was to provide a categorisation for the relevant therapeutic groups of medicines available on the European Union Market.

In this way, DRUID task 4.3 was able to provide categorisation, labelling and patient-oriented information for the following ATC groups (The Anatomical Therapeutic Chemical –ATC-classification system; http://www.whocc.no/).

Individual medicines were categorized according to the DRUID classification system.

A - ALIMENTARY TRACT AND METABOLISM
B - BLOOD AND BLOOD FORMING ORGANS
C - CARDIOVASCULAR SYSTEM
D - DERMATOLOGICALS
M - MUSCULO-SKELETAL SYSTEM
N - NERVOUS SYSTEM
    N01 ANESTHETICS
    N02 ANALGESICS
    N03 ANTIEPILEPTICS
    N04 ANTIPARKINSON
    N05 PSYCHOLEPTICS
        N05A Antipsychotics
        N05B Anxiolytics
        N05C Hypnotics and sedatives
    N06 PSYCHOANALEPTICS
        N06A Antidepressant
        N06B Psychostimulants, agents used for ADHD (attention deficit/hyperactivity disorder) and Nootropics
        N06C Psycholeptics and psychonaleptics in combination
        N06D Anti-dementia drugs
    N07 OTHER NERVOUS SYSTEM DRUGS
R - RESPIRATORY SYSTEM
S - SENSORY ORGANS

Furthermore, Fact Sheets were produced for the N01-N07 (nervous system) and R06 (respiratory system - antihistamines) ATC groups of medicines. Each fact sheet contains information on: source of information, presentations, indications, posology and method of administration, pharmacodynamic and pharmacokinetic properties, possible side-effects related to driving, Summary of Product Characteristics (SmPC) section 4.7 effects on effects on ability to drive and use machines, leaflet section on driving and using machines, studies on psychomotor performance and risk studies, current categorisation in some EU countries, proposed DRUID categorisation, information for the patient, and place and date of agreement by the DRUID WP4 members.

For analysis and categorisation The DRUID project has proposed a total of 3,054 medicines from these ATC groups. Of these 3,054 medicines, 1,513 have not been categorized, because they are not available on the European Union market (not available on DRUID WP4 countries Belgium, France, Greece, Germany, Netherlands, and Spain, as well as in the UK and Ireland), as there is no sense in categorizing/labelling medicines which are not available.

The distribution of the 1,541 categorized medicines was as follows: Category 0 – 50,3%, Category I – 26%, Category II – 11,2%, Category III – 5,8%, Multiple category – 4,4% and the Depending on the medicine in combination 2,3%.

Multiple categories: This appeared when a medicine can be included in more than one category. There can be several reasons for this: In most cases, the different categorisation depended on the route of administration (topical, oral, parenteral, etc). In the case of some medicines, in special ophthalmological preparations (SO1), the different categorisation depended on the presentation form of the medication (aqueous-vehicle, cream, drops or ointment, etc.), which is related with the duration of its action. In one case, codeine, categorisation was based on the dose of codeine base administered. For two hypnotics, zolpidem and zaleplon, categorisation was based on the time after the medication was taken.

Depending on medicines in combination: This was stated when the categorisation depended on another medicine combined with the one under evaluation.

1. Introduction

Within DRUID Work package 4 - Classification, Task 4.3 aims to categorize medicines available on the European Union market in relation to driving.

In fact, the main goal of task 4.3 was to achieve objective 4, “Proposition of a classification/categorisation system for the relevant therapeutic groups of medicines available in the market”. Furthermore, Task 4.3 was also responsible for achieving objective 3, “Development of a methodology to continuously update the i) classification/categorisation system and ii) labelling system on medicines and driving (core contract page 96 out of 184, version 2006).

Please see below for a full description of Task 7.3. in the core contract.

Task 4.3 as described in the Annex I to the Core Contract of DRUID project
Task 4.3 Establishment of framework for classification/categorisation and labelling of medicinal drugs and driving Task leader: Uva (University of Valladolid) Topics: - Classification/categorisation following criteria of Task 4.2 of some groups of medicinal drugs not done in Task 4.1 (for example, anticholinergic drugs, anti-Parkinson drugs, some antihypertensive drugs). This Task will cover some groups of drugs, not all the drugs not-categorised in Task 4.1. The end of this Task is to propose a classification/categorisation system for the relevant therapeutic groups of medicines available in the market. - Classification/categorisation of drugs approved by EMA during the 2nd year of the DRUID project. That is, if the project starts in 2006, the approved medicinal drugs by EMA along 2007 will be classified/categorised using the Task 4.2 criteria. This will allow seeing if the proposed criteria on Task 4.2 could be applied in practice. - If able to agree with EMA the Task 4.3 will be able to provide a classification/categorisation for the “new” medicinal drugs under EMA evaluation on 2007/2008 and not yet approved. That is prior to the approval by EMA of a new drugs, DRUID Task 4.3 will provide the suggested classification prior the registration of a new medicinal drug. - A mechanism for modifying the classification, based on new evidence, will also be proposed. Tasks 1.1 “Methodology and metaanalyses”, Task 1.3 ”Recommendation of thresholds” and Task 2.3 “Relative risk estimation”, Task 4.1 “Review” and Task 4.2 “Consensus” will serve as input for Task 4.3. First 18 months: From month 11 to 18 Task 4.3 will start with categorisation of some of the therapeutics groups not covered by Task 4.1 Involved Partners: UGent, UVa, RUGPha, BASt, UGren, CERTH-HIT Duration of the Task: Month 11 – month 45

1. 1. Input from other DRUID tasks

There was a deep interrelation between Task 4.2 and Task 4.3. The development of Task 4.3 was correlated with task 4.2 “The establishment of criteria for a European categorisation, based on expert consensus”, with the aim of achieving objective 2 “Proposition and agreement on the criteria and the methodology on the establishment of a European i) classification/categorisation system and ii) labelling system of medicines and driving”. Finally, Task 4.3 benefits from the knowledge acquired from Task 4.1, in which the existing i) classification/categorisation systems and ii) labelling systems regarding medicines and driving were reviewed.

While Task 4.2 developed the basis for consensus on the criteria for establishing a European categorisation for medicines and driving, Task 4.3 was more practical and produced a categorisation/labelling for existing medicines, as well as producing specific information for health professionals (physicians and pharmacists) to be delivered to the driver patient.

However, for Task 4.3, due to delays in the development of the respective tasks, not much desirable input has been obtained from Tasks 1.1 “Methodology and metaanalyses”, Task 1.3 ”Recommendation of thresholds” and Task 2.3 “Relative risk estimation”, as was initially expected during the development of the DRUID proposal.

1.2. Input from previous experience of partners and national activities in the field

The work in WP4-tasks has benefitted from previous experience of some of the partners in the field on medicines and driving [1-3], for instance, their contribution to former ICADTS categorisation on medicines and driving [4].

Furthermore, in the last few years, when the DRUID project was being carried out, there have been some national experiences that, without any doubt, have provided input for the WP4 activities. For instance, the introduction of the pictogram in France [5] and later in Spain [6], as well as the development of a national programme regarding medicines and driving in The Netherlands [7].

Several meetings have taken place in collaboration with national agencies. For instance, in AFSSAPS (Agence Francaise de Sécurité Sanitaire des Produits de Santé) on February 28th 2008, where DRUID partners attended a “regular” meeting of the French Medicinal Agency regarding medicines and driving. The criteria used and the experience on labelling medicines regarding to driving in France was shown.

The attendance at the Pharmacovigilance Working Party (PhVWP) at EMA (European Medicinal Agency) has also been of great value for the development of WP4 tasks.

However, the DRUID categorisation system is, although it may have benefitted from many other early experiences, a new categorisation.

1.3. Classification/categorisation system for the relevant therapeutic groups of medicines available in the market

The aim of task 4.3 was to provide a categorisation for the relevant therapeutic groups of medicines available on the European Union Market.

In this way, DRUID task 4.3 was able to provide categorisation, labelling and patient-oriented information for the following ATC groups (The Anatomical Therapeutic Chemical –ATC-classification system; http://www.whocc.no/)

A - ALIMENTARY TRACT AND METABOLISM
B - BLOOD AND BLOOD FORMING ORGANS

C - CARDIOVASCULAR SYSTEM
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M - MUSCULO-SKELETAL SYSTEM
N - NERVOUS SYSTEM
- N01 ANESTHETICS
- N02 ANALGESICS
- N03 ANTIEPILEPTICS
- N04 ANTIPARKINSON
- N05 PSYCHOLEPTICS
  - N05A Antipsychotics
  - N05B Anxiolytics
  - N05C Hypnotics and sedatives
- N06 PSYCHOANALEPTICS
  - N06A Antidepressant
  - N06B Psychostimulants, agents used for ADHD (attention deficit/hyperactivity disorder) and Nootropics
  - N06C Psycholeptics and psychonaleptics in combination
  - N06D Anti-dementia drugs
- N07 OTHER NERVOUS SYSTEM DRUGS

R - RESPIRATORY SYSTEM
S - SENSORY ORGANS

In total, these represent 3,054 different medicines. A key aspect was to identify which medicines are available on the European Union market, as there is no sense in categorizing/labelling medicines which are not available. Of these 3,054 medicines, according to our criteria, 1,513 were not available in most European Union member states and, therefore, categorisation was not provided.

Furthermore, Fact Sheets were produced for the N01-N07 (nervous system) and R06 (respiratory system - antihistamines) ATC groups of medicines. Each fact sheet contains information on: source of information, presentations, indications, posology and method of administration, pharmacodynamic and pharmacokinetic properties, possible side-effects related to driving, Summary of Product Characteristics (SmPC) section 4.7 effects on ability to drive and use machines, leaflet section on driving and using machines, studies on psychomotor performance and risk studies, current categorisation in some EU countries, proposed DRUID categorisation, information for the patient, and place and date of agreement by the DRUID WP4 members.

The following ATC groups were not categorized: G (Genito urinary system and sex hormones), H (Systemic hormonal preparations, excluding sex hormones and insulins), J (Antiinfectives for systemic use), L (Antineoplastic and immunomodulating agents), P (Antiparasitic products, insecticides and repellents) and V (various).

1.4. Structure of Deliverable 4.3

Deliverable 4.3 is divided into three parts.

Chapter 2 includes a description of the methodology used for the categorisation and labelling of medicines and driving used within DRUID Task 4.3. It should be noticed that the Training Manual used by DRUID partners for the categorisation/labelling of medicines regarding driving is provided in Annex 1.

Chapter 3 includes an earlier (2008) document for internal use produced by the French partners to present guidelines regarding DRUID criteria for categorisation and labelling.

Chapter 4 shows some general figures regarding the number of medicines categorized in each category within the DRUID project.

Chapter 5 is an alphabetical list of the medicines categorized in the DRUID WP4.

Chapter 6 shows some examples of information oriented to patients with regard to medicines and driving.

Chapter 7 shows the medicines approved by the EMA since January 2008, as well as the DRUID categorisation for these medicines.

1.5. List of Annexes

This deliverable includes 17 annexes. While Annex 1 is the Training Manual used by DRUID partners for the categorisation/labelling of medicines regarding driving, Annexes 2-17 included categorisation/labelling and patient-oriented information for each ATC medicines group categorized.

Within each annex the following information is included:

- A chapter analysing the relation between the diseases for which the medicines are used, the medicines and fitness to drive.
- Categorisation and labelling on medicines and driving
- Patient-oriented information on medicines and driving
- Fact Sheet for each medicine categorized (available for ATC N-Nervous system and R06-Respiratory System - Antihistamines).

1.6. References

1. Wolschrijn H, de Gier JJ, de Smet PAGM. Drugs and driving: a new categorisation system for drugs affecting psychomotor performance. Institute for drugs, safety and behaviour, University of Limburg, Maastricht, IVGV 91-24, 1991.

2. Toxicological Society of Belgium and Luxembourg asbl. Influence des médicaments sur les capacités de conduire. Toxicological Society of Belgium and Luxembourg asbl, Bruxelles, 1999.

3. Del Río MC, Alvarez FJ, González-Luque JC. Guía de prescripción farmacológica y seguridad vial [The Pharmaceutical Prescription Guidelines and Road Safety], 2nd Ed. Dirección General de Tráfico, Madrid, 2002.

4. ICADTS Working group on Prescribing and Dispensing Guidelines for Medicinal Drugs Affecting Driving Performance. International Council on Alcohol, Drugs & Traffic Safety, 2001.

5. Ministère de la Santé et des Solidarités, Arrêté du 18 Juillet 2005 pris pour l´application de l´article R.5121-139 du code de la santé publique et relative à l´opposition d´un pictogramme sur le conditionnement extérieur de certain médicaments et produits. Journal Officiel de la République Française, 2 Août 2005 (SAN/P0522726A).

6. REAL DECRETO 1345/2007, de 11 de octubre, por el que se regula el procedimiento de autorización, registro y condiciones de dispensación de los medicamentos de uso humano fabricados industrialmente. BOE de 7 de Noviembre de 2007, pp: 45652-45698.

2. A European approach to categorize medicines according to their driving impairment: Outcomes of the DRUID project.

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2.1. Introduction

Driving a motor vehicle is a multifaceted task and it requires appropriate cognitive and psychomotor skills (e.g. alertness, concentration, reaction time, visual acuity) [1]. Psychoactive medications can adversely affect these driving-related skills, and, consequently, be a hazard to traffic safety [2, 3].

The European Council Directive 83/570/EEC of October 1983 established that the summary of product characteristics (SmPC) has to contain, in Article 4, information on clinical particulars, among which the "effects on the ability to drive and to use machines" [4]. In October 1991 the European Committee for Medicinal Products for Human Use (CHMP) provided a Note for Guidance for the SmPC in which it was stated that section 4.7 of medications registered from 1st January 1992 had to indicate, on the basis on the pharmacodynamic profile, reported adverse drug reactions (ADRs) and/or impairment of driving performance or performance related to driving, 3 different levels of impairment with respect to the ability to drive and/or operate machines [1,5]. In September 2009 (which applies as from 1st of May 2010) a new SmPC guideline was issued, partly based on the proposal sent to EMA during the consultation phase of the revision of the SmPC guidelines in March 2008 which established that "" [6].

Table 1: Text of SmPC section 4.7 on Effects on ability to drive and use machines. Version september 2009, in force 1st May 2010.

4.7 Effects on ability to drive and use machines
On the basis of the pharmacodynamic and pharmacokinetic profile, reported adverse reactions and/or specific studies in a relevant target population addressing the performance related to driving and road safety or using machines, specify whether the medicinal product has a) no or

negligible influence b) minor influence, c) moderate influence or d) major influence on these abilities. Other important factors that affect the ability to drive and use machines should be considered if known, e.g. duration of the impairing effect and the development of tolerance or adverse reactions with continued use. For situations c and d, special warnings/precautions for use should be mentioned here (and also in section 4.4 for situation d)

Despite the above mentioned regulations, at this moment, a European categorisation system has not been established yet, and warning systems for potentially driving impairing medicines have mainly been developed and/or implemented at national levels [1,7].

In 2008 Pil et al. performed a review of the existing systems for the classification of medicines and driving [8]. This review was carried out within the Driving Under the Influence of Drugs, Alcohol and Medicines (DRUID) project [9], and identified 15 systems. According to this document, the Netherlands were the first country to introduce a list of medications that can impair driving abilities, in 1973. This list was prepared by the Royal Dutch Society for the Advancement of Pharmacy (KNMP) and the use of a yellow warning label on medication boxes was established. This list was updated in 2008 in conjunction with a campaign of the Dutch Ministry of Transport, Public Works and Water Management and the Ministry of Health, Welfare and Sports, and the Contra-indication “Participation in traffic” was developed where the use of three different categories was set up [10]. In particular, it was established that this three-category-system had to be implemented in the electronic systems of general practitioners and pharmacists, and could also be used as a background document by Dutch Driving Licensing Authority (CBR) while processing the applications for a new driving licence or the renewal of driving licences of professional drivers and drivers older than 70 [10].

In 1981 a warning label was launched and adopted in the Nordic countries (Denmark, Finland, Iceland, Norway, and Sweden). The label consisted of a red triangle printed on packages of “especially dangerous” medications, and, at the moment, it is still in use in Denmark, Finland, and Norway.

Greece was the next European country to introduce a sort of indication concerning the influence of medications on the ability to drive. The Greek system was adopted in 1987, and, despite it is not a real categorisation system, it provides a warning about the risks associated with possible driving impairing medicines.

Another categorisation system was proposed in 1991 by Wolschrijn and colleagues. This system was based on expert ratings, consisted of 7 categories, and covered more than 500 medications [11].

The Wolschrijn categorisation was used in 1997 by the Federal Union of German Associations of Pharmacists (ABDA) who developed a brochure for health care professionals (HCPs) based on the mean values of the above mentioned classification. Later on, in 1999, Belgium elaborated its own categorisation list and used the same system proposed by Wolschrijn et al., as well [12]. Similar categories as the Wolschrijn ones were also used in Portugal, in 2004, but, in this case, a five-level system was developed and adopted as a basic instrument for a proper medication use.

In 1999, France introduced a warning label to indicate potential effects on driving performance. This system did not last long, because it was believed that because it was believed that it several significant downsides [8]. Later on, in 2004, a new warning sign on boxes of medications which could constitute a hazard to traffic safety. This sign was removed after a few years, but, in 2005, the “Journal Officiel de la République Française” published a classification system for medications according to their influence on driving performance which is legally binding and classifies the medications according to three levels of driving impairment [13].

A three-level system was also issued in Spain, in 2001; this system was updated in 2002 and 2005, and this latter update introduced a forth category to rate all those medications which are supposed to impair driving-related skills.

Finally, in 2006, the International Council on Alcohol, Drugs and Traffic Safety (ICADTS) published a list of 389 driving impairing medications; this list is based on the Belgian, French and Spanish classification systems and it contains 3 categories which refer to 3 different levels of impairment [14]. The ICADTS list was recently used as a background document by Slovenia which developed and adopted its own categorisation system in 2008. The Slovenian categorisation system is also based on three categories which indicate the influence of each active substance on fitness to drive and are reflected in the warnings and labels that are printed in the documentation accompanying the medication [15].

Although different categorisation systems are currently available across Europe, it is important to point out that none of these classifications have clearly described or published the criteria for the establishment of a categorisation system for potentially impairing medications nor were officially adopted at European level [8].

The main aim of DRUID Work Package (WP) 4 is to provide the bases and the methodology for the development of a European classification system for medications with respect to their impact on the ability to drive. Furthermore, DRUID WP4 also aims to provide a classification of relevant therapeutic groups of medicines that are currently on the market, in Europe, as well as new medications approved by the European Medicines Agency (EMA) in the years 2007 - 2009 [9].

2.2. The DRUID categorisation/labelling on medicines and driving.

The DRUID WP4 expert group established and agreed that, according to its influence on the ability to drive, a medicine could be categorized as follows regarding driving (Figure 1):

- category 0 (no or negligible influence on fitness to drive),
- category I (minor influence on fitness to drive),
- category II (moderate influence on fitness to drive),
- category III (severe influence on fitness to drive).

This was in line with the recent approved SmPC guidelines adopted in September 2009 by EMA (please see Table 1), proposing that in section 4.7 ”Effects on ability to drive and use machines” it should be specified whether the medicinal product has a) no or negligible influence b) minor; c) moderate influence or d) major influence on these abilities.

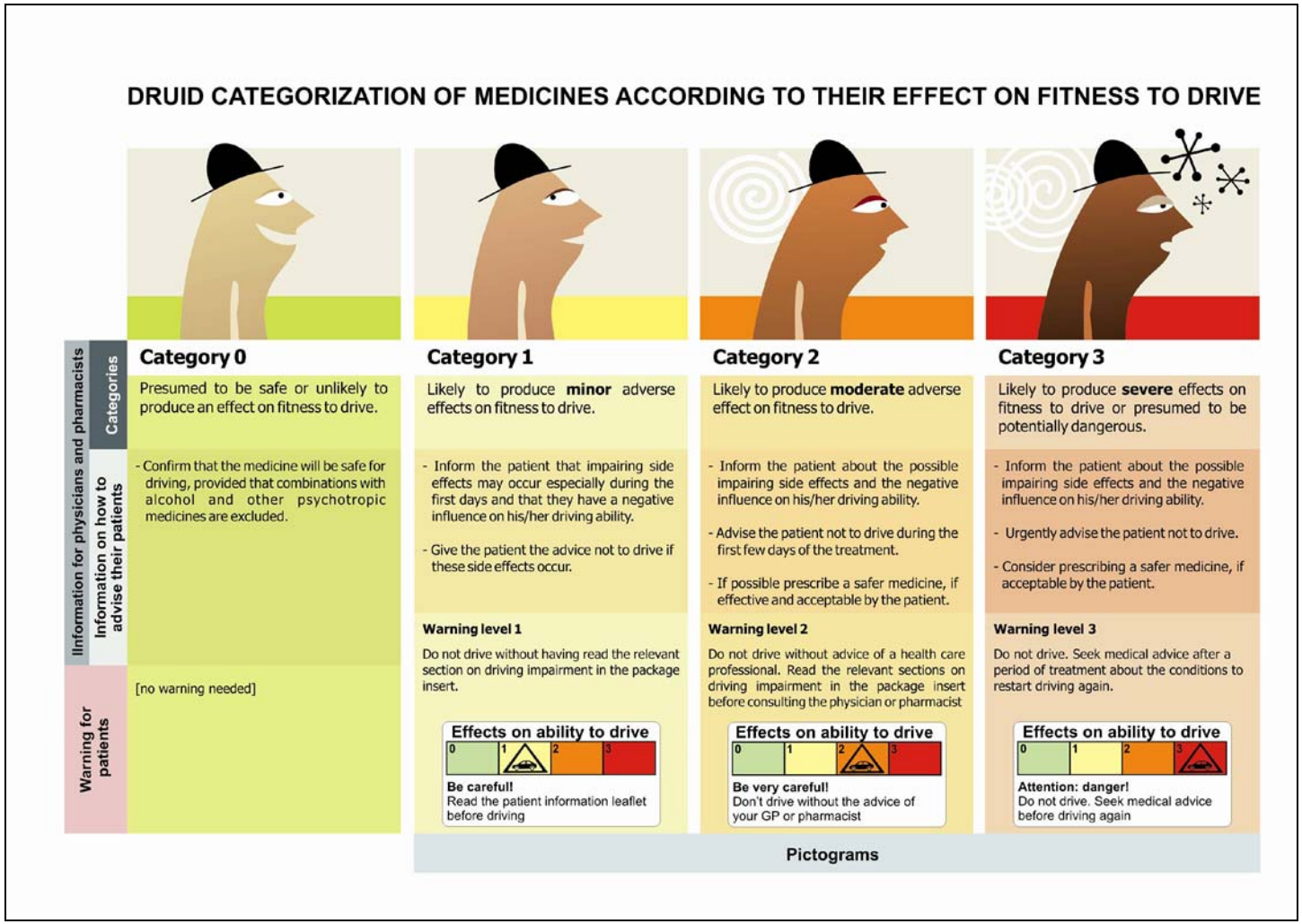

Figure 1: DRUID Categorisation and labelling system for medicines and driving.

2.3. The DRUID methodology on categorisation on medicines and driving.

The development of the DRUID categorisation system was based on the criteria that were established by a group of experts in the field of drugs and driving, involved in DRUID WP4, and based on their consensus [9].

The selection of the active substances was done by means of an inventory of all available medicines in some European countries such as Belgium, France, Germany, Greece, the Netherlands, Spain, United Kingdom and Ireland. Old medications or medications available in only one of the previously mentioned countries were not included in the categorisation process. Figure 2 shows the process of identification if a medicine is available at the European Union market.

After the joint meetings with the French Health Products Safety Agency (AFSSAPS) experts in categorizing medications affecting driving performance, the DRUID group decided to adopt a procedure similar to the one that was used in France, and, specifically, to evaluate the following information and data:

0. Conditions of use of the medicine at the European Union market.
1. Pharmacodynamic and pharmacokinetic data
2. Pharmacovigilance data (including prevalence of unwanted effects reported in the SmPC)
3. Experimental and epidemiological data
4. Additional data derived derived from the Patient Information Leaflet (PIL) and existing categorisation systems [16], and information from other sources.
5. Synthesis

Basically, conditions of use of the medicine, pharmacodynamic and pharmacokinetic data, pharmacovigilance data (including prevalence of unwanted effects) were derived from the SmPC, while section 3 was based on a scientific literature serach.

Figure 3 and Figure 4 summarize the methodology and process followed in assigning a category on driving to a medicine available at the European Union Market.

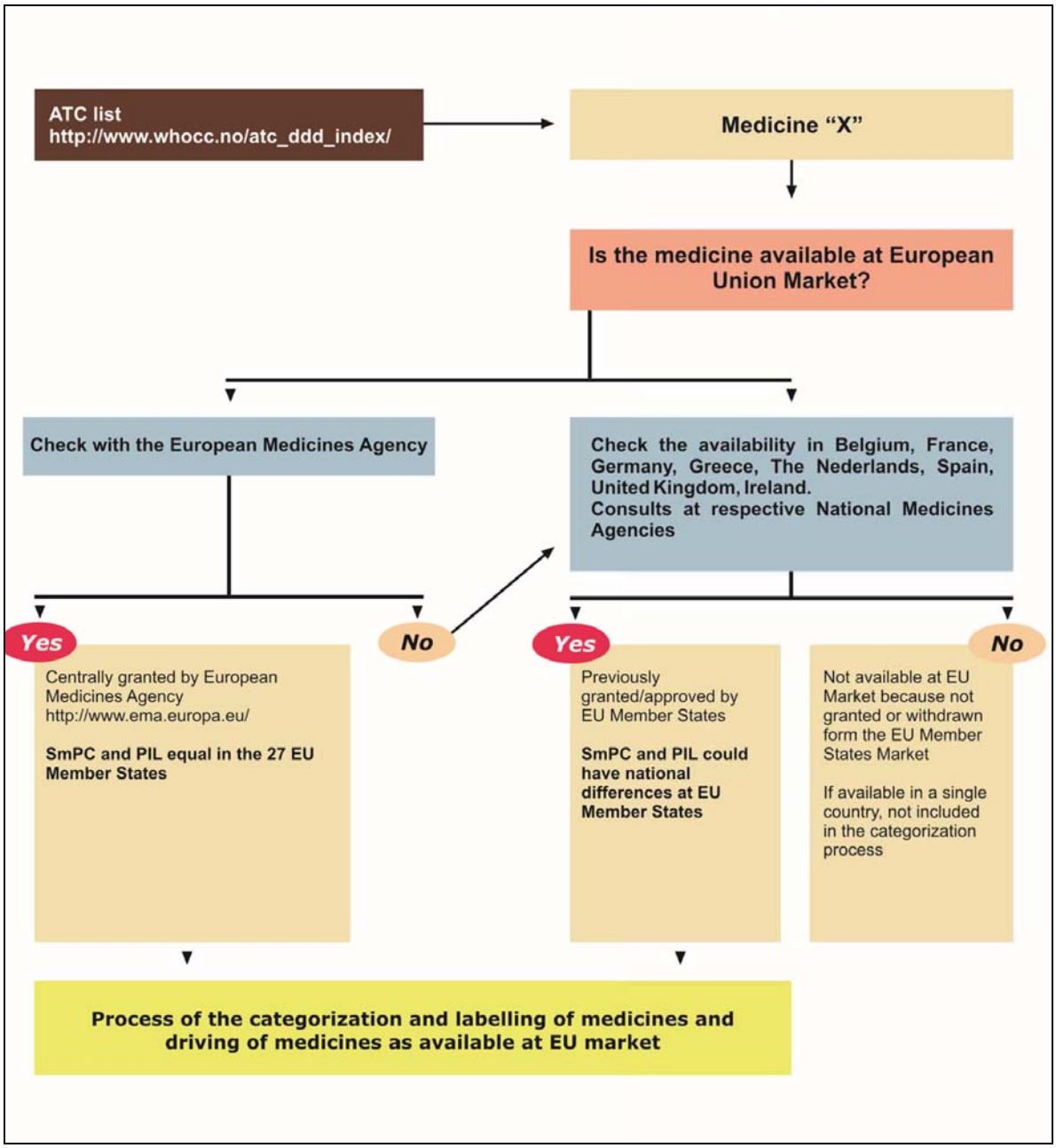

Figure 2: Process of identification if a medicine is available in the European Union market.

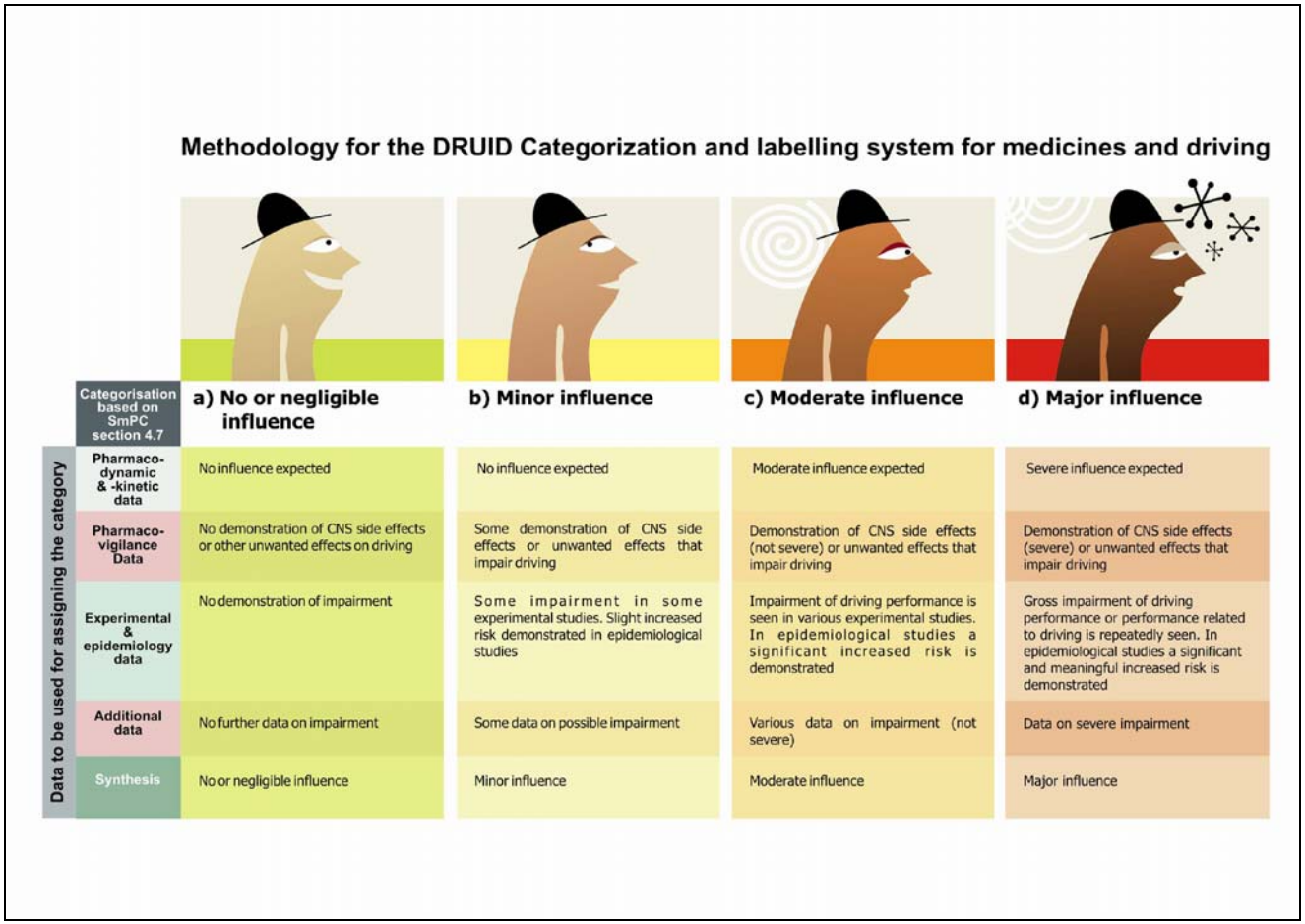

Figure 3: Methodology for the DRUID Categorisation and labelling system for medicines and driving.

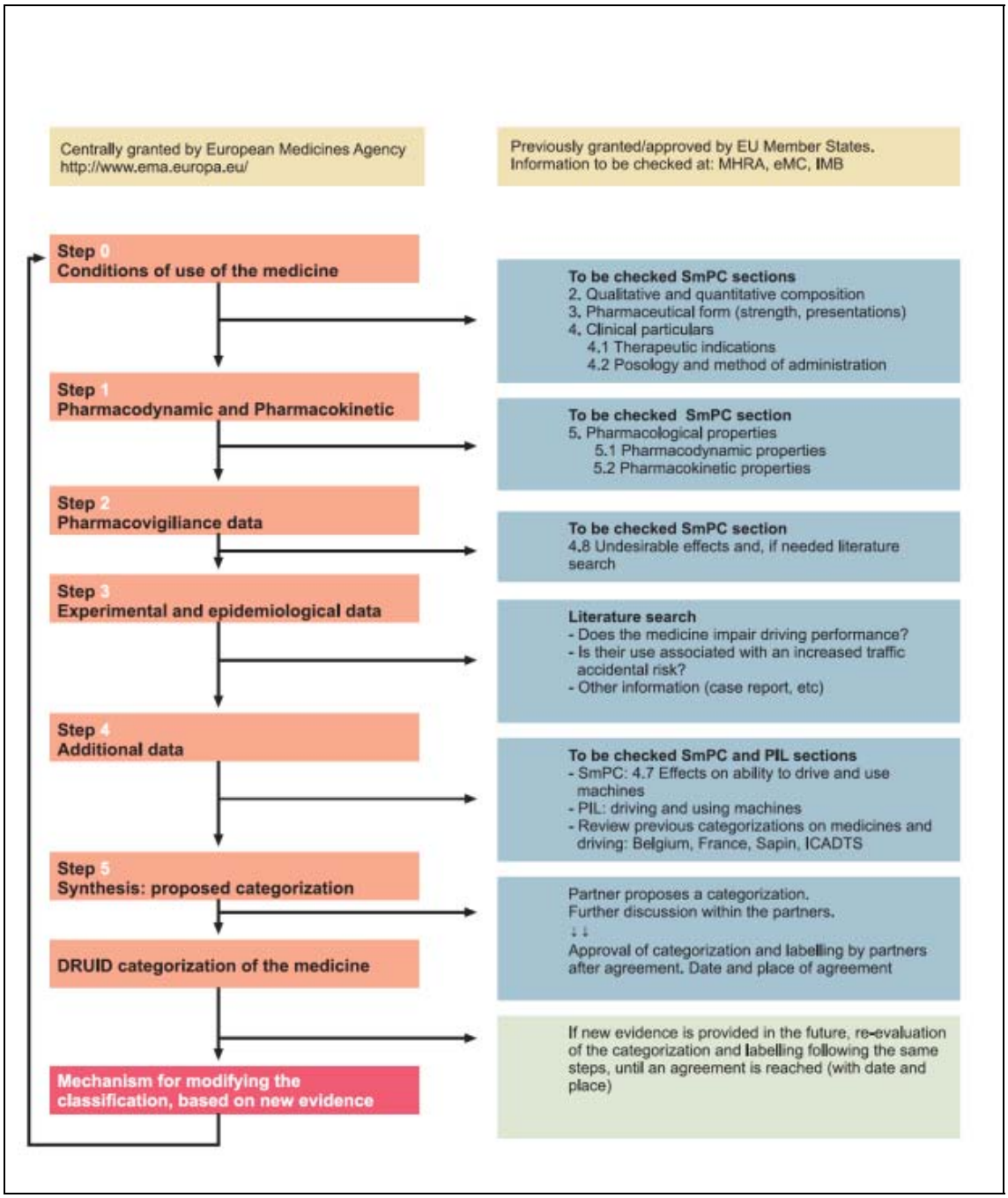

Figure 4: Flowchart representing the methodology that was followed during the DRUID categorisation process.

Legend: SmPC: Summary of Product Characteristics
PIL: Patient Information Leaflet
EMA: European Medicines Agency
MHRA: Medicines and Healthcare products Regulatory Agency
eMC: Electronic Medicines Compendium
IMB: Irish Medicines Board

The SmPC and PIL of the selected medications were found online, in one of the following websites: Medicines and Healthcare products Regulatory Agency (MHRA) [17], Electronic Medicines Compendium (eMC) [18], and Irish Medicines Board (IMB) [19], or, if needed, retrieved from national regulatory agencies. In case of recently approved active substances, the SmPC and PIL were found on the EMA website [20]. The selection of the above mentioned regulatory affairs agencies was simply based on the fact that the required information had to be available either in English or in a language that could be fully understood by DRUID WP4 partners.

Specific sections of the SmPC and PIL were used to retrieve details on the active substance presentations and strength, indications, posology, route of administration (step 0), pharmacodynamic and pharmacokinetic profile (step 1), effects on the ability to drive and use machines (step 4), and undesirable effects related to driving and operating machines (step 2).

During the activities in Task 4.3 on categorisation of the existing medicines, the occurrence of undesirable effects was considered as key information for categorising some medicines, in circumstances that information on experimental studies for assessing a medicine's effect on driving or skills related to driving or epidemiological data was lacking or limited. For that reason, section 4.8 of the SmPC was used (as well as specific literature search, if necessary). Recently, EMA has started to use the following categorisation on frequency of undesirable effects, side effects or adverse reactions:

- very common (>1/10)
- common (>1/100, <1/10)
- uncommon (>1/1,000, <1/100)
- rare (>1/10,000, <1/1,000)
- very rare (<1/10,000)
- not known (cannot be estimated from the available data, since no valid estimate can be derived from clinical trials or epidemiological studies).

DRUID Partners have taken into account this categorisation of undesirable effects, side effects or adverse reactions in their categorisation framework for medicines and driving. Firstly by considering those effects categorised as very common (>1/10) and common (>1/100, <1/10), and secondly, those undesirable effects that can potentially impair the fitness to drive safely. In case rare or very rare unwanted effects or certain severely impairing effects occur, for example sudden sleep attacks, DRUID Partners recommend that this should be mentioned in the patient information leaflet.

The following criteria were used for assigning a medicine to a specific category, in case experimental or epidemiological data are lacking (Table 2).

Table 2: Relationship of the undesirable effects category in the SmPC to the DRUID categorisation system.

Declaration of undesirable effects that can potentially impair the fitness to drive safely	**DRUID Category**
Very common (> 1/10)	Category II or higher
Common (>1/100, <1/10)	Category I (or II)
Rare (>1/10,000, <1/1,000) or very rare (<1/10,000)	Category 0

In Table 3 all relevant potentially undesirable effects to be considered when categorising the effects of medicines on driving are listed.

Table 3: Undesirable effects that can impair the fitness to drive grouped by system organ class.

System organ class	Selection of undesirable effects that can impair the fitness to drive safely
Nervous system disorders	▪ Somnolence, dizziness, drowsiness ▪ Confusion - cognitive disorder- disorientation – co-ordination disturbances ▪ Involuntary movement disorders: ataxia, tremor, Parkinsonism, acute dystonic (dyskinesia) and dyskinetic reactions (dystonia) ▪ Convulsions – seizures ▪ Muscle weakness
Psychiatric disorders	▪ Perception disturbances (hallucination, visual hallucination, auditory hallucination, illusion) ▪ Psychotic reactions and psychotic disorder (including paranoia psychosis) ▪ [Other: Emotional lability, mood swings, aggression, nervousness, irritability, personality disorders, thinking abnormal, abnormal behaviour, euphoric mood, restlessness (emotional state of excitement), depersonalisation]
Eye disorders	▪ Diplopia or double vision ▪ Blurred vision ▪ Accommodation disorders ▪ Visual acuity reduced ▪ Photophobia ▪ [Other: visual field defect, peripheral vision loss, altered visual depth perception, oculogyric crisis].
Ear and Labyrinth disorders	▪ Vertigo ▪ Hearing loss ▪ [Other: buzzing, tinnitus]
Metabolism and nutrition disorders	▪ Hypoglycaemia
Vascular disorders	▪ Hypotension

Data sources for the scientific literature evaluation were the electronic databases Medline, Science Direct, and PsycINFO. The search was performed by using (at least) these combinations of keywords: “active substance name and psychomotor performance”, “active substance name and automobile driving”, and “active substance name and traffic accidents”. The final data selection was limited to full text articles, not only published in English, and referred to side-effects, experimental and pharmacoepidemiological studies, case reports on each active substance to be categorized and its possible driving impairment. No restrictions concerning the publication year were applied.

In case of severely impairing, recently approved medications, and medicines for ATC groups N and R06, all the collected data were compiled in fact sheets, with a standardized lay-out, which were used during the active substance evaluation procedure and the approval of its final category.

Additional steps consisted of reviewing section 4.7 of the SmPC “Effects on ability to drive and use machines” and the PIL section on “Driving and using machines” as well as reviewing the

previous categorisation (if available) of the medicine in Belgium, France, Spain and the ICADTS list.
After evaluating all the available data, a provisional category was assigned to each active substance. The provisional category was proposed and discussed during WP4 meetings where a final and definitive category was assigned and approved by all WP4 partners.

2.4. A mechanism for modifying the classification, based on new evidence.

The existing methodology on DRUID categorisation on medicines and driving allows categorise the medicine or to confirm the previous categorisation following again the same 5 step process, if new evidences emerge (Figure 4).

2.5. Discussion

The current DRUID categorisation system established and defined standard and harmonized criteria to categorize new and old active substances, based on their influence on the ability to drive. Up to date, this system nearly embraces the full ATC index and it intends to provide a complete coverage of the most commonly prescribed medications in Europe. The categorisation procedure was developed by a European group of experts and was meant to go beyond a national context in order to reach a broader European scenario and involve different facets of the health care practice.

The categorisation system could be seen as a tool to improve prescribing and dispensing procedures both at a national and European level, and, therefore, as a instrument to better inform and involve HCPs (Health Care Professionals) [21]. With this respect, it is important that HCPs know the fundamentals of the categorisation system, and, consequently, use it properly in order to fully inform their patients about the risks of driving under the influence of impairing medicines. Furthermore, HCPs should be able to distinguish between the four levels of impairment, and, therefore, if possible, choose the least impairing medication within the same therapeutic group. Moreover, this system should encourage HCPs to update their knowledge on medicines and driving in order to be prepared to answer questions that patients might have on this topic [1, 22].

The DRUID categorisation system should also be used as a tool to motivate health care professionals to provide patients with clear information, communicate to patients the risk associated with driving under the influence of medicines, and start HCP-patient discussion leading to both safer prescriptions and the patient's conscious decision whether to drive or not [1, 21].

From the patient point of view, this classification could play an active role in helping them to be involved along the decision-making process, to understand the hazards of some medications to traffic safety, and to remind them to use caution while driving until their individual responses to the therapy have been well established.

To our knowledge, this is the first time that the European Commission (EC) assigned an expert group in the field of drugs and driving the task of establishing the criteria for a European classification system and developing a categorisation system for relevant therapeutic groups of medications with respect to their impact on driving skills. The categorisation efforts were carried out by an international group of DRUID partners, coming from 6 different institutions in Europe, and gathered all their scientific competence, knowledge, expertise, and experience in the field of road safety research and practice. All the available data, coming from different sources, were collected according to a standardized step-by-step procedure which, on the one hand, allows the future maintenance of the current DRUID categorisation system, and, on the other hand, constitutes a consistent evidence-based classification methodology to categorize new medications, prior to their market authorization. Last but not least, as reported above, the DRUID categorisation system almost encompasses the entire ATC list, and, therefore, provides a nearly complete overview of the influence of frequently prescribed medications on the ability to drive; additionally, in case of severely impairing and new medications, it is integrated with fact

sheets which concisely emphasize the categorisation key-points and can be used as a support in HCP daily practice [9].

Lastly, some limitations of the DRUID categorisation system should be considered. In particular, special attention should be paid to the fact that a category is attributed to the single active substance, given to an adult, for its main indication, in an normal dosage, and at the start of the treatment [1, 5, 8]. Therefore, if a medication is not prescribed according to these conditions, it is crucial to bear in mind that the categorisation system can only be used as background information, and it is necessary to carefully assess all the individual risk factors and avoid strict adherence to the medication classification. Furthermore, the system is focused on the effects of medications on the ability to drive and, consequently, the role of the disease, which could also influence the driving ability, is not considered and certainly needs further attention while counselling the patient [1, 5].

2.6. Next steps and recommendations

The categorisation system presented in this manuscript was developed within the DRUID project, and, therefore, in a European context. As a consequence, it is suggested that European regulatory authorities will be informed about this categorisation process, discuss and reach consensus on the criteria hereby proposed, and carry out special efforts to implement the current system at both international and national level, considering country specificities, as well. Since the categorisation needs a constant revision, it is also advised that an expert working group on drugs and driving could be established in order to keep the system functional, up-to-date, and reliable.

Furthermore, it is recommended that special attention will be paid in educating those subjects who might play an active role in traffic safety. With this respect, medical and pharmacy schools could develop targeted educational programs covering the issue of medication use and driving whereas police officers and driving instructors could be adequately trained on this topic in order to be able to transfer the message to potential patients who also participate in traffic.

Finally, a guideline should be developed to explain the use of the categorisation system to HCPs and to serve as a support in the decision making process. On the other hand, since the patient package leaflet is the most accessible source of information for patients, it would also be advisable to develop an effective strategy to communicate the risk related to the use of medicines and driving. For instances, a straightforward grading system could be included in the patient package leaflet and the use of pictograms (warning labels) could be printed on the medication box to provide clear directions for patients.

2.7. References

1. de Gier JJ, Alvarez FJ, Mercier-Guyon C, Verstraete AG (2009) Prescribing and dispensing guidelines for medicinal drugs affecting driving performance. In: Verster JC, Pandi-Perumal SR, Ramaekers JG, de Gier JJ (eds) Drugs, Driving and Traffic Safety. Birkaeuser Verlag AG, Basel - Boston - Berlin, pp 121-134

2. Augsburger M, Rivier L (1997) Drugs and alcohol among suspected impaired drivers in Canton de Vaud (Switzerland). Forensic Sci Int 85:95-104

3. Drummer OH (2008) The role of drugs in road safety. Australian Prescriber 31:33-35

4. European Council Directive 83/570/EEC of 26 October 1983. In: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31983L0570:EN:HTML

5. Alvarez FJ, del Rio MC (1994) Drugs and driving. Lancet 344:282

6. European Commission - Enterprise and Industry Directorate - General: A guideline on Summary of Product characteristics (SmPC) - September 2009. In: . ec.europa.eu/health/files/eudralex/vol-2/c/smpc_guideline_rev2_en.pdf

7. de Gier JJ (1998) Drugs and driving research: Application of results by drug regulatory authorities. Human psychopharmacology: Clinical and Experimental 13:S133 - S136

8. Pil K, Raes E, van den Neste T, Goessaert AS, Veramme J, Verstraete AG (2008) Review of existing classification efforts. In: http://www.druid-project.eu/cln_007/nn_107534/Druid/EN/deliverales-list/deliverables-list-node.html?__nnn=true

9. Driving Under the Influence of Drugs, Alcohol and Medicines - DRUID. In: http://www.druid-project.eu/

10. Contra-indicatie Verkeersdeelname - Contra-indication “Participation in traffic” (in Dutch). In: www.geneesmiddeleninhetverkeer.nl

11. Wolschrijn H, de Gier JJ, de Smet PAGM (1991) Drugs and driving: A new categorisation system for drugs affecting psychomotor performance.

12. Grenez O (1999) Invloed van geneesmiddelen op de rijvaardigheid, Brussel, Belgisch Instituut voor de Verkeersveiligheid vzw, VI-12.

13. Arrêté du 18 juillet 2005 pris pour l'application de l'article R. 5121-139 du code de la santé publique et relatif l'apposition d'un pictogramme sur le conditionnement extérieur de certains médicaments et produit. In: http://admi.net/jo/20050802/SANP0522726A.html

14. The International Council on Alcohol, Drugs and Traffic Safety - ICADTS . In: http://www.icadts.nl/medicinal.html

15. Various authors. Rules on labelling of medicinal products and on the packaging leaflet - Official Journal of the Republic of Slovenia, No. 54/06 and the Medicinal Products Act (Official Journal of the Republic of Slovenia, No. 31/06).

16. de Gier JJ, Ravera S, Monteiro,S.P. and the DRUID Work Package 4 Partners (2011) Establishment of criteria for a European categorisation system for medicines and driving - DRUID Deliverable 4.2.1.

17. Medicines and Healthcare products Regulatory Agency- MHRA. In: http://www.mhra.gov.uk/index.htm

18. Electronic Medicines Compendium - eMC. In: http://www.medicines.org.uk/

19. Irish Medicines Board - IMB. In: http://www.imb.ie/EN

20. European Medicines Agency - EMA. In: http://www.ema.europa.eu/ema/index.jsp

21. Talbot J, Stephens MDB (2004) Clinical trials: – Collection of safety data and establishing the adverse drug reaction profile. In: Talbot J, Stephens MDB (eds) Stephens' Detection of New Adverse Drug Reactions, 5th edn. John Wiley and Sons, Ltd, Chichester, West Sussex, United Kingdom, pp 167-242

22. Agence française de sécurité sanitaire des produits de santé (AFSSAPS) - Medicinal products and driving (02/07/2009). In: http://www.afssaps.fr/Afssaps-media/Publications/Information-in-English

3. Internal document: Position paper on Harmonization of procedures for classification/labelling on medicines and driving (2008)

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3.1. Introduction

In this position paper it is suggested to build on the experiences from the French experts in categorizing medicines affecting driving performance. It was agreed by WP 4 partners to follow up on their discussions in Task 4.3 (Establishment of a framework for classification/categorisation and labeling of medicinal drugs and driving). Therefore this position paper will focus on the procedures that are recommended within such a framework.

Harmonization at the level of categorizing medicinal substances could be achieved by adopting the French approach for the classification of active substances. In this approach it is stated that the risk of impairment after taking a medicinal product on the ability to drive depends on several factors:

- The pharmacodynamic effect of the medicinal product, knowing that the more serious this effect is (for example from mild sleepiness to sudden sleep), the more dangerous it will be for driving;

- Individual sensitivity, the same dose of the same active substance can have variable effects according to subjects' sensitivity to the substance (example: systemic antihistamines) or to subjects pathology.

This individual sensitivity may concern a great number of treated patients while a substance induces very common or common unwanted effects: in these circumstances with no known pharmacodynamic mechanisms, clinical trials have a great interest in order to specify the prevalence of unwanted effects as well as the relations to changes in behaviour, convulsions, involuntary movements, psychotic reaction, etc.

Pharmacovigilance data are mainly useful for severe or un-expected unwanted effects.

- Conditions of use: doses administered interactions with other medicinal products, interaction with alcohol, etc.

As a consequence, each of these factors cannot be considered separately and the level of risk attributed to a medicinal product shall be the result of all these factors. The categorisation will have to reflect the overall impairment of these factors on the ability to drive, and translate these into three correctly defined levels.

For the medicinal products which have the least impairing effect on driving, it is obvious that the risk depends primarily on the patient's individual sensitivity. Then, as the pharmacodynamic effect on the ability to drive increases, individual sensitivity decreases to become second if the whole population of treated drivers is considered. Finally, for the most dangerous medicinal products, deleterious effects appear in a constant manner in all exposed patients. In order to define the warning level, the contribution of the pharmacodynamic effect on driving is therefore predominant. But potentially dangerous secondary effects, which can notably be identified using the pharmacovigilance data, are also taken into account.

The warning level corresponds to the presumed impact of the medicinal product on the ability to drive. The grading scale may be similar to the scale which the World Health Organisation (WHO) uses in pharmacovigilance to evaluate the seriousness of the impact of the undesirable effects on everyday life.

As the effects likely to have an impact on driving can be varied and multiple, it is necessary to draw up a list of these various effects but to establish one grading only for the overall impact of the medicinal product on the ability to drive.

The problem of some unexpected and severe effects (for example, sudden sleep induced by dopaminergic agonists), which cannot always be predicted in view of the pharmacodynamic properties of the medicinal product, may sometimes arise. This is the reason why pharmacovigilance data should systematically be searched for.

Next to the pharmacovigilance data, the experimental data and the epidemiological data (when they exist) need to be reviewed as well as various additional data [influence of the dose, the pharmaceutical form, the route of administration, the interactions with other medicinal products, the interaction with alcohol, the pharmacokinetic data, the concerned pathology(ies), the misuse data].

To simplify procedures, the evaluation of categorisation is first performed according to the active substance (according to the ATC classification). However, it is also necessary to take in account factors related to the various available medicines which can possibly modify the warning level attributed to the active substance, e.g. the excipients (excipient with a notorious effect), the route of administration, the conditions of use and the general classification for supply (prescription only, OTC or self-medication).

3.2. Evaluation by following different steps

The categorisation by experts includes several steps of evaluation:

1. Pharmacodynamic and pharmacokinetic data
2. Experimental and epidemiological data
3. Pharmacovigilance data
4. Additional data
5. Synthesis

3.2.1. Pharmacodynamic and pharmacokinetic data

Identification of a side effect able to interfere with driving performance is first carried out by reviewing the expected effect regarding to the pharmacological profile. In particular by identification of the pharmacodynamic properties likely to have an effect on driving is carried out on the basis of the SmPCs of the corresponding medicines, the marketing authorization

application dossiers and references (i.e. Goodman & Gilman's, Martindale…). Related medicines can also be examined (same chemical family or same pharmacological class) likely to modify the ability to drive. The pharmacodynamic effects are known thanks to the in vitro studies (for example, GABA receptor affinity studies), the other pre-clinical and clinical studies. These expected effects are frequent but may be more severe if there are other interfering factors (pathology, old age, renal or hepatic insufficiency, etc.). Some pharmacodynamic effects (for example, disinhibition associated with anxiolytics) may be less frequent, while these effects occur only in specific conditions; however, these effects may modify the driving behaviour. Pharmacodynamic effects studies need to include not only sedative (hypnosis; sleep attacks, etc.) effects but also other effects (cognitive, behavioural, visual, cardio-vascular effects). Pharmacodynamic tolerance may explain the sedative effects only during the first days of psychotropic drug treatment and some written cautions in the Summary Product Characteristics (SmPC) for this period. Clinical pharmacokinetic studies may give sufficient information about drug effects due to various drug liposolubility, bioavailability, distribution volume, Blood-Brain-Barrier permeability, different half-lives, drug metabolites activity and the consequences of age, renal or hepatic insufficiency.

Pharmacokinetic studies show also the possible drug-drug interactions and their expected clinical effects.In order to inform the health professional and the patient, it is important to define the time after which the ability to drive is back to normal, in particular for the medicinal products with the highest level of risk.

For a same active substance but different medicinal specialties, the categorisation may also differ with different routes (oral or parenteral use) of drug administration.

3.2.2 Experimental and epidemiological data

Demonstration of the impairing effect can be obtained through study of frequency and intensity of this effect. This can be achieved by

- Preclinical, clinical or epidemiological studies may predict or summarize the frequency and intensity of unwanted effects

An effect linked with dose - blood concentration?

The pharmacodynamic studies may give (or not) good correlations between drug administrated dose, blood concentrations and clinical effects. This may induce, after evaluation, proposals of a different drug categorisation in case of different uses, indications, doses, and pharmaceutical specialties.

Clinical trials have a great interest in order to specify the prevalence of unwanted effects as well as the relations to changes in behaviour, convulsions, involuntary movements, psychotic reactions, etc. These data give new informations about common effects and are arguments to scale up the score of categorisation.

Epidemiological studies give informations about the relative risk of accidents when drivers use some drugs when driving (for an example, benzodiazepine anxiolytics increase approximately two times the accident relative risk in European countries).

For another example, data about a possible increase of accident reports and varenicline which is indicated for nicotine dependence treatment need to be detailed and evaluated by experts. The mechanisms of this possible relationship between varenicline and accidents need also to be specified (unwanted psychiatric, vigilance, cognitive effects due to the drug or to the drug withdrawal syndrome)

- Concerning specific studies

Have they been conducted?

A reference research is necessary in order to look for specific studies. Evaluation of the quality of the studies has to be done by experts. The published data only are examined (evaluation tests, especially with psychomotor and cognitive effects studies, epidemiological studies, reported cases), taking into account their level of evidence. Potential data on related medicines can be taken into consideration as in the first step. When they exist, experimental and epidemiological data will lead to:

- either confirm the warning level, or

- re-examine the level (scaling up or down) depending on these data's relevance.

In case of lacking specific studies, evaluation of drug effects may be possible or not. In the last case, new specific studies may be proposed in order to categorise drugs. The type of studies needed for this purpose can be derived from a document developed by the ICADTS Working Group on Guidelines on experimental studies undertaken to determine a medicinal drug's effect on driving or skills related to driving (see www.ICADTS.org)

Risk Management Plan may include the need of other specific studies. New pharmacovigilance data may induce the need of new specific studies to define the conditions of occurrence of the unwanted effects and the proposals to prevent them.

3.2.3. Pharmacovigilance data

Identification of unexpected effects is carried out by reviewing pharmacovigilance data. Data are collected at the European Pharmacovigilance Evaluation Network. They clearly influence the evaluation of a drug during the post marketing period. The pharmacovigilance data allow identifying undesirable effects (unexpected, new or unpredictable effects) which could seriously alter the ability to drive. The evaluation of pharmacovigilance data (data derived from literature, spontaneous notifications to the national pharmacovigilance system) leads to one of the three following outcomes:

- The pharmacovigilance data don't give any additional information;

- The pharmacovigilance data confirm the pharmacodynamic data;

- The pharmacovigilance data give new information which has to be taken into account; in this case, it seems to be necessary to scale up the score obtained in the categorisation. In some cases, pharmacovigilance data may give new informations indicating that some drugs have less unwanted effects (less sedative effects in a new therapeutic class, etc.): these data may induce a scaling down of the score of categorisation.

For example, in case of unexpected sleep attacks, the pharmacovigilance network may induce a proposal of a modified SmPC in order to prevent consequences of sleep attacks on driving. These unexpected data may also induce a Risk Management Plan (RMP) including a Risk Minimisation Plan about drug effects on driving behaviour.

Level of demonstration of the effect

Expected and unexpected effects may give a level of demonstration which is influenced by the quality of the studies and case reports, the number of treated patients, the duration of studies and follow-up.

a. Confirmation by specific studies

Some specific studies may have been carried out and may define more precisely the drug influence on (experimental or actual traffic) driving. These studies may inform about the lack of significant drug effect or an increasing relative risk of a drug effect on driving.

b. No demonstration of any drug effect (in case of performed studies)

Some studies provide proof of absence of a drug's impairing side effect.

c. Lack or insufficiency of experimental data

Some studies may lack or may be insufficient to conclude about a drug effect on driving for many reasons which must be detailed and discussed in evaluation process.

3.2.4. Additional data

Additional data are needed to answer several questions, such as: is the frequency of the effect quantifiable?

a) With available data

Unwanted effects may be dose dependent effects. Available data may give an evaluation of the effect frequency which can be different in case of increasing doses of the same active substance in different pharmaceutical specialties: therefore, the categorisation may be different for these various pharmaceutical specialties. The categorisation may also differ with different routes of drug administration. Even if specific (preclinical and clinical) data for each drug may be asked, data may be available only for substances of the same pharmacological class of the evaluated drug: in this case, even if some pharmacological and pharmacokinetic differences may exist and modify the drug scaling, comparison with drugs of the same class may help the harmonization of the drug categorisation.

b) With specific data

Experimental data, case reports or epidemiological studies may be specific with a drug effect on drug driving abilities and accidents. Drug categorisation evaluation takes in account all these data.

The effect is influenced by several factors which have to be taken into account before the final evaluation can start. The following factors need to be addressed:

- Patient's age

Age dependent physiological neurological and cognitive evolution may be increased by various drugs i.e. sedative, myorelaxant and anticholinergics. With increasing patient's age, renal and hepatic functions decrease: for these reasons and for age-dependent increasing fat body weight, drug elimination half life may increase.

- Alcohol use

Many psychoactive drugs effects are potentiated by ethyl alcohol. In some drug evaluation, contra-indication of alcohol drinking during the treatment may be written in the SMPC, while data have described the noxious effects of an interaction between a drug an ethyl alcohol..

Some medicinal products (phlebotonics, etc.) may contain ethyl alcohol ; in these cases, if the maximum daily dosage contains a sufficient quantity of alcohol (for example, more than 3g of alcohol) which may disturb driving abilities, there will be a need of information and a pharmaceutical specialty categorisation due to the alcohol effects.If the medicinal product contains an important quantity of alcohol and another substance likely to have effects on driving ability, the expected interaction must influence the specialty's categorisation.

- Combination with other medicinal drugs

Drug interactions are frequent and induce many unwanted effects. There may be an addition, a synergy or potentiation of effects. Interactions may worsen effects when two drugs have the same type of pharmacodynamic effects. Pharmacokinetic interactions (for example, hepatic

microsomial cytochrome P 450 inhibitors) may also induce serious side effects with the increasing inhibited drug blood concentration. These interactions are written in the SMPC. The categorisation does not usually take in account the risks of interaction, unless the two drugs are combined in the same pharmaceutical specialty.

- Pathology

It is necessary to take in account the identification of an indication which makes driving inconsistent. For example, ambulatory surgery needs the use of anaesthesic drugs : the anaesthesist has to specify the necessary interval of time after what the patient is allowed to drive. Benzodiazepine hypnotics are prescribed against insomnia: driving is not allowed during the drug sedative effects. Patient's pathology may be the necessary condition of the occurrence of an unwanted effect: antiparkinsonian drug sleep attacks are only described in Parkinson's disease. Some anticonvulsant drugs may paradoxically induce myoclonic effects in epileptic patients. Pathology itself may (chronically or occasionally) decrease the driving abilities.

3.2.5. Synthesis (Result of the evaluation)

Based on the different steps (or items), a classification notice takes up again the principal items justifying the active substance evaluation procedure. After the evaluation of drug pharmacodynamic, pharmacokinetic, preclinical and clinical pharmacological (clinical trials, pharmacovigilance) studies, epidemiological and additional data, the conclusion of the effect of a drug's effect is the result of the integration of three parameters: likelihood, frequency and intensity.

a. Likelihood

Several levels of likelihood are considered with definitions that are given as follows:

- Certain

A certain or very suggestive degree of likelihood in the drug-effect relationship is not usual unless the drug effects are known pharmacodynamic effects like mydriasis with mydriatics, or sedation with anaesthesics.

- Plausible

The likelihood in the drug effect may be plausible (for example, myorelaxant effects associated with drugs which interfere with GABA or glycine receptors, orthostatic hypotension effect associated with calcium antagonists).

- Doubtful, unlikely

The relationship between a drug and an unwanted effect may be doubtful, unlikely while pharmacological data and clinical data are not sufficient.

- Excluded

There may be no likelihood between a drug and an unwanted effect. The imputability of the drug may be incompatible, especially for chronological or for semiological criteria.

b. Frequency

It is difficult to take into consideration the sole frequency of occurrence of the effects, as those can turn out to be dangerous in any case. However, the frequency may help to influence the categorisation of the warning level:

- Very frequent (very common) : > 1/10
- Frequent (common) : > 1/ 100

- Not frequent (infrequent) : between 1/ 100 and 1/ 1000
- Rare or uncommon : between 1/ 10 000 and 1/ 1000
- Very uncommon : < 1/ 10 000
- Unknown (frequency cannot be estimated from the available data, since no valid estimate can be derived from clinical trials or epidemiological studies). For old medicinal drugs, there is often no available information. Other sources are needed like pharmacological or therapeutic reviews.
- No effect: when no demonstrated effect occurs on driving ability, the drug may be categorised as a drug with no effect on driving ability

c. Intensity

The evaluation of intensity of the effect(s) on the ability to drive is carried out according to the following scale.

- A mild effect may be defined as " not generally questioning the ability to drive",
- A moderate effect may be defined as "possibly questioning, in some cases, the ability to drive",
- A severe effect may be defined as "recommending not to drive".

Work sheet and evaluation

1. IDENTIFICATION OF POTENTIALLY PHARMACODYNAMIC EFFECTS AMENDING THE ABILITY TO DRIVE A VEHICLE

- Sedation
- Vision
- Behaviour
- Other

By type of effect:

2. ASSESSING THE LEVEL OF PROBABILITY AND THE EFFECT OF INTENSITY CHANGE THE ABILITY TO DRIVE A VEHICLE
(justification SmPC + any data from literature)
*for each type of effect, the outcomes **5.1, 4.7, 4.4, of SmPC** of the items are listed*

3. POSITION IN THE CLASSIFICATION

	Intensity of the pharmacodynamic effect on the performance		
Likelihood of the effect on the conduct	Minor	Moderate	Severe
Certain	I	II	III
Possible	I	II	III

The classification needs to take in account the case of no effect on the conduct

Repeat steps 2 and 3 for each type of effect identified

4. REPETITION OF STEPS 1, 2 AND 3 FOR EVERY TYPE OF EFFECTS IDENTIFIED
for each type of effect, the outcome of sections 4.8 or 4.4, of SmPC are listed

5. ADDITIONAL DATA
5.1 about drug interactions
5.2 about the association with alcohol
5.3 about the deadline beyond the capacity of conduct are recovered (when possible)
5.4 about the therapeutic indications possibly falling of pathologies modifying the capacity of conduct

6. SYNTHESIS

Examples of unwanted effects that can impair driving ability

System organ class	Selection of undesirable effects that can impair the ability to drive safely
Nervous system disorders	▪ Somnolence, dizziness, drowsiness ▪ Confusion - cognitive disorder- disorientation ▪ Involuntary movement disorders: ataxia, tremor, Parkinsonism, acute dystonic (dyskinesia) and dyskinetic reactions (dystonia) ▪ Convulsions -seizures
Psychiatric disorders	▪ Perception disturbances (hallucination, visual hallucination, auditory hallucination, illusion) ▪ Psychotic reactions and psychotic disorder (including paranoia psychosis) ▪ [Other: Emotional lability, mood swings, aggression, nervousness, irritability, personality disorders, thinking abnormal, abnormal behaviour, euphoric mood, restlessness (emotional state of excitement), depersonalisation]
Eye disorders	▪ Diplopia or double vision, ▪ Vision blurred ▪ Accommodation disorders ▪ Visual acuity reduced ▪ Photophobia ▪ [Other: visual field defect, peripheral vision loss, altered visual depth perception, oculogyric crisis].
Ear and Labyrinth disorders	▪ Vertigo ▪ Hearing loss ▪ [Other: buzzing, tinnitus]
Metabolism and nutrition disorders	▪ Hypoglycaemia
Vascular disorders	▪ Hypotension

4. Distribution of categorized medicines within DRUID categories

4.1 Number of medicines categorized by ATC groups

Table 4, below, shows the DRUID categorisation of the medicines in the groups ATC, A, B, C, D, M, N, R and S evaluated in DRUID WP4. Tables 5 to 12 show the number of medicines assigned to each category, as well as the number of medicines not evaluated in the various therapeutic groups analyzed.

The DRUID project has proposed for analysis and categorisation a total of 3,054 medicines from the groups ATC, A, B, C, D, M, N, R, and S. Of these 3,054 medicines, 1,513 have not been categorized (49,5%), because they are not available in most of the DRUID WP4 countries (Belgium, France, Greece, Germany, Netherlands, and Spain) as well as in the UK and Ireland.

Table 4: Number of medicines categorized by ATC groups

ATC GROUP	Not evaluated. Not available at EU market	DRUID Categorisation						TOTAL
		0	I	II	III	Multiple categories	Depending on the medicine in combination	
A - ALIMENTARY TRACT AND METABOLISM	243	234	69	8	1	4	4	563
B - BLOOD AND BLOOD FORMING ORGANS	86	135	1	1			2	225
C - CARDIOVASCULAR SYSTEM	246	90	200	11		1		548
D - DERMATOLOGICALS	156	192	1			4		353
M - MUSCULO-SKELETAL SYSTEM	88	22	44	28	15			197
N - NERVOUS SYSTEM	346	9	30	86	53	36		560
R - RESPIRATORY SYSTEM	195	62	24	32	10	5	14	342
S - SENSORY ORGANS	153	31	31	6	11	18	16	266
TOTAL	**1513**	**775**	**400**	**172**	**90**	**68**	**36**	**3054**

Not evaluated. No proposed categorisation and labelling because this medicine is not available in most of the DRUID WP4 countries (Belgium, France, Greece, Germany, The Netherlands, and Spain) as well as in the UK and Ireland.

DRUID Categorisation: Four categories were proposed regarding the possible effect of the medicine on fitness to drive.

- Category 0: Presumed to be safe on fitness to drive.

- Category I: Likely to produce minor adverse effects on fitness to drive.
- Category II: Likely to produce moderate adverse effect on fitness to drive.
- Category III: Likely to produce severe effects on fitness to drive or presumed to be potentially dangerous.

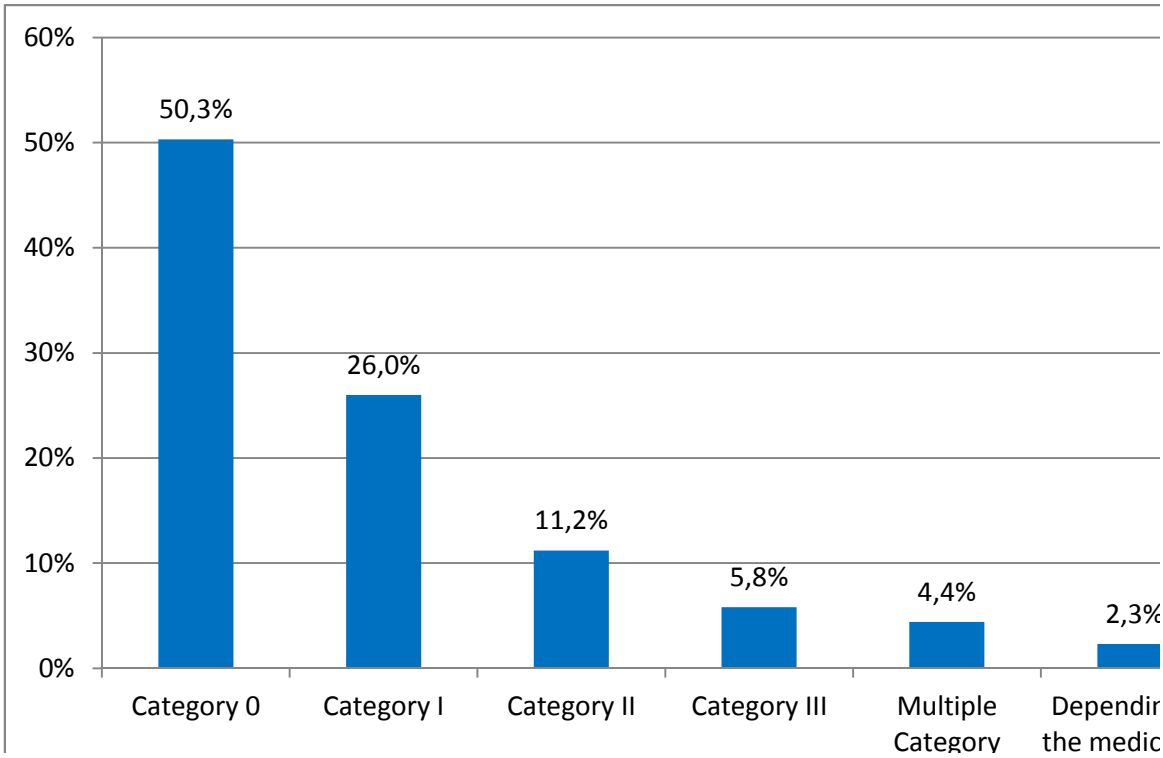
Multiple categories: This is when a medicine can be included in more than one category, generally according to route of administration (topical, oral, parenteral, etc) or according to the presentation form of the medication (aqueous-vehicle, cream, drops or ointiment, etc.). Table 13 shows the cases of multiple classifications.

Depending on medicines in combination: When the categorisation depended on the medicine in combination to with those under evaluation. Table 13 shows the cases of medicines categorized depending on medicines in combination.

4.2 Category percentage

1,541 medicines from the DRUID WP4 categorisation were evaluated. The percentage of medicines assigned to each category is shown in Figure 5. The distribution of the 1,541 categorized medicines was as follows: Category 0 – 50,3%, Category I – 26%, Category II – 11,2%, Category III – 5,8%, Multiple category – 4,4% and the Depending on the medicine in combination 2,3%.

Figure 5: Percentage of medicines categorized within each DRUID category



4.3 Number of medicines assigned to each category

Tables 5 to 12 show the number of medicines assigned to each category, as well as the number of medicines not evaluated in the various therapeutic groups analyzed.

Table 5: Number of medicines from the ATC-Group, A-ALIMENTARY TRACT AND METABOLISM, categorized in each DRUID category

ATC GROUP **A-ALIMENTARY TRACT AND METABOLISM**	**Not evaluated. Not available in EU market**	**DRUID Categorisation**						**TOTAL**
		0	**I**	**II**	**III**	**Multiple categories**	**Depending on the medicine in combination**	
A01 STOMATOLOGICAL PREPARATIONS	15	23						38
A02 DRUGS FOR ACID RELATED DISORDERS	25	30	13					68
A03 DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	73	14	1	2	1	3		94
A04 ANTIEMETICS AND ANTINAUSEANTS	7	7		2		1		17
A05 BILE AND LIVER THERAPY	12	5						17
A06 LAXATIVES	25	35						60
A07 ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	25	30		3			1	59
A08 ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS	12	1						13
A09 DIGESTIVES, INCL. ENZYMES	7	3						10
A10 DRUGS USED IN DIABETES	18	8	44					70
A10A Insulins and analogues			25					25
A10B Blood glucose lowering drugs, excl. insulins	17	8	19					44
A10X Other drugs used in diabetes	1							1
A11 VITAMINS	2	35					1	38
A12 MINERAL SUPPLEMENTS	8	32					2	42
A13 TONICS		1						1
A14 ANABOLIC AGENTS FOR SYSTEMIC USE	9	3						12
A15 APPETITE STIMULANTS				1				1
A16 OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	5	7	11					23
TOTAL	**243**	**234**	**69**	**8**	**1**	**4**	**4**	**563**

Table 6: Number of medicines from the ATC-Group, B-BLOOD AND BLOOD FORMING ORGANS MEDICINES, categorized in each DRUID category

ATC GROUP **B-BLOOD AND BLOOD FORMING ORGANS MEDICINES**	**Not evaluated. Not available in EU market**	DRUID Categorisation						TOTAL
		0	**I**	**II**	**III**	**Multiple categories**	**Depending on the medicine in combination**	
B01 ANTITHROMBOTIC AGENTS	27	37		1			1	66
B02 ANTIHEMORRHAGICS	10	25	1					36
B03 ANTIANEMIC PREPARATIONS	16	30						46
B05 BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	27	41					1	69
B06 OTHER HEMATOLOGICAL AGENTS	6	2						8
TOTAL	**86**	**135**	**1**	**1**			**2**	**225**

Table 7: Number of medicines from the ATC-Group, C-CARDIOVASCULAR SYSTEM MEDICINES, categorized in each DRUID category

ATC GROUP **C - CARDIOVASCULAR SYSTEM**	**Not evaluated. Not available in EU market**	**DRUID Categorisation**						**TOTAL**
		0	**I**	**II**	**III**	**Multiple categories**	**Depending on the medicine in combination**	
C01 CARDIAC THERAPY	94		39					133
C02 ANTIHYPERTENSIVES	43		15	10				68
C03 DIURETICS	38	23	12					73
C04 PERIPHERAL VASODILATORS	16	3	17	1				37
C05 VASOPROTECTIVES	3	40	2			1		46
C07 BETA BLOCKING AGENTS	17		48					65
C08 CALCIUM CHANNEL BLOCKERS	8		16					24
C09 AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	4	2	51					57
C10 LIPID MODIFYING AGENTS	23	22						45
TOTAL	**246**	**90**	**200**	**11**		**1**		**548**

Table 8: Number of medicines from the ATC-Group, D-DERMATOLOGICALS MEDICINES, categorized in each DRUID category

ATC GROUP D-DERMATOLOGICALS	Not evaluated. Not available in EU market	DRUID Categorisation						TOTAL
		0	I	II	III	Multiple categories	Depending on the medicine in combination	
D01 ANTIFUNGALS FOR DERMATOLOGICAL USE	33	20						53
D02 EMOLLIENTS AND PROTECTIVES		12						12
D03 PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	9	3						12
D04 ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	11	10				1		22
D05 ANTIPSORIATICS	8	8	1					17
D06 ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	10	25						35
D07 CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	29	47						76
D08 ANTISEPTICS AND DISINFECTANTS	28	24						52
D09 MEDICATED DRESSINGS	5	10						15
D10 ANTI-ACNE PREPARATIONS	10	19				2		31
D11 OTHER DERMATOLOGICAL PREPARATIONS	13	14				1		28
TOTAL	**156**	**192**	**1**			**4**		**353**

Table 9: Number of medicines from the ATC-Group, M-MUSCULO-SKELETAL SYSTEM MEDICINES, categorized in each DRUID category

ATC GROUP **M-MUSCULO-SKELETAL SYSTEM MEDICINES**	**Not evaluated. Not available in EU market**	**DRUID Categorisation**						**TOTAL**
		0	**I**	**II**	**III**	**Multiple categories**	**Depending on the medicine in combination**	
M01 ANTI-INFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	53	2	32					87
M02 TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	17	12						29
M03 MUSCLE RELAXANTS	4			27	15			46
M04 ANTIGOUT PREPARATIONS	7	1	4					12
M05 DRUGS FOR TREATMENT OF BONE DISEASES	5	7	5	1				18
M09 OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	2		3					5
TOTAL	**88**	**22**	**44**	**28**	**15**			**197**

Table 10: Number of medicines from the ATC-Group, N-NERVOUS SYSTEM MEDICINES, categorized in each DRUID category

ATC GROUP N-NERVOUS SYSTEM	Not evaluated. Not available at EU market	DRUID Categorisation						TOTAL
		0	I	II	III	Multiple categories	Depending on the medicine in combination	
N01 ANESTHETICS	**31**	**3**	**3**	**1**	**12**	**10**		**60**
N01A Anesthetics, general	20				11	1		32
N01B Anesthetics, local	11	3	3	1	1	9		28
N02 ANALGESICS	**93**	**2**	**7**	**10**	**3**	**7**		**122**
N02A Opioids	31				2	7		40
N02B Other analgesics and antipyretics	52	2	6	1	1			62
N02C Antimigraine preparations	10		1	9				20
N03 ANTIEPILEPTICS	**23**			**14**	**4**	**2**		**43**
N03A Antiepileptics	23			14	4	2		43
N04 ANTIPARKINSON	**16**		**3**	**16**		**1**		**36**
N04A Anticholinergic agents	10			4		1		15
N04B Dopaminergic agents	6		3	12				21
N05 PSYCHOLEPTICS	**107**		**4**	**16**	**26**	**12**		**165**
N05A Antipsychotics	31			13	8	9		65
N05B Anxiolytics	23		1	3	7	1		35
N05C Hypnotics and sedatives	53		3		11	2		69
N06 PSYCHOANALEPTICS	**62**	**2**	**10**	**20**	**7**	**1**		**102**
N06A Antidepressant	37	1	7	12	7	1		65
N06B Psychostimulants, agents used for ADHD (attention deficit/hyperactivity disorder) and Nootropics	22		3	4				29
N06C Psycholeptics and psychonaleptics in combination	2							2
N06D Anti-dementia drugs	1	1		4				6
N07 OTHER NERVOUS SYSTEM DRUGS	**14**	**2**	**3**	**9**	**1**	**3**		**32**
N07A Parasympathomimetics	6			2		1		9
N07B Drugs used in addictive disorders	2	2	1	4	1	2		12
N07C Antivertigo preparations	2		1	2				5
N07X Other nervous system drugs	4		1	1				6
TOTAL	**346**	**9**	**30**	**86**	**53**	**36**		**560**

Table 11: Number of medicines from the ATC-Group, R-RESPIRATORY SYSTEM MEDICINES, categorized in each DRUID category

ATC GROUP **R-RESPIRATORY SYSTEM**		**Not evaluated. Not available at EU market**	**DRUID Categorisation**						**TOTAL**
			0	**I**	**II**	**III**	**Multiple categories**	**Depending on the medicine in combination**	
R01	NASAL PREPARATIONS	32	22	2			1	3	60
R02	THROAT PREPARATIONS	15	11				1		27
R03	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	65	19	4			2	5	95
R05	COUGH AND COLD PREPARATIONS	44	9	5	4	1	1	4	68
R06	ANTIHISTAMINES FOR SYSTEMIC USE	27		11	28	9		2	77
R07	RESPIRATORY SYSTEM	12	1	2					15
TOTAL		**195**	**62**	**24**	**32**		**5**	**14**	**342**

Table 12: Number of medicines from the ATC-Group, S-SENSORY ORGANS MEDICINES, categorized in each DRUID category

ATC GROUP S-SENSORY ORGANS	Not evaluated. Not available at EU market	DRUID Categorisation						TOTAL
		0	I	II	III	Multiple categories	Depending on the medicine in combination	
S01 OPHTHALMOLOGICALS								
S01A Antiinfectives	40	6	2			9	2	59
S01B Antiinflammatory agents	17	4	1			3	4	29
S01C Antiinflammatory agents and antiinfectives in combination	5	1				6	5	17
S01E Antiglaucoma preparations and miotics	21		13	6				40
S01F Mydriatics and cycloplegics	4				8			12
S01G Decongestants and antiallergics	7		13				2	22
S01H Local Anesthetics	6		2					8
S01J Diagnostic agents	1	1					1	3
S01K Surgical aids	3	1						4
S01L Ocular vascular disorder agents	1				3			4
S01XA Other ophthalmologicals	13	4						17
S02 OTOLOGICALS	**24**	**8**					**2**	**34**
S03 OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	**11**	**6**						**17**
TOTAL	**153**	**31**	**31**	**6**	**11**	**18**	**16**	**266**

4.4 Multiple categories and categorisation depending on the medicine in combination

A medicine has been placed in multiple categories when it can be in more than one category. There can be several reasons for this:

- In most cases, the different categorisation depended on the route of administration (topical, oral, parenteral, etc).
- In the case of some medicines, in special ophthalmological preparations (SO1), the different categorisation depended on the presentation form of the medication (aqueous-vehicle, cream, drops or ointment, etc.), which is related with the duration of its action.
- In one case, codeine, categorisation was based on the dose of codeine base administered.
- For two hypnotics, zolpidem and zaleplon, categorisation was based on the time after the medication was taken.
- In some cases, the categorisation depended on the medicines in combination.

Table 13 shows the cases of multiple classifications and categorisations depending on the medicine in combination.

Table 13: Medicines with multiple categorisations and depending on the medicine in combination, according to the ATC code.

A - ALIMENTARY TRACT AND METABOLISM		**CATEGORISATION**
A03BB01	Butylscopolamine - Oral administration - Parenteral administration (i.v)	 I II
A03DB04	Butylscopolamine and analgesics. - Oral administration - Parenteral administration	 I II
A03FA01	Metoclopramide - Oral administration - Parenteral administration	 I II
A04AD01	Scopolamine - Oral and rectal administration - Parenteral administration	 I II
A07DA53	Loperamide, combinations	Depending on the medicine in combination
A11CC20	Combinations (Vitamin D and analogues)	Depending on the medicine in combination
A12BA30	Combinations (Potassium)	Depending on the medicine in combination
A12BA51	Potassium chloride, Combinations	Depending on the medicine in combination
B BLOOD AND BLOOD FORMING ORGANS		
B01AC30	Combinations (Platelet aggregation inhibitors excl. heparin)	Depending on the medicine in combination
B05XA31	Electrolytes in combination with other drugs	Depending on the medicine in combination
D - DERMATOLOGICALS		
D10BA01	Isotretinoin - Oral administration	 II

	- Topical use	0
D11AH01 (L04AD02 in intravenous and oral administration)	Tacrolimus - Intravenous administration - Oral administration - Topical use	 III II 0
D11AX19	Alitretinoin - Oral administration - Topical use	 I 0
N - NERVOUS SYSTEM		
N01B Anesthetics, local	The categorisation was depending on the route of administration and place of administration. Not all local anesthetics are available for all routes of administration. For example use in topical anaesthesia was considered as category 0. – Surface o topical anaesthesia: – Infiltration anaesthesia: – Intravenous regional anaesthesia – Regional nerve block – Spinal	
N01BA02	Procaine	0 to III
N01BA03	Tetracaine	0 to III
N01BB01	Bupivacaine	I to III
N01BB02	Lidocaine	0 to III
N01BB03	Mepivacaine (carbocaine)	I to III
N01BB04	Prilocaine	0 to III
N01BB10	Levobupivacaine	I to III
N01BB51	Bupivacaine combinations	I to III
N01BB52	Lidocaine combinations	0 to III
N02 ANALGESICS		
N02AA01	Morphine - Oral administration - Parenteral admin.	III/II* III
N02AA03	Hydromorphone	III/II*
N02AA05	Oxycodone	III/II*
N02AA08	Dihydrocodeine	III/II*
N02AA59	Codeine, combinations excl. psycholeptics > 20 mg of codeine base ≤ 20 mg of codeine base	 II I
N02AB03	Fentanyl - Oral administration - Parenteral admin. - Transdermal administration	 III III III/II*
N02AE01	Buprenorphine - Oral administration - Parenteral admin. - Transdermal administration	 III III III/II*
N03 ANTIEPILEPTICS		
N03AE01	Clonazepam - Oral administration - Parenteral administration	 II III
N03AG01	Valproic acid - Oral administration - Parenteral administration	 II III
N04 ANTIPARKINSON		
N04AA02	Biperiden - Oral administration	 II

	- Parenteral administration	III
N05 PSYCHOLEPTICS		
N05AD01	Haloperidol - Oral administration - Parenteral administration:i.v./i.m.	 II III
N05AD06	Bromperidol - Oral administration - Parenteral administration: depot i.m.	 II III
N05AE04	Ziprasidone - Oral administration - Parenteral administration: i.m.	 II III
N05AF01	Flupentixol - Oral administration - Parenteral administration: depot i.m.	 II III
N05AF05	Zuclopenthixol - Oral administration - Parenteral administration: depot i.m.	 II III
N05AH03	Olanzapine - Oral administration - Parenteral administration: i.m.	 II III
N05AX08	Risperidone - Oral administration - Parenteral administration: depot i.m.	 II III
N05AX09	Clotiapine - Oral administration - Parenteral administration: i.m./i.v.	 II III
N05AX12	Aripiprazole - Oral administration - Parenteral administration: i.m.	 II III
N05BA05	Potassium clorazepate - Oral administration - Parenteral administration im/iv	 II III
N05CF02	Zolpidem - after 8h of administration	III II
N05CF03	Zaleplon - after 12 h of administration	III I
N06 PSYCHOANALEPTICS		
N06A Antidepressant		
N06AA21	Maprotiline - Oral administration - Parenteral administration	 II III
N07 OTHER NERVOUS SYSTEM DRUGS		
N07AA01	Neostigmine - Oral administration - Parenteral administration	 II III
N07BC01	Buprenorphine - Oral administration - Parenteral admin. - Transdermal administration	 III III III/II*
N07BC02	Methadone - Oral administration - Parenteral administration	 II III
R-RESPIRATORY SYSTEM		
R01AB01	Phenylephrine (Sympathomimetics, combinations excl. corticosteroids)	Depending on the medicine in combination
R01AB05	Ephedrine (Sympathomimetics, combinations excl.	Depending on the medicine in

	corticosteroids)	combination
R01BA52	Pseudoephedrine, combinations + loratadine + triprolidine	 I III
R01BA53	Phenylephrine, combinations	Depending on the medicine in combination
R03AK03	Fenoterol and other drugs for obstructive airway diseases	Depending on the medicine in combination
R03AK04	Salbutamol and other drugs for obstructive airway diseases	Depending on the medicine in combination
R03AK06	Salmeterol and other drugs for obstructive airway diseases	Depending on the medicine in combination
R03AK07	Formoterol and other drugs for obstructive airway diseases	Depending on the medicine in combination
R03DA04	Theophylline - Oral administration - Parenteral administration	 0 I
R03DA05	Aminophylline - Oral administration - Parenteral administration	 0 I
R03DB04	Theophylline and adrenergics	Depending on the medicine in combination
R05DA04	Codeine > 20 mg of codeine base ≤ 20 mg of codeine base	 II I
R05DA20	Combinations (Opium alkaloids and derivatives)	Depending on the medicine in combination
R05FA02	Opium derivatives and expectorants	II or higher depending on the medicine in combination
R05FB01	Cough suppressants and mucolytics	Depending on the medicine in combination
R05FB02	Cough suppressants and expectorants	Depending on the medicine in combination
R06AE51	Buclizine, combinations	Depending on the medicine in combination
R06AE53	Cyclizine, combinations	Depending on the medicine in combination
S01 OPHTHALMOLOGICALS		
S01AA01	Chloramphenicol	Drops: 0 Oinment: I
S01AA02	Chlortetracycline	
S01AA03	Neomycin	
S01AA04	Oxytetracycline	
S01AA11	Gentamicin	
S01AA12	Tobramycin	
S01AA13	Fusidic acid	
S01AA20	Antibiotics in combination	Depending on the

	with other drugs	medicine in combination
S01AA30	Combinations of different antibiotics	Depending on the medicine in combination
S01AX13	Ciprofloxacin	Drops: 0 Oinment: I
S01AX17	Lomefloxacin	
S01BA01	Dexamethasone	
S01BA07	Fluorometholone	
S01BA13	Rimexolone	
S01BB01	Hydrocortisone and mydriatics	Depending on the mydriatic in combination
S01BB02	Prednisolone and mydriatics	
S01BB03	Fluorometholone and mydriatics	
S01BB04	Betamethasone and mydriatics	
S01CA01	Dexamethasone and antiinfectives	Drops: 0 Oinment: I
S01CA02	Prednisolone and antiinfectives	
S01CA03	Hydrocortisone and antiinfectives	
S01CA05	Betamethasone and antiinfectives	
S01CA06	Fludrocortisone and antiinfectives	
S01CA07	Flourometholone and antiinfectives	
S01CB01	Dexamethasone (Corticosteroids/antiinfectives/mydriatics in combination)	Depending on the mydriatic in combination
S01CB02	Prednisolone (Corticosteroids/antiinfectives/mydriatics in combination)	
S01CB03	Hydrocortisone (Corticosteroids/antiinfectives/mydriatics in combination)	
S01CB04	Betamethasone (Corticosteroids/antiinfectives/mydriatics in combination)	
S01CB05	Fluorometholone (Corticosteroids/antiinfectives/mydriatics in combination)	
S01GA51	Naphazoline, combinations	Depending on the medicine in combination
S01GA55	Phenylephrine, combinations	
S01JA51	Fluorescein, combinations	
S02DA30	Combinations (Analgesics and anesthetics)	
S02DC	Combinations (Indifferent preparations)	

*) prolonged release formulation; when a steady state of dosage has been reached

5. Alphabetical list of the medicines categorized with the DRUID WP4

A list of all the medicines categorized within the DRUID project in alphabetical order is now presented (Table 14).

Some active substances have more than one ATC code, as they can be used for different indications. The categorisation has been carried out by analyzing each medicine within its therapeutic group. Sometimes, the categorisation of the same active substance has been the same in all the therapeutic groups, while in other cases the same active substance has been categorized differently in each ATC code. For example: Beclometasone has 4 ATC codes (A07EA07, D07AC15, R01AD01, R03BA01) and in all cases has been categorized as category 0. However, Cromoglicic acid has 5 ATC codes and different categorisations according to the pharmaceutical group (ATC code) it belongs to, (A07EB01, R01AC01, R03BC01 Category 0), (S01GX01 Category I) and (D11AH03 Not evaluated).

Table 14: Alphabetical list of the medicines categorized with the DRUID WP4

A	**ATC CODE**	**CATEGORISATION labelling**
(2-benzhydryloxyethyl)diethyl-methylammonium iodide	A03AB16	NE
2-(4-chlorphenoxy)-ethanol	D01AE06	NE
Abciximab	B01AC13	0
Absorbable gelatin sponge	B02BC01	0
Acadesine	C01EB13	NE
Acamprosate	N07BB03	0
Acarbose	A10BF01	0
Acebutolol	C07AB04	I
Acebutolol and thiazides	C07BB04	I
Aceclidine	S01EB08	NE
Aceclidine, combinations	S01EB58	NE
Aceclofenac	M01AB16	I
Aceclofenac	M02AA25	0
Acefylline piperazine	R03DA09	NE
Acemetacin	M01AB11	I
Acenocoumarol	B01AA07	0
Acepromazine	N05AA04	NE
Acetarsol	A07AX02	NE
Acetazolamide	S01EC01	II
Acetic acid	S02AA10	NE
Acetohexamide	A10BB31	NE
Acetophenazine	N05AB07	NE
Acetoxolone	A02BX09	NE
Acetylcarnitine	N06BX12	NE
Acetylcholine	S01EB09	II
Acetylcysteine	R05CB01 S01XA08	0
Acetyldigitoxin	C01AA01	NE
Acetyldigoxin	C01AA02	NE
Acetyldigoxin, combinations	C01AA52	NE
Acetyldihydrocodeine	R05DA12	II
Acetylglycinamide chloralhydrate	N05CC03	NE
Acetylic acid and corticosteroids	M01BA03	NE
Acetylleucine	N07CA04	NE

Acetylsalicylic acid	A01AD05 B01AC06 N02BA01	0
Acetylsalicylic acid, combinations excl psycholeptics	N02BA51	NE
Acetylsalicylic acid, combinations with psycholeptics	N02BA71	NE
Acexamato de zinc	A02BX	0
Aciclovir	D06BB03	0
Aciclovir	S01AD03	I
Aciclovir, combinations	D06BB53	NE
Acipimox	C10AD06	0
Acitretin	D05BB02	I
Acriflavinium chloride	R02AA13	NE
Acrivastine	R06AX18	I
Adapalene	D10AD03	0
Adapalene, combinations	D10AD53	0
Ademetionine	A16AA02	NE
Adenosine	C01EB10	I
Adinazolam	N05BA07	NE
Adrafinil	N06BX17	NE
Adrenalone	A01AD06	NE
Adrenalone	B02BC05	NE
Agalsidase alfa	A16AB03	I
Agalsidase beta	A16AB04	I
Agomelatine	N06AX22	II
Ajmaline	C01BA05	NE
Alanyl glutamine	B05XB02	NE
Alaproclate	N06AB07	NE
Albumin	B05AA01	0
Albumin tannate	A07XA01	NE
Albumin tannate, combinations	A07XA51	NE
Alclofenac	M01AB06	NE
Alclometasone	D07AB10	0
Alclometasone	S01BA10	NE
Alcuronium	M03AA01	III
Alendronic acid	M05BA04	0
Alendronic acid and colecalciferol	M05BB03	I
Alfa1 antitrypsin	B02AB02	0
Alfacalcidol	A11CC03	0
Alfaxalone	N01AX05	NE
Alfentanil	N01AH02	III
Algeldrate	A02AB02	0
Alginic acid	A02BX13	NE
Alglucerase	A16AB01	NE
Alglucosidase alfa	A16AB07	I
Alimemazine	R06AD01	III
Alipogene tiparvovec	C10AX10	NE
Aliskiren	C09XA02	0
Aliskiren and hydrochlorothiazide	C09XA52	0
Alitretinoin - Oral administration - Topical use	D11AX19	 I 0
Alizapride	A03FA05	NE
Allobarbital	N05CA21	NE
Allopurinol	M04AA01	I
Allopurinol, combinations	M04AA51	I

Almagate	A02AD03	0
Almasilate	A02AD05	0
Alminoprofen	M01AE16	NE
Almitrine	R07AB07	I
Almotriptan	N02CC05	II
Alogliptin	A10BH04	NE
Aloglutamol	A02AB06	0
Alosetron	A03AE01	NE
Aloxiprin	B01AC15 N02BA02	NE
Alprazolam	N05BA12	III
Alprenolol	C07AA01	I
Alprostadil	C01EA01	I
Alteplase	B01AD02	0
Alteplase	S01XA13	NE
Althea root	R05CA05	NE
Altizide and potassium-sparing agents (spironolactone)	C03EA04	I
Alum	S01XA07	NE
Aluminium acetoacetate	A02AB05	0
Aluminium acetotartrate	S02AA04	NE
Aluminium chloride	D10AX01	0
Aluminium chlorohydrate	D09AA08 M05BX02	NE
Aluminium clofibrate	C10AB03	NE
Aluminium glycinate	A02AB07	0
Aluminium hydroxide	A02AB01	0
Aluminium nicotinate	C10AD04	NE
Aluminium oxide	D10AX04	NE
Aluminium phosphate	A02AB03	0
Aluminium preparations	C05AX01	0
Alverine	A03AX08	0
Alverine, combinations	A03AX58	NE
Alvimopan	A06AH02	NE
Amantadine	N04BB01	I
Ambazone	R02AA01	NE
Ambenonium	N07AA30	NE
Ambrisentan	C02KX02	I
Ambroxol	R05CB06	0
Ambutonium and psycholeptics	A03CA07	NE
Amcinonide	D07AC11	NE
Amfepramone	A08AA03	NE
Amfetamine	N06BA01	NE
Amifampridine	N07XX05	II
Amikacin	D06AX12	0
Amikacin	S01AA21	NE
Amiloride	C03DB01	0
Amineptine	N06AA19	NE
Amino (diphenylhydantoin) valeric acid	N03AB03	NE
Amino acids	B05BA01	0
Aminoacridine	D08AA02	0
Aminobenzoic acid	D02BA01	0
Aminobutyric acid (GABA)	N03AG03	NE
Aminomethylbenzoic Acid	B02AA03	NE
Aminophenazone	N02BB03	NE
Aminophenazone, combinations excl. Psycholeptics	N02BB53	NE

Aminophenazone, combinations with. Psycholeptics	N02BB73	NE
Aminophylline - Oral administration - Parenteral administration	R03DA05	 0 I
Aminophylline and adrenergics	R03DB05	NE
Aminophylline, combinations	R03DA55	NE
Amiocaproic acid	B02AA01	0
Amiodarone	C01BD01	I
Amisulpride	N05AL05	II
Amitriptyline	N06AA09	III
Amitryptiline and psycholeptics	N06CA01	NE
Amlexanox	A01AD07 R03DX01	NE
Amlodipine	C08CA01	I
Ammonium chloride	B05XA04	0
Amobarbital	N05CA02	NE
Amorolfine	D01AE16	0
Amoxapine	N06AA17	NE
Amphotericin B	A01AB04 A07AA07	0
Ampicilin	S01AA19	NE
Amrinone	C01CE01	NE
Ancrod	B01AD09	NE
Androstanolone	A14AA01	NE
Anecortave	S01LA02	NE
Anethole trithione	A16AX02	NE
Angiotensinamide	C01CX06	NE
Anileridine	N01AH05	NE
Aniracetam	N06BX11	NE
Anistreplase	B01AD03	NE
Antacids with antispasmodics	A02AG	NE
Antacids, other combinations	A02AH	0
Antacids with sodium bicarbonate	A02AG	0
Antazoline	R01AC04 R06AX05	NE
Antibiotics in combination with other drugs	S01AA20	Depending on the medicine in combination
Antiinfectives, combinations	S02AA30	0
Antimony pentasulfide	R05CA07	NE
Antispasmodics in combination with other drugs	A03ED	II
Antithrombin III	B01AB02	0
Apomorphine	N04BC07	II
Apraclonidine	S01EA03	II
Aprepitant	A04AD12	0
Aprindine	C01BB04	I
Aprobarbital	N05CA05	NE
Apronal	N05CM12	NE
Aprotinin	B02AB01	0
Arbutamine	C01CA22	NE
Argatroban	B01AE03	NE
Arginine glutamate	A05BA01	NE
Arginine hydrochloride	B05XB01	NE
Aripiprazole - Oral administration	N05AX12	 II

- Parenteral administration: i.m.		III
Articaine	N01BB08	NE
Articaine combinations	N01BB58	I
Artificial tears and other indifferent preparations	S01XA20	0
Ascorbic acid	S01XA15	NE
Ascorbic acid (vit C)	A11GA01	0
Ascorbic acid (vit C) and calcium	A11GA02	0
Astemizole	R06AX11	I
Atenolol	C07AB03	I
Atenolol - chlortalidone	C07FB03	NE
Atenolol - nifedipine	C07FB03	NE
Atenolol and other antihypertensives	C07FB03	I
Atenolol and other diuretics	C07CB03	I
Atenolol and other diuretics, combinations	C07CB53	I
Atenolol and thiazide	C07BB03	I
Atenolol, thiazides and other diuretics	C07DB01	I
Atomoxetine	N06BA09	I
Atorvastatin	C10AA05	0
Atorvastatin and amlodipine	C10BX03	NE
Atracurium	M03AC04	III
Atropine	A03BA01 S01FA01	III
Atropine and psycholeptics	A03CB03	NE
Atropine+escopolamine+phenylephrine	S01FAP1	III
Attapulgite	A07BC04	NE
Attapulgite, combinations (combination with morphine)	A07BC54	II
Auranofin	M01CB03	NE
Aurothioglucose	M01CB04	NE
Aurotioprol	M01CB05	NE
Azapetine	C04AX30	NE
Azapropazone	M01AX04	NE
Azatadine	R06AX09	II
Azelaic acid	D10AX03	0
Azelastine	R06AX19 S01GX07	I
Azelastine antazoline	R01AC03	0
Azidamfenicol	S01AA25	NE
Azithromycin	S01AA26	0
B	**ATC CODE**	**CATEGORISATION labelling**
Bacitracin	D06AX05	0
Bacitracin	R02AB04	NE
Baclofen	M03BX01	II
Balsalazide	A07EC04	0
Bambuterol	R03CC12	NE
Bamethan	C04AA31	I
Bamifylline	R03DA08	NE
Bamipine	D04AA15 R06AX01	NE
Barbexaclone	N03AA04	NE
Barbital	N05CA04	NE
Barbiturates in combinations with other drugs	N05CB02	NE
Barnidipine	C08CA12	NE
Batroxobin	B02BX03	NE
Becaplermin	A01AD08	0

	D03AX06	
Beclamide	N03AX30	NE
Beclometasone	A07EA07 D07AC15 R01AD01 R03BA01	0
Beclometasone and antibiotics	D07CC04	0
Befunolol	S01ED06	I
Belladonna total alkaloids	A03BA04	NE
Belladonna total alkaloids and psycholeptics	A03CB02	NE
Bemegride	R07AB05	NE
Bemiparin	B01AB12	0
Benazepril	C09AA07	I
Benazepril and diuretics	C09BA07	I
Bencyclane	C04AX11	NE
Bendazac	M02AA11 S01BC07	NE
Bendroflumethiazide	C03AA01	0
Bendroflumethiazide and potassium	C03AB01	0
Bendroflumethiazide and potassium-sparing agents (spirolactone)	C03EA13	I
Benflumethiazide - reserpine	C02LA01	NE
Benfluorex	A10BX06 C10AX04	NE
Benfotiamine	A11DA03	0
Benidipine	C08CA15	NE
Benorilate	N02BA10	NE
Benoxaprofen	M01AE06	NE
Benperidol	N05AD07	II
Benproperine	R05DB02	NE
Benzalkonium	D08AJ01 D09AA11 R02AA16	0
Benzatropine	N04AC01	NE
Benzbromarone	M04AB03	NE
Benzethonium	R02AA09	NE
Benzethonium chloride	D08AJ08	0
Benzethonium chloride, combinations	D08AJ58	0
Benzilone	A03AB01	NE
Benziodarone	C01DX04	NE
Benziodarone, combinations	C01DX54	NE
Benzocaine	C05AD03 D04AB04 N01BA05 R02AD01	0
Benzoctamide	N05BD01	NE
Benzododecinium	D09AA05	NE
Benzonatate	R05DB01	NE
Benzoxonium chloride	A01AB14 D08AJ05	NE
Benzoyl peroxide	D10AE01	0
Benzoyl peroxide, combinations	D10AE51	0
Benzydamine	A01AD02 M02AA05	0
Benzydamine	M01AX07	I
Benzylpenicilin	S01AA14	NE
Bepridil	C08EA02	NE

Beraprost	B01AC19	NE
Bergapten	D05BA03	NE
Betacarotene	A11CA02 D02BB01	0
Betahistine	N07CA01	I
Betaine	A16AA06	0
Betaine hydrochloride	A09AB02	NE
Betamethasone	A07EA04 C05AA05 D07AC01 D07XC01 R01AD06	0
Betamethasone	R03BA04 S01BA06 S02BA07 S03BA03	NE
Betamethasone (Corticosteroids/antiinfectives/mydriatics in combination)	S01CB04	Depending on the mydriatic in combination
Betamethasone and antibiotics	D07CC01	0
Betamethasone and antiinfectives - Drops - Oinment	S01CA05	 0 I
Betamethasone and antiinfectives	S03CA06	0
Betamethasone and antiseptics	D07BC01	0
Betamethasone and mydriatics	S01BB04	Depending on the mydriatic in combination
Betanidine	C02CC01	NE
Betaxolol	C07AB05 S01ED02	I
Betaxolol, combinations	S01ED52	NE
Bethanechol	N07AB02	NE
Bevantolol	C07AB06	NE
Bevantolol and thiazides	C07BB06	NE
Bevonium	A03AB13	NE
Bevonium and Analgesics	A03DA03	NE
Bevonium and psycholeptics	A03CA06	NE
Bezafibrate	C10AB02	0
Bezitramide	N02AC05	NE
Bibenzonium bromide	R05DB12	NE
Bibrocathol	S01AX05	NE
Bietaserpine	C02AA07	NE
Bietaserpine and diuretics	C02LA07	NE
Bietaserpine, combinations	C02AA57	NE
Bifemelane	N06AX08	NE
Bifonazole	D01AC10	NE
Bifonazole, combinations	D01AC60	NE
Bimatoprost	S01EE03	I
Biotin	A11HA05	0
Biperiden - Oral administration - Parenteral administration	N04AA02	 II III
Biphenylol	D08AE06	NE
Bisacodyl	A06AB02 A06AG02	0
Bisacodyl, combinations	A06AB52	0
Bismuth preparations, combinations	C05AX02	0

Bismuth subcitrate	A02BX05	0
Bismuth subnitrate	A02BX12	NE
Bisoprolol	C07AB07	I
Bisoprolol - hydrochlorothiazide	C07BB Not yet determined	NE
Bisoprolol and thiazide	C07BB07	I
Bisoprolol, combinations	C07AB57	I
Bisoxatin	A06AB09	NE
Bithionol	D10AB01	NE
Bitolterol	R03AC17	NE
Bivalirudin	B01AE06	0
Blood plasma	B05AX03	NE
Bopindolol	C07AA17	NE
Bopindolol and other diuretics	C07CA17	NE
Boric acid	S02AA03	NE
Bornaprine	N04AA11	NE
Bosentan	C02KX01	I
Botulinum toxin A Botulinum toxin B	M03AX01	II II
Bretylium tosilate	C01BD02	NE
Brimonidine	S01EA05	II
Brinase	B01AD06	NE
Brinzolamide	S01EC04	I
Bromazepam	N05BA08	III
Bromazine	R06AA01	NE
Bromelains	B06AA11	NE
Bromhexine	R05CB02	0
Bromides	N05CM11	NE
Bromisoval	N05CM03	NE
Bromochlorosalicylanilide	D01AE01	NE
Bromocriptine	N04BC01	II
Bromopride	A03FA04	NE
Bromperidol - Oral administration - Parenteral administration: depot i.m.	N05AD06	 II III
Brompheniramine	R06AB01	II
Brompheniramine, combinations	R06AB51	II
Brotizolam	N05CD09	III
Broxyquinoline	A07AX01	NE
Bucetin	N02BE04	NE
Bucetin, combinations excl. Psycholeptics	N02BE54	NE
Bucetin, combinations with Psycholeptics	N02BE74	NE
Bucillamine	M01CC02	NE
Bucladesine	C01CE04	NE
Buclizine	R06AE01	II
Buclizine, combinations	R06AE51	Depending on the medicine in combination
Budesonide	A07EA06 D07AC09 R01AD05 R03BA02	0
Budipine	N04BX03	NE
Bufexamac	M01AB17 M02AA09	NE
Buflomedil	C04AX20	I
Buformin	A10BA03	NE
Bufylline	R03DA10	NE

Bumadizone	M01AB07	NE
Bumetanide	C03CA02	0
Bumetanide and potassium	C03CB02	0
Bumetanide and potassium-sparing agents	C03EB02	0
Bunaftine	C01BD03	NE
Buphenine	C04AA02	I
Bupivacaine	N01BB01	I to III Depending on the route of administration
Bupivacaine combinations	N01BB51	I to III Depending on the route of administration
Bupranolol	C07AA19	I
Buprenorphine - Oral administration - Parenteral admin. - Transdermal admin	N02AE01 N07BC01	 III III III/II* *) prolonged release formulation; when a steady state of dosage has been reached
Buprenorphine, combinations	N07BC51	III
Bupropion (amfebutamone)	N07BA02	II
Buspirone	N05BE01	I
Butalamine	C04AX23	I
Butamirate	R05DB13	NE
Butanilicaine	N01BB05	NE
Butaperazine	N05AB09	NE
Butenafine	D01AE23	NE
Butizide and potassium-sparing agents(spironolactone)	C03EA14	NE
Butobarbital	N05CA03	NE
Butorphanol	N02AF01	NE
Butriptyline	N06AA15	NE
Butylscopolamine - Oral administration - Parenteral administration (i.v)	A03BB01	 I II
Butylscopolamine and analgesics. - Oral administration - Parenteral administration	A03DB04	 I II
C	**ATC CODE**	**CATEGORISATION labelling**
C1-inhibitor	B02AB03	0
Cabergoline	N04BC06	II
Cadexomer iodine	D03AX01	NE
Cadmium compounds	D11AC02	0
Cadralazine	C02DB04	NE
Cafedrine	C01CA21	NE
Caffeine	N06BC01	NE
Calcifediol	A11CC06	0
Calcipotriol	D05AX02	0
Calcipotriol, combinations	D05AX52	0
Calcitriol	A11CC04 D05AX03	0
Calcium (different salts in combination)	A12AA20	0
Calcium acetate anhydrous	A12AA12	0

Calcium alginate	B02BC08	NE
Calcium carbasalate - metoclopramide	N02BA15	NE
Calcium carbimide	N07BB02	II
Calcium carbonate	A02AC01 A12AA04	0
Calcium chloride	A12AA07 B05XA07	0
Calcium citrate lysine complex	A12AA09	0
Calcium compounds	A07XA03	NE
Calcium dobesilate	C05BX01	0
Calcium dobesilate, combinations	C05BX51	0
Calcium glubionate	A12AA02	0
Calcium glucoheptonate	A12AA10	0
Calcium gluconate	A12AA03	0
Calcium gluconate	D11AX03	NE
Calcium glycerylphosphate	A12AA08	0
Calcium hexamine thiocyanate	R01AX01	NE
Calcium lactate	A12AA05	0
Calcium lactate gluconate	A12AA06	0
Calcium laevulate	A12AA30	0
Calcium pangamate	A12AA11	0
Calcium pantothenate	A11HA31 D03AX04	NE
Calcium phosphate	A12AA01	0
Calcium silicate	A02AC02	0
Camazepam	N05BA15	NE
Camolenic acid	D11AX02	NE
Camostat	B02AB04	NE
Camphora	C01EB02	NE
Camylofin	A03AA03	NE
Camylofin and analgesics	A03DA05	NE
Candesartan	C09CA06	I
Candesartan and diuretics	C09DA06	I
Canrenone	C03DA03	NE
Capsaicin	M02AB01 N01BX04	0
Captodiame	N05BB02	NE
Captopril	C09AA01	I
Captopril and diuretics	C09BA01	I
Carbachol	N07AB01 S01EB02	NE
Carbamazepine	N03AF01	II
Carbamide	B05BC02	NE
Carbamide	D02AE01	0
Carbamide, combinations	D02AE51	0
Carbamide products	D02AE	0
Carbasalate calcium	B01AC08	0
Carbasalate calcium combinations excl. Psycholeptics	N02BA65	NE
Carbazochrome	B02BX02	NE
Carbenoxolone	A02BX01	0
Carbenoxolone, combinations excl. psycholeptics	A02BX51	NE
Carbenoxolone, combinations with psycholeptics	A02BX77	NE
Carbinoxamine	R06AA08	II
Carbocisteine	R05CB03	0

Carbocromen	C01DX05	NE
Carbohydrates	B05BA03	0
Carbon dioxide producing drugs	A06AX02	NE
Carbromal	N05CM04	NE
Carbutamide	A10BB06	NE
Carbuterol	R03AC10 R03CC10	NE
Cardioplegia solutions	B05XA16	0
Carglumic acid	A16AA05	0
Carisoprodol	M03BA02	II
Carisoprodol, combinations excl. psycholeptics	M03BA52	II
Carisoprodol, combinations with psycholeptics	M03BA72	II
Caroverine	A03AX11	NE
Carteolol	C07AA15 S01ED05	I
Carteolol, combinations	S01ED55	NE
Carvedilol	C07AG02	I
Cascara	A06AB07	0
Cascara, combinations	A06AB57	0
Casopitant	A04AD13	NE
Castor oil	A06AB05	0
Cathine	A08AA07	NE
Celecoxib	M01AH01	I
Celiprolol	C07AB08	I
Ceratonia	A07XA02	NE
Cerium oxalate	A04AD02	NE
Cerivastatin	C10AA06	NE
Cetiedil	C04AX26	I
Cetirizine	R06AE07	II
Cetrimide	D08AJ04 D11AC01	0
Cetrimonium	D08AJ02	0
Cetrimonium	R02AA17	NE
Cetylpyridinium	B05CA01	NE
Cetylpyridinium	D08AJ03 D09AA07 R02AA06	0
Chenodeoxycholic acid	A05AA01	NE
Chloral hydrate	N05CC01	NE
Chloralodol	N05CC02	NE
Chloramphenicol	D06AX02 D10AF03	0
Chloramphenicol - Drops - Oinment	S01AA01	 0 I
Chloramphenicol	S02AA01 S03AA08	NE
Chlorbenzoxamine	A03AX03	NE
Chlorcyclizine	R06AE04	NE
Chlordiazepoxide	N05BA02	II
Chlorhexidine	A01AB03 D08AC02 D09AA12 R02AA05	0
Chlorhexidine	B05CA02 S02AA09 S03AA04	NE

Chlorhexidine, combinations	D08AC52	0
Chlormezanone	M03BB02	II
Chlormezanone, combinations excl. psycholeptics	M03BB52	II
Chlormezanone, combinations with psycholeptics	M03BB72	II
Chlormidazole	D01AC04	NE
Chlorobutanol	A04AD04	NE
Chlorobutanol, combinations	A04AD54	0
Chloroform	N01AB02	NE
Chloroprednisolone and antiinfectives	S01CA09	NE
Chloroprocaine	N01BA04	NE
Chloropyramine	D04AA09 R06AC03	NE
Chloropyramine, combinations	R06AC53	NE
Chlorothiazide	C03AA04	NE
Chlorothiazide and potassium	C03AB04	NE
Chlorothiazide, combinations	C03AH01	NE
Chloroxylenol	D08AE05	0
Chlorphenamine	R06AB04	II
Chlorphenamine, combinations	R06AB54	II
Chlorphenesin	D01AE07	NE
Chlorphenoxamine	D04AA34	NE
Chlorphenoxamine	R06AA06	II
Chlorphenoxamine, Combinations	R06AA56	NE
Chlorproethazine	N05AA07	NE
Chlorpromazine	N05AA01	III
Chlorpropamide	A10BB02	I
Chlorprothixene	N05AF03	NE
Chlorquinaldol	D08AH02	0
Chlorquinaldol	R02AA11	NE
Chlortalidone	C03BA04	I
Chlortalidone and potassium	C03BB04	I
Chlortalidone and potassium-sparing agents (spirolactone)	C03EA06	I
Chlortetracycline	A01AB21 D06AA02	0
Chlortetracycline - Drops - Oinment	S01AA02	 0 I
Chlorzoxazone	M03BB03	II
Chlorzoxazone, combinations excl. psycholeptics	M03BB53	II
Chlorzoxazone, combinations with psycholeptics	M03BB73	II
Cholic acid	A05AA03	NE
Choline alfoscerate	N07AX02	NE
Choline salicylate	N02BA03	NE
Choline theophyllinate	R03DA02	NE
Choline theophyllinate and adrenergics	R03DB02	NE
Chondroitin sulfate	M01AX25	NE
Chondroitin sulfate-iron complex	B03AB07	NE
Chymopapain	M09AB01	NE
Chymotrypsin	B06AA04 S01KX01	NE
Cibenzoline	C01BG07	I

Ciclesonide	R03BA08	0
Cicletanine	C03BX03	0
Ciclonicate	C04AC07	NE
Ciclonium and analgesics	A03DA04	NE
Ciclopirox	D01AE14	0
Ciclosporin	S01XA18	NE
Cilansetron	A03AE03	NE
Cilazapril	C09AA08	I
Cilazapril and diuretics	C09BA08	I
Cilnidipine	C08CA14	NE
Cilostazol	B01AC	0
Cimetidine	A02BA01	I
Cimetidine, combinations	A02BA51	I
Cimetropium bromide	A03BB05	NE
Cinchocaine	C05AD04 D04AB02	0
Cinchocaine	N01BB06 S01HA06	NE
Cinchophen	M04AC02	NE
Cinepazet	C01DX14	NE
Cinepazide	C04AX27	NE
Cinitapride	A03FA (not ATC code)	0
Cinnarizine	N07CA02	II
Cinnarizine, combinations	N07CA52	NE
Cinolazepam	N05CD13	NE
Ciprofibrate	C10AB08	0
Ciprofloxacin - Drops - Oinment	S01AX13	 0 I
Ciprofloxacin	S02AA15	0
Ciprofloxacin	S03AA07	NE
Cisapride	A03FA02	0
Cisatracurium	M03AC11	III
Citalopram	N06AB04	I
Citicoline	N06BX06	NE
Citiolone	A05BA04	NE
Citric acid	A09AB04	0
Clebopride	A03FA06	0
Clemastine	D04AA14	NE
Clemastine	R06AA04	III
Clemastine, combinations	R06AA54	III
Clenbuterol	R03AC14 R03CC13	NE
Clidinium and psycholeptics	A03CA02	NE
Clindamycin	D10AF01	0
Clindamycin, combinations	D10AF51	0
Clioquinol	D08AH30	0
Clioquinol	D09AA10 S02AA05	0
Clobazam	N05BA09	II
Clobenzorex	A08AA08	NE
Clobetasol	D07AD01	0
Clobetasol and antibiotics	D07CD01	NE
Clobetasone	D07AB01	0
Clobetasone	S01BA09	NE
Clobetasone and antiinfectives	S01CA11	NE

Clobutinol	R05DB03	NE
Clocortolone	D07AB21	NE
Clodronic acid	M05BA02	0
Clofedanol	R05DB10	NE
Clofenamide	C03BA07	NE
Clofenamide and potassium	C03BB07	NE
Clofezone	M01AA05 M02AA03	NE
Clofibrate	C10AB01	NE
Clofibride	C10AB10	NE
Clomethiazol	N05CM02	I
Clomipramine	N06AA04	II
Clonazepam - Oral administration - Parenteral administration	N03AE01	 II III
Clonidine	C02AC01 N02CX02 S01EA04	II
Clonidine and diuretics	C02LC01	II
Clonidine and diuretics, combinations with other drugs	C02LC51	II
Clonixin	N02BG Not yet determined	NE
Clopamide	C03BA03	I
Clopamide and potassium	C03BB03	I
Clopenthixol	N05AF02	NE
Cloperastine	R05DB21	I
Clopidogrel	B01AC04	0
Clopidogrel + Acetilsalicilic acid	B01AC30	Depending on the medicine in combination
Cloranolol	C07AA27	NE
Clorazepate combinations	N05CX04	NE
Clorexolone	C03BA12	NE
Clorexolone, comb. with psycholeptics	C03BA82	NE
Clorhexidine	S01AX09	NE
Cloricromen	B01AC02	NE
Cloridarol	C01DX15	I
Clorindione	B01AA09	NE
Clotiapine - Oral administration - Parenteral administration: i.m./i.v.	N05AX09	 II III
Clotiazepam	N05BA21	III
Clotrimazole	A01AB18	NE
Clotrimazole	D01AC01	0
Clovoxamine	N06AA Not yet determined	NE
Cloxazolam	N05BA22	NE
Clozapine	N05AH02	III
Coagulation factor IX	B02BD04	0
Coagulation factor IX, II, VII and X in combination	B02BD01	0
Coagulation factor VII (in combination with other factors)	B02BD05	0
Coagulation factor VIII	B02BD02	0
Coagulation factor XIII	B02BD07	NE
Cobamamide	B03BA04	0
Cocaine	N01BC01	NE

	R02AD03 S01HA01 S02DA02	
Cod-liver oil ointments	D03AA	0
Codeine > 20 mg ≤ 20 mg	R05DA04	 II I
Codeine, combinations excl .psycholeptics > 20 mg ≤ 20 mg	N02AA59	 II I
Codeine, combinations with psycholeptics	N02AA79	NE
Colchicine	M04AC01	0
Colecalciferol	A11CC05	0
Colesevelam	C10AC04	0
Colestipol	C10AC02	0
Colestyramine	C10AC01	0
Colextran	C10AC03	0
Colfosceril palmitate	R07AA01	NE
Colistin	A07AA10	0
Collagen	B02BC07	NE
Collagen, combinations	D11AX57	NE
Collagenase	D03BA02	NE
Collagenase, combinations	D03BA05	NE
Comb. of rauwolfia alkaloids and diuretics incl. other combinations	C02LA50	NE
Combinations (Adrenergic and dopaminergic agents)	C01CA30	I
Combinations (Aluminium compounds)	A02AB10	0
Combinations (Analgesics and anesthetics)	S02DA30	Depending on the medicine in combination
Combinations (Anesthetics, local, amides)	N01BB20	NE
Combinations (Antifungals for topical use, Antibiotics)	D01AA20	NE
Combinations (Butylpyrazolidines)	M01AA99	NE
Combinations (Calcium compounds)	A02AC10	0
Combinations (Caries prophylactic agents)	A01AA30	NE
Combinations (Enemas)	A06AG20	0
Combinations (Expectorants)	R05CA10	NE
Combinations (Imidazole and triazole derivatives)	D01AC20	NE
Combinations (Insulins and analogues for injection, fast-acting)	A10AB30	I
Combinations (Insulins and analogues for injection, intermediate-acting)	A10AC30	I
Combinations (Insulins and analogues for injection, intermediate-acting combined with fast-acting)	A10AD30	I
Combinations (Insulins and analogues for injection, long-acting)	A10AE30	I
Combinations (Irrigating solutions, Antiinfectives)	B05CA10	NE
Combinations (Irrigating solutions, Salt solutions)	B05CB10	0
Combinations (Local anesthetics)	S01HA30	I
Combinations (Local hemostatics)	B02BC30	0
Combinations (Lung surfactants)	R07AA30	NE
Combinations (Magnesium compounds)	A02AA10	0
Combinations (Mucolytics)	R05CB10	NE
Combinations (Opium alkaloids and derivatives)	R05DA20	Depending on the medicine in combination
Combinations (Other cough suppressants)	R05DB20	NE
Combinations (Other intestinal adsorbents)	A07BC30	NE
Combinations (Other irrigating solutions)	B05CX10	0
Combinations (Other nasal preparations)	R01AX30	NE

Combinations (Platelet aggregation inhibitors excl. heparin)	B01AC30	Depending on the medicine in combination
Combinations (Solutions for parenteral nutrition)	B05BA10	0
Combinations (Vitamin A and D, incl. combinations of the two)	A11CC20	Depending on the medicine in combination
Combinations of barbiturates	N05CB01	NE
Combinations of corticosteroids	D07AB30 D07XB30	0
Combinations of different antibiotics	S01AA30	Depending on the medicine in combination
Combinations of electrolytes	B05XA30	0
Combinations of rauwolfia alkaloids	C02AA03	NE
Combinations of rauwolfia alkoloids, combinations	C02AA53	NE
Combinations of vitamins	A11JA	0
Combinations of xanthines	R03DA20	NE
Combinations (Other antifungals for topical use)	D01AE20	NE
Combinations, (potassium)	A12BA30	Depending on the medicine in combination
Conivaptan	C03XA02	NE
Contact laxatives in combination	A06AB20	0
Contact laxatives in combination with belladonna alkaloids	A06AB30	NE
Cortisone	S01BA03	NE
Cosfocreatine	C01EB06	NE
Cough suppressants and expectorants	R05FB02	Depending on the medicine in combination
Cough suppressants and mucolytics	R05FB01	Depending on the medicine in combination
Crataegus glycosides	C01EB04	NE
Creatinolfosfate	C01EB05	NE
Creosote	R05CA08	NE
Cromoglicic acid	A07EB01 R01AC01 R03BC01	0
Cromoglicic acid	D11AH03	NE
Cromoglicic acid	S01GX01	I
Cromoglicic acid, combinations	R01AC51 S01GX51	NE
Crospovidone	A07BC03	NE
Curcuma	A05AX Not yet determined	0
Cxyphenonium, combinations	A03AB53	NE
Cyacobalamin	B03BA01	0
Cyamemazine	N05AA06	NE
Cyanocobalamin tannin complex	B03BA02	NE
Cyanocobalamin, combinations	B03BA51	0
Cyclandelate	C04AX01	I
Cyclizine	R06AE03	II
Cyclizine, combinations	R06AE53	Depending on the medicine in combination
Cyclobarbital	N05CA10	NE
Cyclobenzaprine	M03BX08	II
Cyclobutyrol	A05AX03	0
Cyclopentamine	R01AA02	NE
Cyclopenthiazide	C03AA07	0
Cyclopenthiazide and potassium.	C03AB07	NE

Cyclopenthiazide and potassium-sparing agents (spironolactone)	C03EA07	NE
Cyclopentolate	S01FA04	III
Cyclothiazide	C03AA09	NE
Cyclothiazide and potassium	C03AB09	NE
Cymarin	C01AC03	NE
Cyproheptadine	R06AX02	II
D	**ATC CODE**	**CATEGORISATION labelling**
Dabigatran etexilate	B01AE07	0
Dalteparin	B01AB04	0
Danaparoid	B01AB09	0
Dantrolene	M03CA1	II
Dantron	A06AB03	0
Dantron, combinations	A06AB53	0
Dantron, incl. Combinations	A06AG03	0
Dapiprazole	S01EX02	NE
Dapsone	D10AX05	0
Darbepoetin alfa	B03XA02	0
Deanol	N06BX04	I
Debrisoquine	C02CC04	NE
Defibrotide	B01AX01	NE
Delapril	C09AA12	I
Delapril and diuretics	C09BA12	I
Delapril and manidipine	C09BB12	I
Demecarium	S01EB04	NE
Demeclocycline	D06AA01	NE
Denosumab	M05BX04	I
Deptropine	R06AX16	NE
Dequalinium	D08AH01 R02AA02	0
Dermatan sulfate	B01AX04	NE
Deserpidine	C02AA05	NE
Deserpidine and diuretics.	C02LA03	NE
Desflurane	N01AB07	III
Desipramine	N06AA01	NE
Desirudin	B01AE01	0
Deslanoside	C01AA07	NE
Desloratadine	R06AX27	I
Desonide	D07AB08 S01BA11	NE
Desonide and antiseptics	D07BB02	NE
Desoximetasone	D07AC03	0
Desoximetasone	D07XC02	NE
Desoxyribonuclease	B06AA10	NE
Desvenlafaxine	N06AX23	NE
Dexamethasone	A01AC02 C05AA09 D07AB19 D07XB05 D10AA03 R01AD03	0
Dexamethasone - Drops - Oinment	S01BA01	 0 I
Dexamethasone	S01CB01	Depending on the mydriatic in

		combination
Dexamethasone	S02BA06 S03BA01	NE
Dexamethasone and antibiotics	D07CB04	NE
Dexamethasone and antiinfectives - Drops - Oinment	S01CA01	 0 I
Dexamethasone and antiinfectives	S02CA06 S03CA01	0
Dexamethasone, combinations	R01AD53	NE
Dexamfetamine	N06BA02	II
Dexbrompheniramine	R06AB06	II
Dexbrompheniramine, combinations	R06AB56	NE
Dexchlorpheniramine	R06AB02	II
DexchlorpheniramineCombinations	R06AB52	II
Dexetimide	N04AA08	NE
Dexfenfluramine	A08AA04	NE
Dexibuprofen	M01AE14	I
Dexketoprofen	M01AE17	I
Dexmedetomidine	N05CM18	NE
Dexpanthenol	A11HA30	0
Dexpanthenol	D03AX03 S01XA12	NE
Dextran	B05AA05	0
Dextranomer	D03AX02	NE
Dextriferron	B03AB05	NE
Dextriferron	B03AC01	0
Dextriferron (carboximaltosa)	B03AD04	0
Dextromethorphan	R05DA09	I
Dextromoramide	N02AC01	NE
Dextropropoxyphene	N02AC04	NE
Dextropropoxyphene combinations excl. psycholeptics	N02AC54	NE
Dextropropoxyphene, comb. With psycholepctics	N02AC74	NE
Dextrothyroxine	C10AX01	NE
Dezocine	N02AX03	NE
Diacerein	M01AX21	NE
Diamorphine	N02AA09	NE
Diastase	A09AA01	NE
Diazepam	N05BA01	III
Diazoxide	C02DA01	I
Dibenzepin	N06AA08	III
Dibotermin alfa (Kit for implant)	M05BC01	0
Dibrompropamidine	D08AC01	0
Dibrompropanamidine	S01AX14	NE
Dibunate	R05DB16	NE
Dichloralphenazone	N05CC04	NE
Dichlorobenzyl alcohol	R02AA03	0
Diclofenac	M01AB05 N02BG	I
Diclofenac (ophtalmologic use)	S01BC03	0
Diclofenac (topic use)	M02AA15 D11AX18	0
Diclofenac and antiinfectives	S01CC01	0
Diclofenac, combinations	M01AB55	I
Diclofenamide	S01EC02	I

Dicoumarol	B01AA01	NE
Dicycloverine	A03AA07	0
Didecyldimethylammonium chloride	D08AJ06	NE
Diethyl ether	N01AA01	NE
Difemerine	A03AA09	NE
Difenoxin	A07DA04	NE
Difenpiramide	M01AB12	NE
Diflorasone	D07AC10	0
Diflucortolone	D07AC06	0
Diflucortolone	D07XC04	NE
Diflucortolone and antiseptics	D07BC04	0
Diflunisal	N02BA11	NE
Difluprednate	D07AC19	NE
Digitalis leaves	C01AA03	NE
Digitoxin	C01AA04	I
Digoxin	C01AA05	I
Dihexyverine	A03AA08	NE
Dihydralazine	C02DB01	NE
Dihydralazine and diuretics	C02LG01	NE
Dihydralazine and diuretics, combinations with other drugs	C02LG51	NE
Dihydrocodeine	N02AA08	III/II* *)prolonged release formulation; when a steady state of dosage has been reached
Dihydrocodeine combinations	N02AA58	NE
Dihydroergocristine	C04AE04	I
Dihydroergocristine, combinations	C04AE54	I
Dihydroergocrypti mesylate	N04BC03	NE
Dihydroergocryptine mesylate	N04BC03	NE
Dihydroergotamine	N02CA01	NE
Dihydrostreptomycin	S01AA15	NE
Dihydrotachysterol	A11CC02	0
Dihydroxialumini sodium carbonate	A02AB04	0
Diiodohydroxypropane	D08AG04	NE
Diisopromine	A03AX02	NE
Dilazep	C01DX10	NE
Diltiazem	C08DB01	I
Dimazole	D01AE17	NE
Dimecrotico acido	A05AA (Not yet determined)	0
Dimefline	R07AB08	NE
Dimemorfan	R05DA11	NE
Dimetacrine	N06AA18	NE
Dimethoxanate	R05DB28	NE
Dimethyl sulfoxide	M02AX03	NE
Dimethylaminopropionylphenothiazine	A03AC2	NE
Dimethyltubocurarine	M03AA04	III
Dimetindene	D04AA13	0
Dimetindene	R06AB03	II
Dimetofrine	C01CA12	NE
Dimetotiazine	N02CX05	NE
Diosmectite	A07BC05	NE
Diosmin	C05CA03	0
Diosmin, combinations	C05CA53	0
Diphemanil	A03AB15	NE

Diphemanil and psycholeptics	A03CA08	NE
Diphenadione	B01AA10	NE
Diphenhydramine	D04AA32	0
Diphenhydramine	R06AA02	III
Diphenhydramine methylbromide	D04AA33	0
Diphenhydramine, combinations	R06AA52	III
Diphenoxylate	A07DA01	NE
Diphenylpyraline	R06AA07	NE
Diphenylpyraline, combinations	R06AA57	NE
Dipiperonylamino-ethanol, combinations	N05CX06	NE
Dipivefrine	S01EA02	NE
Diprophylline	R03DA01	NE
Diprophylline and adrenergics	R03DB01	NE
Diprophylline, combinations	R03DA51	NE
Dipyridamole	B01AC07	0
Dipyrocetil, combinations with psycholeptics	N02BA79	NE
Dipyrocetyl	N02BA09	NE
Dipyrocetyl and corticosteroids	M01BA02	NE
Dipyrocetyl, combinations excl. Psycholeptics	N02BA59	NE
Disopyramide	C01BA03	I
Distigmine	N07AA03	NE
Disulfiram	N07BB01	II
Ditazole	B01AC01	NE
Dithranol	D05AC01	0
Dithranol, combinations	D05AC51	0
Dixyrazine	N05AB01	NE
Dobutamine	C01CA07	I
Docosanol	D06BB11	NE
Docusate sodium	A06AA02	0
Docusate sodium, incl. combinations	A06AG10	0
Dodeclonium bromide, combinations	D08AJ59	NE
Dofetilide	C01BD04	NE
Dolasetron	A04AA04	NE
Domiodol	R05CB08	NE
Domiphen	A01AB06	NE
Domperidone	A03FA03	0
Donepezil	N06DA02	II
Dopamine	C01CA04	I
Dopexamine	C01CA14	NE
Dornase alfa (desoxyribonuclease)	R05CB13	0
Dorzolamide	S01EC03	I
Dosmalfato	A02BX	0
Dosulepin	N06AA16	III
Doxacurium chloride	M03AC07	III
Doxapram	R07AB01	I
Doxazosin	C02CA04	I
Doxefazepam	N05CD12	NE
Doxepin	N06AA12	III
Doxofylline	R03DA11	NE
Doxycycline	A01AB22	0
Doxylamine	R06AA09	III
Dronabinol	A04AD10	NE
Droperidol	N01AX01	III
Droperidol, injectable	N05AD08	III
Dropropizine	R05DB19	NE
Drotaverine	A03AD02	NE
Drotrecogin alfa (activated)	B01AD10	0

Droxicam	M01AC04	NE
Droxypropine	R05DB17	NE
Duloxetine	N06AX21	II
Dyclonine	N01BX02 R02AD04	NE
Dyhydroergotamine, combinations	N02CA51	NE
E	**ATC CODE**	**CATEGORISATION labelling**
Ebastine	R06AX22	I
Econazole	D01AC03	0
Ecothiopate	S01EB03	NE
Edoxudine	D06BB09	NE
Eflornithine	D11AX16	0
Efloxate	C01DX13	NE
Electrolytes	B05BB01	0
Electrolytes in combination with other drugs	B05XA31	Depending on the medicine in combination
Electrolytes with Carbohydrates	B05BB02	0
Eletriptan	N02CC06	II
Eltrombopag	B02BX05	0
Emedastine	S01GX06	I
Emepronium and psycholeptics	A03CA30	NE
Emepronium, combinations	N05CX05	NE
Emodina	A05AX Not yet determined	NE
Emylcamate	N05BC03	NE
Enalapril	C09AA02	I
Enalapril and diuretics	C09BA02	I
Enalapril and lercanidipine	C09BB02	I
Encainide	C01BC08	NE
Endralazine	C02DB03	NE
Enflurane	N01AB04	NE
Enoxaparin	B01AB05	0
Enoximone	C01CE03	NE
Enoxolone	D03AX10	NE
Enprostil	A02BB02	NE
Entacapone	N04BX02	II
Eosin	D08AX02	NE
Epanolol	C07AB10	NE
Eperisone	M03BX09	NE
Ephedrine	R01AB05	Depending on the medicine in combination
Ephedrine	R03CA02	I
Ephedrine	S01FB02	NE
Ephedrine, combinations	A08AA56	NE
Epinastine	R06AX24	I
Epinastine	S01GX10	NE
Epinephrine	A01AD01 B02BC09	0
Epinephrine	C01CA24	I
Epinephrine	R01AA14 R03AA01 S01EA01	NE
Epinephrine and other drugs for obstructive airway diseases	R03AK01	NE
Epinephrine, combinations	S01EA51	NE

Epitizide and potassium-sparing agents (spironolactone)	C03EA03	NE
Eplerenone	C03DA04	0
Epomediol	A05BA05	NE
Epoprostenol	B01AC09	0
Eprazinone	R05CB04	NE
Eprosartan	C09CA02	I
Eprosartan and diuretics	C09DA02	I
Eprozinol	R03DX02	NE
Eptacog alfa (activated)	B02BD08	0
Eptifibatide	B01AC16	0
Eptotermin alfa	M05BC02	0
Erdosteine	R05CB15	0
Ergocalciferol (in combinacion, Vitalipid)	A11CC01	0
Ergoloid mesylates	C04AE01	NE
Ergoloid mesylates, combination	C04AE51	I
Ergotamine	N02CA02	NE
Ergotamine, combinations	N02CA72	NE
Ergotamine, combinations excl. psycholeptics	N02CA52	I
Erityl tetranitrate	C01DA13	NE
Erityl tetranitrate, combinations	C01DA63	NE
Erythrocytes	B05AX01	NE
Erythromycin	D10AF02	0
Erythromycin, combinations	D10AF52	0
Erythropoietin (epoetin alfa, beta, theta)	B03XA01	0
Erytromycin	S01AA17	I
Escitalopram	N06AB10	I
Esketamine	N01AX14	NE
Eslicarbazepine	N03AF04	II
Esmolol	C07AB09	I
Esomeprazole	A02BC05	I
Esomeprazole, amoxicillin and clarithromycin	A02BD06	NE
Estazolam	N05CD04	NE
Eszopiclone	N05CF04	NE (SMPC not yet published)
Etacrynic acid	C03CC01	NE
Etafenone	C01DX07	NE
Etallobarbital	N05CA20	NE
Etamiphylline	R03DA06	NE
Etamiphylline and adrenergics	R03DB06	NE
Etamivan	R07AB04	NE
Etamsylate	B02BX01	0
Etanautine	N04AB01	NE
Ethacridine lactate	B05CA08 D08AA01	NE
Ethadione	N03AC03	NE
Ethanol	D08AX08	0
Ethchlorvynol	N05CM08	NE
Ethenzamide	N02BA07	NE
Ethenzamide, combinations excl. Psycholeptics	N02BA57	NE
Ethenzamide, combinations with psycholeptics	N02BA77	NE
Ethosuximide combinations	N03AD51	NE
Ethotoin	N03AB01	NE
Ethoxusimide	N03AD01	II
Ethulose	A06AC02	NE
Ethyl biscoumacetate	B01AA08	NE
Ethyl chloride	N01BX01	NE
Ethyl hydroxybenzoate	D01AE10	NE

Ethyl loflazepate	N05BA18	NE
Ethylestrenol	A14AB02	NE
Ethylmorphine	R05DA01	III
Ethylmorphine	S01XA06	NE
Etidocain combinations	N01BB57	NE
Etidocaine	N01BB07	NE
Etidronic acid	M05BA01	I
Etidronic acid and calcium, sequential	M05BB01	NE
Etifoxine	N05BX03	NE
Etilamfetamine	A08AA06	NE
Etilefrine	C01CA01	I
Etilefrine, combinations	C01CA51	I
Etilevodopa and decarboxylase inhibitor	N04BA06	NE
Etizolam	N05BA19	NE
Etodolac	M01AB08	I
Etofenamate	M02AA06	0
Etofibrate	C10AB09	NE
Etofylline nicotinate	C04AD04	NE
Etomidate	N01AX07	III
Etoperidone	N06AB09	NE
Etoricoxib	M01AH05	I
Etozolin	C03CX01	I
Etretinate	D05BB01	NE
Etybenzatropine	N04AC30	NE
Euflavine	D08AA03	NE
Exenatide	A10BX04	I
Ezetimibe	C10AX09	0
F	**ATC CODE**	**CATEGORISATION labelling**
Factor VIII inhibitor bypassing activity	B02BD03	0
Famciclovir	S01AD07	NE
Famotidine	A02BA03	I
Famotidine, combinations	A02BA53	I
Fasudil	C04AX32	NE
Fat emulsions	B05BA02	NE
Fazadinium bromide	M03AC08	III
Febarbamate	M03BA05	II
Febuxostat	M04AA03	I
Fedrilate	R05DB14	NE
Felbamate	N03AX10	NE
Felbinac	M02AA08	0
Felodipine	C08CA02	I
Femoxetine	(N06AB) Not yet determined	NE
Fenazocine	N02AD02	NE
Fenbufen	M01AE05	NE
Fencamfamin	N06BA06	NE
Fendiline	C08EA01	NE
Fenetylline	N06BA10	NE
Fenfluramine	A08AA02	NE
Fenofibrate	C10AB05	0
Fenoldopam	C01CA19	NE
Fenoprofen	M01AE04 N02BG	NE
Fenoterol	R03AC04	0
Fenoterol	R03CC04	NE

Fenoterol and other drugs for obstructive airway diseases	R03AK03	Depending on the medicine in combination
Fenoverine	A03AX05	NE
Fenoxazoline	R01AA12	NE
Fenozolone	N06BA08	NE
Fenpiprane	A03AX01	NE
Fenpiverinium	A03AB21	NE
Fenproporex	N06BA	NE
Fenquizone	C03BA13	NE
Fenspiride	R03BX01 R03DX03	NE
Fentanyl - Oral administration - Parenteral administration - Transdermal administration	N01AH01 N02AB03	 III III III/II* *) prolonged release formulation; when a steady state of dosage has been reached
Fentanyl combinations	N01AH51	NE
Fentiazac	M01AB10 M02AA14	NE
Fenticonazole	D01AC12	0
Fentonium	A03BB04	NE
Fenyramidol	M03BX30	NE
Feprazone	M01AX18 M02AA16	NE
Feprazone, combinations	M01AX68	NE
Ferric acetyl transferrin	B03AB08	NE
Ferric citrate	B03AB06	0
Ferric hydroxide	B03AB04	0
Ferric oxide dextran complex	B03AC06	0
Ferric proteinsuccinylate	B03AB09	0
Ferric sodium citrate	B03AB01	NE
Ferric sodium gluconate complex	B03AC07	NE
Ferric sorbitol gluconic acid complex	B03AC05	NE
Ferrous amino acid complex	B03AD01	0
Ferrous ascorbate	B03AA10	NE
Ferrous aspartate	B03AA09	NE
Ferrous carbonate	B03AA04	NE
Ferrous chloride	B03AA05	NE
Ferrous fumarate	B03AA02 B03AD02	0
Ferrous gluconate	B03AA03	0
Ferrous glycine sulfate	B03AA01	0
Ferrous iodine	B03AA11	NE
Ferrous succinate	B03AA06	NE
Ferrous sulfate	B03AA07 B03AD03	0
Ferrous tartrate	B03AA08	NE
Fexofenadine	R06AX26	I
Fibrinogen, human	B02BC10	0
Fibrinolysin	B01AD05	NE
Fibrinolysin and desoxyribonuclease	B06AA02	NE
Finasteride	D11AX10	0
Fipexide	N06BX05	NE
Flecainide	C01BC04	I

Floctafenine	N02BG04	NE
Flosequinan	C01DB01	NE
Flourometholone and antiinfectives - Drops - Oinment	S01CA07	 0 I
Fluanisone	N05AD09	NE
Flubiprofen	S01BC04	NE
Fluclorolone	D07AC02	0
Fluconazole	D01AC15	NE
Flucytosine	D01AE21	NE
Fludiazepam	N05BA17	NE
Fludrocortisone and antiinfectives - Drops - Oinment	S01CA06	 0 I
Fludrocortisone and antiinfectives	S02CA07 S03CA05	0
Fludroxycortide	D07AC07	NE
Fludroxycortide and antibiotics	D07CC03	NE
Flufenamic acid	M01AG03	NE
Flumedroxone	N02CB01	NE
Flumetasone	D07AB03 D07XB01	0
Flumetasone and antibiotics	D07CB05	NE
Flumetasone and antiinfectives	S02CA02	NE
Flumetasone and antiseptics	D07BB01	0
Flunarizine	N07CA03	II
Flunisolide	R03BA03	NE
Flunitrazepam	N05CD03	III
Flunoxaprofen	M01AE15	NE
Fluocinolone acetonide	C05AA10 D07AC04	0
Fluocinolone acetonide	S01BA15 S02BA08	NE
Fluocinolone acetonide and antibiotics	D07CC02	0
Fluocinolone acetonide and antiinfectives	S01CA10	NE
Fluocinolone acetonide and antiinfectives	S02CA05	0
Fluocinolone acetonide and antiseptics	D07BC02	0
Fluocinonide	C05AA11 D07AC08	0
Fluocinonide and antibiotics	D07CC05	0
Fluocortin	D07AB04	0
Fluocortolone	C05AA08	NE
Fluocortolone	D07AC05	0
Fluocortolone and antibiotics	D07CC06	NE
Fluocortolone and antiinfectives	S01CA04	NE
Fluocortolone and antiseptics	D07BC03	0
Fluorescein	S01JA01	0
Fluorescein, combinations	S01JA51	Depending on the medicine in combination
Fluoride, combinations	A12CD51	0
Fluorocarbon blood substitutes	B05AA03	NE
Fluorometholone	C05AA06 D07XB04	0
Fluorometholone - Drops - Oinment	S01BA07	 0 I
Fluorometholone	D07AB06	NE

	D10AA01	
Fluorometholone	S01CB05	Depending on the mydriatic in combination
Fluorometholone and antibiotics	D07CB03	NE
Fluorometholone and mydriatics	S01BB03	Depending on the mydriatic in combination
Fluostigmine	S01EB07	NE
Fluoxetine	N06AB03	I
Flupentixol - Oral administration - Parenteral administration: depot i.m.	N05AF01	 II III
Fluperolone	D07AB05	NE
Fluphenazine: injection depot i.m.	N05AB02	II
Flupirtine	N02BG07	NE
Fluprednidene	D07AB07 D07XB03	NE
Fluprednidene and antibiotics	D07CB02	NE
Flurazepam	N05CD01	III
Flurbiprofen	M01AE09	I
Flurbiprofen	M02AA19 R02AX01	0
Fluspirilene: injection i.m.	N05AG01	II
Fluticasone	D07AC17 R01AD08 R03BA05	0
Fluticasone furoate	R01AD12	0
Flutrimazole	D01AC16	0
Fluvastatin	C10AA04	0
Fluvoxamine	N06AB08	I
Folic acid	B03BB01	0
Folic acid, combinations	B03BB51	0
Fomivirsen	S01AD08	NE
Fondaparinux	B01AX05	0
Formocortal	S01BA12	NE
Formoterol	R03AC13	0
Formoterol and other drugs for obstructive airway diseases	R03AK07	Depending on the medicine in combination
Fosaprepitant	A04AD	0
Fosinopril	C09AA09	I
Fosinopril and diuretics	C09BA09	I
Fosphenytoin	N03AB05	NE
Framycetin	D09AA01 R01AX08 S01AA07	NE
Frovatriptan	N02CC07	II
Fructose 1,6-diphosphate	C01EB07	NE
Fumaric acid	D05AX01	NE
Fumaric acid derivatives, combinations	D05BX51	NE
Funisolide	R01AD04	0
Furosemide	C03CA01	0
Furosemide and potassium	C03CB01	0
Furosemide and potassium-sparing agents	C03EB01	0
Fusafungine	R02AB03	NE
Fusidic acid	D06AX01 D09AA02	0
Fusidic acid - Drops	S01AA13	 0

- Oinment		I
G	**ATC CODE**	**CATEGORISATION labelling**
Gabapentin	N03AX12	II
Galantamine	N06DA04	II
Gallamine	M03AC02	III
Gallopamil	C08DA02	NE
Galsulfase	A16AB08	I
Gamolenic acid, combinations	D11AX52	NE
Ganciclovir	S01AD09	0
Gatifloxacin	S01AX21	NE
Gedocarnil	N05BX02	NE
Gefarnate	A02BX07	NE
Gefarnate, combinations with psycholeptics	A02BX77	NE
Gelatin agents	B05AA06	0
Gemfibrozil	C10AB04	0
Gentamicin	D06AX07	0
Gentamicin - Drops - Oinment	S01AA11	 0 I
Gentamicin	S02AA14 S03AA06	NE
Gepefrine	C01CA15	NE
Gepirone	N06AX19	NE
Ginkgo Biloba	N06DX02	0
Gitoformate	C01AA09	NE
Glafenine	N02BG03	NE
Glibenclamide	A10BB01	I
Glibornuride	A10BB04	NE
Gliclazide	A10BB09	I
Glimepiride	A10BB12	I
Glimepiride and pioglitazone	A10BD06	I
Glimepiride and rosiglitazone	A10BD04	I
Glipizide	A10BB07	I
Gliquidone	A10BB08	I
Glisoxepide	A10BB11	NE
Glucosamine	M01AX05	I
Glucosaminoglykan polysulfate	M01AX12	NE
Glucose	B05CX01	0
Glucose, combinations	C05BB56	0
Glutamic acid hydrochloride	A09AB01	NE
Glutamine	A16AA03	0
Glutethimide	N05CE01	NE
Glycerol	A06AG04 A06AX01	0
Glyceryl trinitrate	C01DA02 C05AE01	I
Glyceryl trinitrate, combinations	C01DA52	NE
Glycine	B05CX03	0
Glycopyrronium	A03AB02	0
Glycopyrronium and psycholeptics	A03CA05	NE
Glycyrrhizic acid	A05BA08	NE
Glymidine	A10BC01	NE
Gramicidin	R02AB30	NE
Granisetron	A04AA02	0
Griseofulvin	D01AA08	NE

Griseofulvin	D01BA01	0
G-strophanthin	C01AC01	NE
Guacetisal	N02BA14	NE
Guaiacolsulfonate	R05CA09	NE
Guaiazulen	S01XA01	NE
Guaifenesin	R05CA03	I
Guanazodine	C02CC06	NE
Guanethidine	C02CC02	I
Guanethidine	S01EX01	NE
Guanethidine and diuretics	C02LF01	I
Guanfacine	C02AC02	II
Guanoclor	C02CC05	NE
Guanoxabenz	C02CC07	NE
Guanoxan	C02CC03	NE
Guar gum	A10BX01	0
H	**ATC CODE**	**CATEGORISATION labelling**
Hachimycin	D01AA03	NE
Halazepam	N05BA13	NE
Halcinonide	D07AD02	NE
Halometasone	D07AC12	0
Haloperidol - Oral administration - Parenteral administration:i.v./i.m.	N05AD01	 II III
Haloprogin	D01AE11	NE
Halothane	N01AB01	NE
Hematin	B06AB01	0
Hemoglobin crosfumaril	B05AA08	NE
Hemoglobin glutamer (bovine)	B05AA10	NE
Hemoglobin raffimer	B05AA09	NE
Heparin	B01AB01 C05BA03	0
Heparin	S01XA14	NE
Heparin, combinations	B01AB51	NE
Heparin, combinations	C05BA53	0
Heparinoid, combinations	C05BA51	0
Heptabarbital	N05CA11	NE
Heptaminol	C01DX08	NE
Hexachlorophene	D08AE01	NE
Hexafluronium	M03AC05	III
Hexamidine	D08AC04 R01AX07 R02AA18 S01AX08 S03AA05	NE
Hexapropymate	N05CM10	NE
Hexetidine	A01AB12	0
Hexobarbital	N01AF02 N05CA16	NE
Hexobendine	C01DX06	I
Hexocyclium	A03AB10	NE
Hexoprenaline	R03AC06 R03CC05	NE
Hexylresorcinol	R02AA12	0
Hidrosmin	C05CA05	0
Histapyrrodine	R06AC02	II

Histapyrrodine, combinations	R06AC52	NE
Homatropine	S01FA05	III
Human fibrinogen	B02BB01	0
Human fibrinogen / Human thrombin (Evicel®)	B02BC	0
Hyaluronic acid	M09AX01	I
Hyaluronic acid	R01AX09 S01KA01 D03AX05	NE
Hyaluronic acid, combinations	S01KA51	NE
Hyaluronidase	B06AA03	0
Hydralazine	C02DB02	I
Hydralazine and diuretics	C02LG02	I
Hydrixybutiric acid	N01AX11	NE
Hydrochloric acid	A09AB03	NE
Hydrochloric acid	B05XA13	0
Hydrochlorothiazide	C03AA03	0
Hydrochlorothiazide and potassium	C03AB03	0
Hydrochlorothiazide and potassium-sparing agents (spironolactone)	C03EA01	I
Hydrochlorothiazide, combinations	C03AX01	0
Hydrocodone	R05DA03	II
Hydrocortisone	A01AC03 A07EA02 C05AA01 D07AA02 D07XA01	0
Hydrocortisone	S01BA02	I Oinment
Hydrocortisone (with mydriatics)	S01CB03	Depending on the mydriatic in combination
Hydrocortisone	S02BA01	NE
Hydrocortisone aceponate	D07AC16	NE
Hydrocortisone and antibiotics	D07CA01	0
Hydrocortisone and antiinfectives - Drops - Oinment	S01CA03	 0 I
Hydrocortisone and antiinfectives	S02CA03	0
Hydrocortisone and antiinfectives	S03CA04	0
Hydrocortisone and antiseptics	D07BA04	0
Hydrocortisone and mydriatics	S01BB01	Depending on the mydriatic in combination
Hydrocortisone buteprate	D07AB11	NE
Hydrocortisone butyrate	D07AB02	0
Hydrocortisone butyrate and antiseptics	D07BB04	NE
Hydrocortisone, combinations	R01AD60	NE
Hydroflumethiazide	C03AA02	0
Hydroflumethiazide and potassium	C03AB02	0
Hydroflumethiazide, combinations	C03AH02	NE
Hydrogen peroxide	A01AB02 D08AX01	0
Hydrogen peroxide	S02AA06	NE
Hydromorphone	N02AA03	III/II* *) prolonged release formulation; when a steady state of dosage has been reached
Hydromorphone and antispasmodics	N02AG04	NE
Hydroquinidine	C01BA	NE

Hydroquinine	M09AA01	I
Hydroquinone	D11AX11	0
Hydrotalcite	A02AD04	0
Hydroxocobalamin	B03BA03	0
Hydroxocobalamin, combinations	B03BA53	0
Hydroxybutyryc acid	N07XX04	NE
Hydroxyethylpromethazine	R06AD05	NE
Hydroxyethylpromethazine, combinations	R06AD55	NE
Hydroxyethylstarch	B05AA07	0
Hydroxyzine	N05BB01	II
Hydroxyzine, combinations	N05BB51	NE
Hymecromone	A05AX02	NE
Hyoscyamine	A03BA03	NE
Hyoscyamine and Psycholeptics	A03CB31	NE
Hypericine	N06AX20	0
Hypertonic solutions	B05DB	0
Hypromellose	S01KA02	0
I	**ATC CODE**	**CATEGORISATION labelling**
Ibacitabine	D06BB08	NE
Ibandronic acid	M05BA06	I
Ibopamine	C01CA16 S01FB03	NE
Ibudilast	R03DC04	NE
Ibuprofen	C01EB16	NE
Ibuprofen	M02AA13	0
Ibuprofen	M01AE01 N02BG	I
Ibuprofen, combinations	M01AE51	I
Ibuproxam	M01AE13	NE
Ibutilide	C01BD05	I
Icatibant	C01EB19	I
Ichtasol	D10BX01	NE
Idanpramine	A03AX06	NE
Idebenone	N06BX13	NE
Idoxuridine	D06BB01	0
Idoxuridine	S01AD01	NE
Idursulfase	A16AB09	I
Ifenprodil	C04AX28	NE
Iloprost (for inhalation use)	B01AC11	II
Imidapril	C09AA16	I
Imidazole salicylate	N02BA16	NE
Imiglucerase	A16AB02	0
Imipramine	N06AA02	II
Imipramine oxide	N06AA03	NE
Imiquimod	D06BB10	0
Imolamine	C01DX09	NE
Indacaterol	R03AC18	0
Indalpine	N06AB Not yet determined	NE
Indapamide	C03BA11	0
Indifferent preparations	S02DC	Depending on the medicine in combination
Indobufen	B01AC10	NE
Indometacin	C01EB03 S01BC01	NE

Indometacin	M01AB01	I
Indometacin	M02AA23	0
Indometacin, combinations	M01AB51	I
Indoprofen	M01AE10	NE
Indoramin	C02CA02	I
Inosine	D06BB05	0
Inosine	S01XA10	NE
Inositol	A11HA07	0
Inositol nicotinate	C04AC03	0
Insulin (beef)	A10AB02	I
Insulin (beef)	A10AC02	I
Insulin (beef)	A10AD02	I
Insulin (beef)	A10AE02	I
Insulin (human)	A10AB01	I
Insulin (human)	A10AC01	I
Insulin (human)	A10AD01	I
Insulin (human)	A10AE01	I
Insulin (human)	A10AF01	I
Insulin (pork)	A10AB03	I
Insulin (pork)	A10AC03	I
Insulin (pork)	A10AD03	I
Insulin (pork)	A10AE03	I
Insulin aspart	A10AB05	I
Insulin aspart	A10AD05	I
Insulin detemir	A10AE05	I
Insulin glargine	A10AE04	I
Insulin glulisine	A10AB06	I
Insulin lispro	A10AB04	I
Insulin lispro	A10AC04	I
Insulin lispro	A10AD04	I
Insulin (human)	A10AF01	I
Interferon	S01AD05	NE
Invert sugar	C05BB03	0
Iodine	D08AG03	0
Iodine/octylphenoxypolyglycolether	D08AG01	NE
Iodoform	D09AA13	NE
Iodoheparinate	S01XA09	NE
Ipecacuanha	R05CA04	0
Ipratropium bromide	R01AX03	0
Ipratropium bromide	R03BB01	I
Iprazochrome	N02CX03	NE
Ipriflavone	M05BX01	NE
Iprindole	N06AA13	NE
Iproclozide	N06AF06	NE
Iproniazide	N06AF05	NE
Irbesartan	C09CA04	I
Irbesartan and diuretics	C09DA04	I
Iron and multivitamins	B03AE03	0
Iron, multivitamins and folic acid	B03AE02	0
Iron, multivitamins and minerals	B03AE04	0
Iron, vitamin B12 and folic acid	B03AE01	0
Iron-sorbitol-citric acid complex	B03AC03	NE
Isoaminile	R05DB04	NE
Isobromindione	M04AB04	NE
Isocarboxazide	N06AF01	NE
Isoconazole	D01AC05	NE
Isoetarine	R03AC07	NE

	R03CC06	
Isoflurane	N01AB06	III
Isometheptene	A03AX10	0
Isoprenaline	C01CA02	I
Isoprenaline	R03AB02 R03CB01	NE
Isoprenaline and other drugs for obstructive airway diseases	R03AK02	NE
Isoprenaline, combinations	R03CB51	NE
Isopropamide	A03AB09	NE
Isopropamide and psycholeptics	A03CA01	NE
Isopropanol	D08AX05	NE
Isosorbide dinitrate	C01DA08 C05AE02	I
Isosorbide dinitrate, combinations	C01DA58	NE
Isosorbide mononitrate	C01DA14	I
Isothipendyl	D04AA22	NE
Isothipendyl	R06AD09	II
Isotonic solutions	B05DA	0
Isotretinoin - Oral administration - Topical use	D10AD04 D10BA01	 II 0
Isotretinoin, combinations (with erythromycin, topical use)	D10AD54	0
Isoxsuprine	C04AA01	I
Ispaghula (psylla seeds)	A06AC01	0
Ispaghula, combinations	A06AC51	0
Isradipine	C08CA03	I
Itramin tosilate	C01DX01	NE
Itramin tosilate, combinations	C01DX51	NE
Ivabradine	C01EB17	I
K	**ATC CODE**	**CATEGORISATION labelling**
Kallidinogenase	C04AF01	NE
Kanamycin	A07AA08 S01AA24	NE
Kaolin	A07BC02	NE
Kebuzone	M01AA06	NE
Ketamine	N01AX03	III
Ketanserin	C02KD01	NE
Ketazolam	N05BA10	NE
Ketobemidone	N02AB01	NE
Ketobemidone and antispasmodics	N02AG02	NE
Ketoconazole	D01AC08	0
Ketoprofen	M02AA10	0
Ketoprofen	M01AE03 N02BG	I
Ketoprofen, combinations	M01AE53	I
Ketorolac	M01AB15	I
Ketorolac	S01BC05	0
Ketotifen	R06AX17	II
Ketotifen	S01GX08	I
L	**ATC CODE**	**CATEGORISATION labelling**
Labetalol	C07AG01	I

Labetalol and other diuretics	C07CG01	I
Labetalol and thiazides	C07BG01	I
Lacidipine	C08CA09	I
Lacosamide	N03AX18	II
Lactic acid producing organisms	A07FA01	0
Lactic acid producing organisms, combinations	A07FA02	0
Lactitol	A06AD12	0
Lactulose	A06AD11	0
Lactulose, combinations	A06AD61	NE
Lafutidine	A02BA08	NE
Lamotrigine	N03AX09	II
Lanatoside C	C01AA06	NE
Lansoprazole	A02BC03	I
Lansoprazole, amoxicillin and clarithromycin	A02BD07	NE
Lansoprazole, amoxicillin and metronidazole	A02BD03	NE
Lansoprazole, tetracycline and metronidazole	A02BD02	NE
Laronidase	A16AB05	I
Latanoprost	S01EE01	I
Laurilsulfate, incl. combinations	A06AG11	0
Lepirudin	B01AE02	0
Lercanidipine	C08CA13	I
Letosteine	R05CB09	NE
Levacetylmethadol	N07BC03	NE
Levetiracetam	N03AX14	II
Levobunolol	S01ED03	I
Levobupivacaine	N01BB10	I to III Depending on the route of administration
Levocabastine	R01AC02	0
Levocabastine	S01GX02	I
Levocarnitine	A16AA01	0
Levocetirizine	R06AE09	I
Levodopa	N04BA01	II
Levodopa and decarboxylase inhibitor Levodopa+carbidopa Levodopa+benserazide	N04BA02	II
Levodopa, decarboxylase inhibitor and COMT inhibitor Levodopa+carbidopa+entocapone	N04BA03	II
Levodropropizine	R05DB27	I
Levofloxacin	S01AX19	NE
Levomepromazine	N05AA02	III
Levopenbutolol	C07AA	I
Levorphanol	N02AF	NE
Levosimendan	C01CX08	I
Levosulpiride	N05AL07 A04AD	II
Levoverbenone	R05CA11	NE
Lidocaine	S01HA07 S02DA01	NE
Lidocaine (Anesthetics, local)	N01BB02 C05AD01 D04AB01 R02AD02	0 to III Depending on the route of administration
Lidocaine (Antiarrhytmics, parenteral use)	C01BB01	I
Lidocaine, combinations (Anesthetics, local)	N01BB52	0 to III Depending on the route of

		administration
Lidoflazine	C08EX01	NE
Linopirdine	N06BX09	NE
Linseed	A06AC05	0
Linseed, combinations	A06AC55	NE
Linsidomine	C01DX18	NE
Liquid paraffin	A06AA01	0
Liquid paraffin, combinations	A06AA51	0
Liquid plaster	D02AD	0
Liraglutide	A10BX07	I
Lisinopril	C09AA03	I
Lisinopril and amlodipine	C09BB03	I
Lisinopril and diuretics	C09BA03	I
Lisuride	N02CA07 G02CB02	NE
Lithium	N05AN01	II
Lithium succinate	D11AX04	NE
Lodoxamide	S01GX05	I
Lofepramine	N06AA07	II
Lofexidine	N07BC04	NE
Lomefloxacin - Drops - Oinment	S01AX17	 0 I
Lomoxicam	M01AC05	NE
Lonazolac	M01AB09	NE
Loperamide	A07DA03	0
Loperamide oxide	A07DA05	NE
Loperamide, combinations	A07DA53	Depending on the medicine in combination
Loprazolam	N05CD11	III
Lorajmine	C01BA12	NE
Loratadine	R06AX13	I
Lorazepam	N05BA06	III
Lorazepam, combinations	N05BA56	NE
Lorcainide	C01BC07	NE
Lormetazepam	N05CD06	III
Losartan	C09CA01	I
Losartan and diuretics	C09DA01	I
Loteprednol	S01BA14	NE
Lovastatin	C10AA02	0
Lovastatin and nicotinic acid	C10BA01	0
Loxapine	N05AH01	NE
Lubiprostone	A06AX03	NE
Lumiracoxib	M01AH06	NE
Lysine	B05XB03	NE
Lysozyme	D06BB07	0
M	**ATC CODE**	**CATEGORISATION labelling**
Macrogol	A06AD15	0
Macrogol, combinations	A06AD65	0
Mafenide	D06BA03	NE
Magaldrate	A02AD02	0
Magaldrate and antiflatulents	A02AF01	0
Magnesium (different salts in combination)	A12CC30	0
Magnesium aspartate	A12CC05	NE
Magnesium carbonate	A02AA01	0

Magnesium carbonate	A06AD01	NE
Magnesium chloride	A12CC01 B05XA11	0
Magnesium citrate	A06AD19 A12CC04 B05CB03	NE
Magnesium gluconate	A12CC03	NE
Magnesium hydroxide	A02AA04	0
Magnesium lactate	A12CC06	0
Magnesium levulinate	A12CC07	NE
Magnesium orotate	A12CC09	NE
Magnesium oxide	A06AD02	NE
Magnesium oxide	A12CC10	0
Magnesium peroxide	A02AA03 A06AD03	NE
Magnesium phosphate	B05XA10	0
Magnesium pidolate	A12CC08	0
Magnesium pyridoxal 5-phosphate glutamate	C10AX07	NE
Magnesium silicate	A02AA05	0
Magnesium sulfate	A06AD04 B05XA05	NE
Magnesium sulfate	A12CC02 D11AX05	NE
Mandelic acid	B05CA06	NE
Manidipine	C08CA11	I
Mannitol	A06AD16	NE
Mannitol	B05BC01 B05CX04	0
Maprotiline - Oral administration: - Parenteral administration	N06AA21	 II III
Mazaticol	N04AA10	NE
Mazindol	A08AA05	NE
Mebeverine	A03AA04	0
Mebhydrolin	R06AX15	II
Mebutamate	N05BC04	NE
Mebutizide	C03AA13	NE
Mebutizide and potassium-sparing agents (spironolactone)	C03EA05	NE
Meclocycline	D10AF04	0
Meclofenamic acid	M01AG04 M02AA18	NE
Meclofenoxate	N06BX01	NE
Meclozine	R06AE05	II
Meclozine, combinations	R06AE55	NE
Mecobalamin	B03BA05	NE
Medazepam	N05BA03	NE
Medicinal charcoal	A07BA01	0
Medicinal charcoal, combinations	A07BA51	0
Medifoxamine	N06AX13	NE
Medrysone	S01BA08	NE
Mefenamic Acid	M01AG01 N02BG	I
Mefenorex	A08AA09	NE
Mefruside	C03BA05	NE
Mefruside and potassium	C03BB05	NE
Meglutol	C10AX05	NE

Melagatran	B01AE04	NE
Melatonin	N05CH01	I
Melevodopa	N04BA04	NE
Melevodopa and decarboxylase inhibitor	N04BA05	NE
Melitracen	N06AA14	NE
Melitracen and psycholeptics	N06AC02	NE
Meloxicam	M01AC06	I
Melperone	N05AD03	NE
Memantine	N06DX01	II
Menadione	B02BA02	0
Mepartricin	A01AB16 D01AA06	NE
Mepenzolate	A03AB12	NE
Mephenesin	M03BX06	II
Mephenoxalone	N05BX01	NE
Mephentermine	C01CA11	NE
Mephenytoin	N03AB04	NE
Mephenytoin, combinations	N03AB54	NE
Mepivacaine	N01BB03	0 to III Depending on the route of administration
Mepivacaine combinations	N01BB53	I
Mepixanox	R07AB09	NE
Meprobamate	N05BC01	NE
Meprobamate in association	N05CX01	NE
Meprobamate, combinations	N05BC51	NE
Meprotixol	R05DB22	NE
Meptazinol	N02AX05	NE
Mepyramine	D04AA02	0
Mepyramine	R06AC01	II
Mequinol	D11AX06	0
Mequitazine	R06AD07	II
Mercaptamine	A16AA04	I
Mercuric amidochloride	D08AK01	NE
Mercuric chloride	D08AK03	NE
Mercuric iodide	D08AK30	NE
Mercurochrome	D08AK04	0
Mercury compounds	S01AX01	NE
Mercury, metallic	D08AK05	NE
Mersalyl	C03BC01	NE
Mesalazine	A07EC02	0
Mesna	R05CB05	NE
Mesoridiazine	N05AC03	NE
Mesulfen	D10AB05	NE
Mesuximide	N03AD03	NE
Metabutethamine	N01BA01	NE
Metahexamide	A10BB10	NE
Metamfetamine	N06BA03	NE
Metamizole sodium (noramydopyrine)	N02BB02	NE
Metamizole sodium, combinations excl. Psycholeptics	N02BB52	NE
Metamizole sodium, combinations with. Psycholeptics	N02BB72	NE
Metandienone	A14AA03 D11AE01	NE
Metaraminol	C01CA09	NE
Metenolone	A14AA04	0

Metformin	A10BA02	0
Metformin and pioglitazone	A10BD05	0
Metformin and rosiglitazone	A10BD03	0
Metformin and sitagliptin	A10BD07	I
Metformin and sulfonamides	A10BD02	I
Metformin and vildagliptin	A10BD08	I
Methabarbital	N03AA30	NE
Methadone - Oral administration: - Parenteral administration	N07BC02	 II III
Methadone. Comb. Excl. Psycholectics	N02AC52	NE
Methantheline	A03AB07	NE
Methapyrilene	R06AC05	NE
Methaqualone	N05CM01	NE
Methaqualone, combinations	N05CX02	NE
Methazolamide	S01EC05	NE
Methdilazine	R06AD04	NE
Methiosulfonium chloride	A02BX04	NE
Methocarbamol	M03BA03	II
Methocarbamol, combinations excl. psycholeptics	M03BA53	II
Methocarbamol, combinations with psycholeptics	M03BA73	II
Methohexital	N01AF01	NE
Methoserpidine	C02AA06	NE
Methoserpidine and diuretics	C02LA04	NE
Methoxamine	C01CA10	NE
Methoxsalen	D05AD02	NE
Methoxsalen	D05BA02	0
Methoxy polyethylene glycol-epoetin beta	B03XA03	0
Methoxyflurane	N01AB03	NE
Methoxyphenamine	R03CB02	NE
Methyclothiazide	C03AA08	NE
Methyclothiazide and potassium.	C03AB08	NE
Methylatropine	A03BB02	NE
Methylcellulose	A06AC06	0
Methyldigoxin	C01AA08	I
Methyldopa (levorotatory)	C02AB01	II
Methyldopa (levorotatory) and diuretics	C02LB01	II
Methyldopa (racemic)	C02AB02	II
Methylhomatropine and psycholeptics	A03CB04	NE
Methylnaltrexone Bromide	A06AH01	0
Methylpentynol	N05CM15	NE
Methylpentynol, combinations	N05CX03	NE
Methylphenidate	N06BA04	II
Methylphenobarbital	N03AA01	NE
Methylprednisolone	D07AA01	NE
Methylprednisolone	D10AA02	0
Methylprednisolone aceponate	D07AC14	0
Methylprednisolone and antibiotics	D07CA02	NE
Methylprednisolone and antiinfectives	S01CA08	NE
Methylpropylpropanediol dinitrate	C01DA04	NE
Methylpropylpropanediol dinitrate, combinations	C01DA54	NE
Methylprylon	N05CE02	NE
Methylrosaniline	D01AE02	0
Methylscopolamine	A03BB03 S01FA03	NE

Methylscopolamine and psycholeptics (with Chlordiazepoxide)	A03CB01	II
Methysergide	N02CA04	NE
Meticrane	C03BA09	NE
Metipranolol	S01ED04	NE
Metipranolol and thiazides, combinations	C07BA68	NE
Metipranolol, combinations	S01ED54	NE
Metirosine	C02KB01	NE
Metixene	N04AA03	NE
Metizoline	R01AA10	NE
Metoclopramide - Oral administration - Parenteral administration	A03FA01	 I II
Metolazone	C03BA08	I
Metolazone and potassium-sparing agents (spironolactone)	C03EA12	NE
Metopimazine	A04AD05	NE
Metoprolol	C07AB02	I
Metoprolol - chlortalidone	C07BB02	NE
Metoprolol - felodipin	C07FB02	NE
Metoprolol and other antihypertensives	C07FB02	I
Metoprolol and other diuretics	C07CB02	I
Metoprolol and thiazides	C07BB02	I
Metoprolol and thiazides, combinations	C07BB52	I
Metoprolol, combinations	C07AB52	I
Metronidazole	A01AB17 D06BX01	0
Mexiletine	C01BB02	I
Mianserin	N06AX03	III
Miconazole	A01AB09 A07AC01 D01AC02	0
Miconazole	S02AA13	NE
Miconazole, combinations	D01AC52	0
Micronomicin	S01AA22	NE
Midazolam	N05CD08	III
Midodrine	C01CA17	NE
Miglitol	A10BF02	0
Miglustat	A16AX06	I
Milnacipran	N06AX17	NE
Milrinone	C01CE02	I
Minaprine	N06AX07	NE
Mineral salts in combination	A06AD10	NE
Minocycline	A01AB23	0
Minoxidil	C02DC01	I
Minoxidil	D11AX01	0
Mirtazapine	N06AX11	III
Misoprostol	A02BB01	0
Mitiglinide	A10BX08	NE
Mivacurium chloride	M03AC10	III
Mizolastine	R06AX25	II
Moclobemide	N06AG02	II
Modafinil	NO6BA07	II
Moexipril	C09AA13	I
Moexipril and diuretics	C09BA13	I
Mofebutazone	M01AA02 M02AA02	NE

Molindone	N05AE02	NE
Molsidomine	C01DX12	NE
Mometasone	D07AC13 D07XC03 R01AD09 R03BA07	0
Monobenzone	D11AX13	NE
Monoethanolamine oleate	C05BB01	0
Monoxerutin	C05CA02	0
Montelukast	R03DC03	0
Moperone	N05AD04	NE
Moracizine	C01BG01	NE
Morclofone	R05DB25	NE
Morniflumate	M01AX22	I
Morphine - Oral administration - Parenteral administration	N02AA01	 III/II* III *) prolonged release formulation; when a steady state of dosage has been reached
Morphine and antispasmodics	N02AG01	NE
Morphine combinations	N02AA51	NE
Morphine, combinations.	A07DA52	II
Morpholine salicylate	N02BA08	NE
Mosapramine	N05AX10	NE
Motretinide	D10AD05	NE
Moxaverine	A03AD30	NE
Moxifloxacin	S01AX22	0
Moxisylyte	C04AX10	I
Moxonidine	C02AC05	II
Moxonidine and diuretics	C02LC05	II
Multienzymes (lipase, protease etc.)	A09AA02	0
Multienzymes and acid preparations	A09AC02	NE
Multivitamins and calcium	A11AA02	0
Multivitamins and iron	A11AA01	0
Multivitamins and other minerals, incl. combinations	A11AA03	0
Multivitamins and trace elements	A11AA04	0
Mupirocin	D06AX09 R01AX06	0
Muzolimine	C03CD01	NE
Myristyl-benzalkonium	R02AA10	NE
N	**ATC CODE**	**CATEGORISATION labelling**
Nabilone	A04AD11	II
Nabumetone	M01AX01	I
Nadolol	C07AA12	I
Nadolol and thiazides	C07BA12	I
Nadroparin	B01AB06	0
Naftidrofuryl	C04AX21	I
Naftifine	D01AE22	0
Nalbuphine	N02AF02	NE
Naltrexone	N07BB04	II
Nandrolone	A14AB01	0
Nandrolone	S01XA11	NE

Naphazoline	R01AA08	0
Naphazoline	R01AB02	NE
Naphazoline	S01GA01	I
Naphazoline, combinations	S01GA51	Depending on the medicine in combination
Naproxen	M02AA12	NE
Naproxen	M01AE02 N02BG	I
Naratriptan	N02CC02	II
Narcobarbital	N01AG01	NE
Natamycin	A01AB10 A07AA03 D01AA02 S01AA10	NE
Nateglinide	A10BX03	I
Natural phospholipids	R07AA02	NE
Nebivolol	C07AB12	I
Nedocromil	R01AC07 R03BC03	0
Nedocromil	S01GX04	I
Nefazodone	N06AX06	II
Nefopam	N02BG06	II
Neltenexine	R05CB14	NE
Neomycin	A01AB08 A07AA01 D06AX04	0
Neomycin	B05CA09 R02AB01 S02AA07 S03AA01	NE
Neomycin - Drops - Oinment	S01AA03	 0 I
Neomycin, combinations	A07AA51	0
Neostigmine - Oral administration - Parenteral administration	N07AA01	 II III
Neostigmine	S01EB06	NE
Neostigmine, combinations	N07AA51	NE
Nepafenac	S01BC10	NE
Nepinalone	R05DB26	NE
Nesiritide	C01DX19	NE
Netilmicin	S01AA23	NE
Nialamide	N06AF02	NE
Niaprazine	N05CM16	NE
Nicardipine	C08CA04	I
Nicergoline	C04AE02	I
Niceritrol	C10AD01	NE
Nicofetamide	A03AC04	NE
Nicofuranose	C10AD03	NE
Nicomorphine	N02AA04	NE
Nicorandil	C01DX16	I
Nicotinamide	A11HA01	0
Nicotine	N07BA01	0
Nicotinic acid	C04AC01 C10AD02	0
Nicotinic acid, combinations	C10AD52	0

Nicotinyl alcohol (pyridylcarbinol)	C04AC02 C10AD05	NE
Nicotinyl methylamide	A05AB01	NE
Nifedipine	C08CA05	I
Nifedipine, combinations	C08CA55	I
Nifenazone	M02AA24 N02BB05	NE
Niflumic acid	M01AX02	I
Niflumic acid (topic use)	M02AA17	0
Nifuroxazide	A07AX03	NE
Nifurzide	A07AX04	NE
Nikethamide	R07AB02	NE
Nikethamide, combinations	R07AB52	NE
Nilvadipine	C08CA10	I
Nimesulide	M01AX17	I
Nimodipine	C08CA06	I
Niperotidine	A02BA05	NE
Nisoldipine	C08CA07	I
Nitisinone	A16AX04	I
Nitrazepam	N05CD02	III
Nitrendipine	C08CA08	I
Nitric oxide	R07AX01	0
Nitrofural	D08AF01 D09AA03	0
Nitrofural	B05CA03 S01AX04 S02AA02	NE
Nitroprusside	C02DD01	I
Nitrous acid combinations	N01AX63	NE
Nitrous oxide	N01AX13	III
Nizatidine	A02BA04	I
Nizofenone	N06BX10	NE
Nomifensine	N06AX04	NE
Nonacog alfa	B02BD09	0
Nordazepam	N05BA16	NE
Norepinephrine	C01CA03	I
Norethandrolone	A14AA09	NE
Norfenefrine	C01CA05	NE
Norfloxacin	S01AX12	0
Normethadone	R05DA06	NE
Nortriptyline	N06AA10	II
Noscapine	R05DA07	0
Noxytiolin	B05CA07	NE
Nystatin	A07AA02 D01AA01	0
O	**ATC CODE**	**CATEGORISATION labelling**
Octenide, combinations	D08AJ57	NE
Octinoxate	D02BA02	0
Octopamine	C01CA18	NE
Ofloxacin	S01AX11	0
Ofloxacin	S02AA16	NE
Oil	A06AG06	0
Olaflur	A01AA03	NE
Olanzapine - Oral administration	N05AH03	 II

- Parenteral administration: i.m.		III
Olmesartan medoxomil	C09CA08	I
Olmesartan medoxomil and amlodipine	C09DB02	I
Olmesartan medoxomil and diuretics	C09DA08	I
Olopatadine	S01GX09	I
Olopatadine	R01AC08	NE
Olsalazine	A07EC03	0
Omalizumab	R03DX05	0
Omega-3-triglycerides	C10AX06	NE
Omeprazole	A02BC01	I
Omeprazole, amoxicillin and clarithromycin	A02BD05	NE
Omeprazole, amoxicillin and metronidazole	A02BD01	NE
Omoconazole	D01AC13	NE
Ondansetron	A04AA01	0
Opipramol	N06AA05	NE
Opium	A07DA02	II
Opium	N02AA02	NE
Opium alkaloids with morphine	R05DA05	NE
Opium derivatives and expectorants	R05FA02	II or higher depending on the medicine in combination
Opium derivatives and mucolytics	R05FA01	NE
Oral rehydration salt formulations	A07CA	0
Orciprenaline	R03AB03	NE
Orciprenaline	R03CB03	I
Orciprenaline, combinations	R03CB53	NE
Ordinary salt combinations	A02AD01	0
Ordinary salt combinations and antiflatulents	A02AF02	0
Organic nitrates in combination	C01DA20	NE
Organic nitrates in combination with psycholeptics	C01DA70	NE
Organo-heparinoid	C05BA01	0
Orgotein	M01AX14	NE
Orlistat	A08AB01	0
Ornithine oxoglurate	A05BA06	NE
Orphenadrine	N04AB02	II
Orphenadrine (citrate)	M03BC01	II
Orphenadrine, combinations	M03BC51	II
Other antipruritics	D04AX	NE
Other emollients and protectives	D02AX	0
Other plasma protein fractions	B05AA02	NE
Other preparations, combinations	C05AX03	0
Others (Medicated shampoos)	D11AC30	NE
Otilonium bromide	A03AB06	0
Otilonium bromide and psycholeptics	A03CA04	NE
Oxabolone cipionate	A14AB03	NE
Oxaceprol	D11AX09 M01AX24	NE
Oxaflozane	N06AX10	NE
Oxametacin	M01AB13	NE
Oxandrolone	A14AA08	NE
Oxaprotilin	N06AA Not yet determined	NE
Oxaprozin	M01AE12	NE
Oxatomide	R06AE06	II
Oxazepam	N05BA04	III
Oxcarbazepine	N03AF02	II
Oxedrine	C01CA08	NE

	S01GA06	
Oxedrine, combinations	S01GA56	NE
Oxeladin	R05DB09	NE
Oxetacaine	C05AD06	0
Oxetorone	N02CX06	NE
Oxiconazole	D01AC11	0
Oxidized cellulose	B02BC02	NE
Oxiracetam	N06BX07	NE
Oxitriptan	N06AX01	NE
Oxitropium bromide	R03BB02	NE
Oxolamine	R05DB07	NE
Oxomemazine	R06AD08	II
Oxovinca	C04AX Not yet determined	NE
Oxprenolol	C07AA02	I
Oxprenolol - chlortalidone	C07BA Not yet determined	NE
Oxprenolol and other diuretics	C07CA02	I
Oxprenolol and thiazides	C07BA02	I
Oxybuprocaine	D04AB03	NE
Oxybuprocaine	S01HA02	I
Oxycinchophen	M01CA03	NE
Oxycodone	N02AA05	III/II* *) prolonged release formulation; when a steady state of dosage has been reached
Oxyfedrine	C01DX03	I
Oxyfedrine, combinations	C01DX53	NE
Oxymetazoline	R01AA05	0
Oxymetazoline	R01AB07	NE
Oxymetazoline	S01GA04	I
Oxymetholone	A14AA05	NE
Oxymorphone	N02AA Not yet determined	NE
Oxypertine	N05AE01	NE
Oxyphenbutazone	M01AA03 M02AA04 S01BC02	NE
Oxyphencyclimine	A03AA01	NE
Oxyphencyclimine and psycholeptics	A03CA03	NE
Oxyphenisatine	A06AB01	NE
Oxyphenonium	A03AB03	NE
Oxyquinoline	A01AB07	0
Oxyquinoline	D08AH03	NE
Oxyquinoline	R02AA14	NE
Oxytetracycline	D06AA03	0
Oxytetracycline - Drops - Oinment	S01AA04	 0 I
P	**ATC CODE**	**CATEGORISATION labelling**
Paliperidone	N05AX13	NE
Palonosetron	A04AA05	0
Pamidronic acid	M05BA03	II
Pancuronium	M03AC01	III

Pantethine	A11HA32	NE
Pantoprazole	A02BC02	I
Pantoprazole, amoxicillin and clarithromycin	A02BD04	NE
Papaveretum	N02AA10	NE
Papaverine	A03AD01	NE
Paracetamol	N02BE01	0
Paracetamol, combinations excl psycholeptics	N02BE51	NE
Paracetamol, combinations with Psycholeptics	N02BE71	NE
Paraldehyde	N05CC05	NE
Paramethadione	N03AC01	NE
Paraoxon	S01EB10	NE
Parecoxib	M01AH04 N02BG	I
Pargyline	C02KC01	NE
Pargyline and diuretics	C02LL01	NE
Parnaparin	B01AB07	NE
Paromomycin	A07AA06	0
Paroxetine	N06AB05	I
Passiflore aubepine	C01EB Not yet determined	NE
Passiflore-extract	N05CM20	NE
Pecilocin	D01AA04	NE
Pectin	A07BC01	0
Pegaptanib	S01LA03	III
Pegloticase	M04AX02	NE
Pemoline	N06BA05	I
Penbutolol	C07AA23	I
Penbutolol and other diuretics	C07CA23	I
Penciclovir	D06BB06	0
Penfluridol	N05AG03	II
Penicillamine	M01CC01	0
Pentaerithrityl	A06AD14	NE
Pentaerithrityl tetranitrate	C01DA05	I
Pentaerithrityl tetranitrate, combinations	C01DA55	NE
Pentazocine	N02AD01	NE
Pentetrazol	R07AB03	NE
Pentetrazol, combinations	R07AB53	NE
Penthienate	A03AB04	NE
Pentifylline	C04AD01	NE
Pentobarbital	N05CA01	NE
Pentosan polysulfate sodium	C05BA04	0
Pentoxifylline	C04AD03	0
Pentoxyverine	R05DB05	I
Pepsin	A09AA03	0
Pepsin and acid preparations	A09AC01	NE
Perazine	N05AB10	NE
Pergolide	N04BC02	II
Perhexiline	C08EX02	NE
Periciazine	N05AC01	III
Perindopril	C09AA04	I
Perindopril and amlodipine	C09BB04	I
Perindopril and diuretics	C09BA04	I
Perphenazine	N05AB03	II
Peruvoside	C01AX02	NE
Pethidine	N02AB02	III
Pethidine and antispasmodics	N02AG03	NE
Pethidine, combinations excl. Psycholeptics	N02AB52	NE

Pethidine, combinations with. Psycholeptics	N02AB72	NE
Phedrine	R01AA03	0
Phenacemide	N03AX07	NE
Phenacetin	N02BE03	NE
Phenacetin, combinations excl. Psycholeptics	N02BE53	NE
Phenacetin, combinations with Psycholeptics	N02BE73	NE
Phenazone	N02BB01 S02DA03	NE
Phenazone, combinations excl. Psycholeptics	N02BB51	NE
Phenazone, combinations with. Psycholeptics	N02BB71	NE
Phenelzine	N06AF03	II
Pheneturide	N03AX13	NE
Phenformin	A10BA01	NE
Phenformin and sulfonamides	A10BD01	NE
Phenglutarimide	N04AA09	NE
Phenindamine	R06AX04	NE
Phenindione	B01AA02	NE
Pheniramine	R06AB05	II
Phenobarbital	N03AA02	III
Phenobarbital - calcium gluconate and bromate	C01EB Not yet determined	NE
Phenol	C05BB05 D08AE03 R02AA19	0
Phenol (other local anesthetics)	N01BX03	I
Phenolphthalein	A06AB04	NE
Phenoperidine	N01AH04	NE
Phenoxybenzamine	C04AX02	I
Phenprobamate	M03BA01	II
Phenprobamate, combinations excl. psycholeptics	M03BA51	II
Phenprobamate, combinations with psycholeptics	M03BA71	II
Phenprocoumon	B01AA04	NE
Phensuximide	N03AD02	NE
Phentermine	A08AA01	NE
Phentolamine	C04AB01	I
Phenylbutazone	M01AA01 M02AA01	NE
Phenylbutazone and corticosteroids	M01BA01	NE
Phenylephrine	R01AA04	0
Phenylephrine	R01BA03	I
Phenylephrine	C01CA06	NE
Phenylephrine (<<< 10%, 0.125%)	S01GA05	I
Phenylephrine (≥ 10%)	S01FB01	III
Phenylephrine, combinations	R01BA53, S01GA55	Depending on the medicine in combination
Phenylephrine, sympathomimetics, combinations excl. corticosteroids	R01AB01	Depending on the medicine in combination
Phenylephrine+tetracaine	S01FBP1	III
Phenylmercuric borate	D08AK02	NE
Phenylmercuric nitrate	D09AA04	NE
Phenylpropanolamine	R01BA01	0
Phenylpropanolamine, Combinations	R01BA51	NE
Phenytoin	N03AB02	III
Phenytoin, combinations	N03AB052	III
Phloroglucinol	A03AX12	NE

Pholcodine	R05DA08	II
Phthalylsulfathiazole	A07AB02	NE
Physostigmine	S01EB05	NE
Phytomenadione	B02BA01	0
Picloxydine	S01AX16	NE
Picodralazine and diuretics	C02LG03	NE
Picodralazine and diuretics, combinations with psycholeptics.	C02LG73	NE
Picotamide	B01AC03	NE
Pilocarpine	N07AX01 S01EB01	II
Pilocarpine, combinations	S01EB51	NE
Pimecrolimus (topical use)	D11AH02	0
Pimethixene	R06AX23	II
Pimozide	N05AG02	II
Pinacidil	C02DG01	NE
Pinacidil and diuretics	C02LX01	NE
Pinaverium	A03AX04	0
Pinazepam	N05BA14	NE
Pindolol	C07AA03	I
Pindolol and other diuretics	C07CA03	I
Pioglitazone	A10BG03	0
Pioglitazone and alogliptin	A10BD09	NE
Pipamperone	N05AD05	II
Pipazetate	R05DB11	NE
Pipecuronium bromide	M03AC06	III
Pipenzolate	A03AB14	NE
Piperidione	R05DB23	NE
Piperidolate	A03AA30	NE
Pipotiazine palmitate: injection depot i.m.	N05AC04	III
Pipradrol	N06BX15	NE
Piprozolin	A05AX01	NE
Piracetam	N06BX03	II
Pirbuterol	R03AC08 R03CC07	NE
Pirenzepine	A02BX03	NE
Piretanide	C03CA03	0
Piribedil	N04AX13 C04AX13	II
Piribedil	N04BC08	NE
Pirisunadol	N06BX08	NE
Piritramide	N02AC03	NE
Pirlindole	N06AF Not yet detemined	NE
Piroxicam	M01AC01	I
Piroxicam	S01BC06	NE
Piroxicam (topical use)	M02AA07	0
Pirprofen	M01AE08	NE
Pitavastatin	C10AA08	NE
Pitofenone and analgesics	A03DA02	NE
Pivagabine	N06AX15	NE
Pizotifen	N02CX01	II
Podophyllotoxin	D06BB04	0
Poldine	A03AB11	NE
Policosanol	C10AX08	NE
Policresulen	D08AE02	NE
Polidocanol	C05BB02	0

Polihexanide	D08AC05	NE
Polycarbophil calcium	A06AC08	NE
Polymyxin	S02AA11	NE
Polymyxin B	A07AA05 S01AA18 S03AA03	NE
Polynoxylin	A01AB05 D01AE05	NE
Polythiazide	C03AA05	NE
Polythiazide and potassium	C03AB05	NE
Potassium acetate	B05XA17	0
Potassium canrenoate	C03DA02	0
Potassium chloride	A12BA01 B05XA01	0
Potassium chloride, Combinations (Depending on the medicine in combination)	A12BA51	Depending on the medicine in combination
Potassium citrate	A12BA02	0
Potassium clorazepate - Oral administration - Parenteral administration	N05BA05	 II III
Potassium gluconate	A12BA05	0
Potassium hydrogencarbonate	A12BA04	0
Potassium hydrogentartrate	A12BA03	0
Potassium iodide	R05CA02 S01XA04	NE
Potassium lactate	B05XA15	0
Potassium permanganate	D08AX06	NE
Potassium phosphate, incl. comb. with other potassium salts	B05XA06	0
Potassium salicylate	N02BA12	NE
Povidone-iodine	D08AG02 D09AA09 D11AC06 R02AA15	0
Povidone-iodine	S01AX18	NE
Practolol	C07AB01	NE
Prajmaline	C01BA08	NE
Pramipexole	N04BC05	II
Pramlintide	A10BX05	NE
Pramocaine	C05AD07 D04AB07	0
Pranlukast	R03DC02	NE
Pranoprofen	S01BC09	0
Prasterone	A14AA07	NE
Prasugrel	B01AC22	0
Pravastatin	C10AA03	0
Pravastatin and acetylsalicylic acid	C10BX02	NE
Pravastatin and fenofibrate	C10BA03	0
Prazepam	N05BA11	III
Prazosin	C02CA01	I
Prazosin and diuretics	C02LE01	I
Prednicarbate	D07AC18	0
Prednisolone	A07EA01 C05AA04 D07AA03 D07XA02 S01BA04	0

Prednisolone	R01AD02 S02BA03 S03BA02	NE
Prednisolone (Corticosteroids/antiinfectives/mydriatics in combination)	S01CB02	Depending on the mydriatic in combination
Prednisolone and antibiotics	D07CA03	NE
Prednisolone and antiinfectives - Drops - Oinment	S01CA02	 0 I
Prednisolone and antiinfectives	S02CA01	NE
Prednisolone and antiinfectives	S03CA02	0
Prednisolone and antiseptics	D07BA01	NE
Prednisolone and mydriatics	S01BB02	Depending on the mydriatic in combination
Prednisolone, Combinations	A01AC54	0
Prednisolone, combinations	R01AD52	NE
Prednisone	A07EA03	0
Pregabalin	N03AX16	II
Prenalterol	C01CA13	NE
Prenoxdiazine	R05DB18	NE
Prenylamine	C01DX02	NE
Prenylamine, combinations	C01DX52	NE
Prethcamide	R07AB06	NE
Pridinol	M03BX03	II
Prifinium bromide	A03AB18	NE
Prilocaine	N01BB04	0 to III Depending on the route of administration
Prilocaine combinations	N01BB54	0
Primidone	N03AA03	III
Probenecid	M04AB01	I
Probucol	C10AX02	NE
Procainamide	C01BA02	I
Procaine	C05AD05	0
Procaine	S01HA05	NE
Procaine (Anesthetic, local)	N01BA03	0 to III Depending on the route of administration
Procaine combinations	N01BA52	II
Procaterol	R03AC16 R03CC08	NE
Prochlorperazine	N05AB04	NE
Procyclidine	N04AA04	II
Profenamine	N04AA05	NE
Progabide	N03AG05	NE
Proglumetacin	M01AB14	NE
Proglumide	A02BX06	NE
Prolintane	N06BX14	NE
Promazine	N05AA03	III
Promethazine	D04AA10	0
Promethazine	R06AD02	III
Promethazine, combinations	R06AD52	III
Propacetamol	N02BE05	NE
Propafenone	C01BC03	I
Propamidine	D08AC03	NE
Propanamidine	S01AX15	NE

Propanidid	N01AX04	NE
Propanol	D08AX03	NE
Propanol, combinations	D08AX53	NE
Propantheline	A03AB05	0
Propantheline and psycholeptics	A03CA34	NE
Propatylnitrate	C01DA07	NE
Propatylnitrate, combinations	C01DA57	NE
Propiomazine	N05CM06	NE
Propiphenazone, combinations with. Psycholeptics	N02BB74	NE
Propofol	N01AX10	III
Propranolol	C07AA05	I
Propranolol and other antihypertensives	C07FA05	I
Propranolol and thiazides	C07BA05	I
Propyphenazone	N02BB04	NE
Propyphenazone, combinations excl. Psycholeptics	N02BB54	NE
Proquazone	M01AX13	NE
Proscillaridin	C01AB01	NE
Proscillaridin, combinations	C01AB51	NE
Protein C	B01AD12	0
Protein hydrolysates	B05BA04	0
Prothipendyl	N05AX07	NE
Protriptyline	N06AA11	NE
Proxazole	A03AX07	NE
Proxibarbital	N05CA22	NE
Proxymetacaine	S01HA04	NE
Proxyphylline	R03DA03	NE
Proxyphylline and adrenergics	R03DB03	NE
Prucalopride	A03AE04	I
Pseudoephedrine	R01BA02	I
Pseudoephedrine, combinations + loratadine + triprolidine	R01BA52	 I III
Pyridostigmine	N07AA02	II
Pyridoxal phosphate	A11HA06	0
Pyridoxine (vit B6)	A11HA02	0
Pyrithione zinc	D11AX12	0
Pyrithyldione	N05CE03	NE
Pyritinol	N06BX02	NE
Pyrrobutamine	R06AX08	NE
Pyrrobutamine, combinations	R06AX58	NE
Pyrrolnitrin	D01AA07	NE
Q	**ATC CODE**	**CATEGORISATION labelling**
Quazepam	N05CD10	NE
Quetiapine	N05AH04	II
Quinapril	C09AA06	I
Quinapril and diuretics	C09BA06	I
Quinbolone	A14AA06	NE
Quinethazone	C03BA02	NE
Quinethazone and potassium	C03BB02	NE
Quinidine	C01BA01	I
Quinidine, combinations excl. psycholeptics	C01BA51	NE
Quinidine, combinations with psycholeptics	C01BA71	NE
Quinine, combinations with psycholeptics	M09AA72	I

Quinisocaine	D04AB05	NE
R	**ATC CODE**	**CATEGORISATION labelling**
Rabeprazole	A02BC04	I
Racecadotril	A07XA04	0
Ramelteon	N05CH02	NE
Ramipril	C09AA05	I
Ramipril and diuretics	C09BA05	I
Ramipril and felodipine	C09BB05	I
Ranibizumab	S01LA04	III
Ranitidine	A02BA02	I
Ranitidine bismuth citrate	A02BA07	I
Ranolazine	C01EB18	I
Rasagiline	N04BD02	I
Rauwolfia alkaloids, whole root	C02AA04	NE
Rauwolfia alkaloids, whole root and diuretics	C02LA08	NE
Reboxetine	N06AX18	I
Regadenoson	C01EB21	NE
Remifentanil	N01AH06	III
Remikiren	C09XA01	NE
Remoxipride	N05AL04	NE
Repaglinide	A10BX02	I
Reposal	N05CA12	NE
Reproterol	R03AC15 R03CC14	NE
Reproterol and other drugs for obstructive airway diseases	R03AK05	NE
Rescinnamine	C02AA01	NE
Rescinnamine and diuretics	C02LA02	NE
Rescinnamine and diuretics, combinations with other drugs	C02LA52	NE
Reserpine	C02AA02	NE
Reserpine and diuretics	C02LA01	NE
Reserpine and diuretics, combinations with other drugs	C02LA51	NE
Reserpine and diuretics, combinations with psycholeptics	C02LA71	NE
Reserpine, combinations	C02AA52	NE
Resorcinol	D10AX02 S01AX06	NE
Retapamulin	D06AX13	0
Reteplase	B01AD07	0
Retinol	D10AD02 R01AX02 S01XA02	NE
Retinol (vit A)	A11CA01	0
Reviparin	B01AB08	NE
Riboflavin (vit B2)	A11HA04	0
Rifamycin	S01AA16	0
Rifamycin	S02AA12	NE
Rifaximin	A07AA11	0
Rifaximin	D06AX11	NE
Rilanomer	D03AX09	NE
Rilmenidine	C02AC06	II
Riluzole	N07XX02	I
Rimazolium	N02BG02	NE

Rimexolone - Drops - Oinment	S01BA13	 0 I
Rimiterol	R03AC05	NE
Rimonabant	A08AX01	NE
Risedronic acid	M05BA07	0
Risedronic acid and calcium, sequential	M05BB02	NE
Risedronic acid, calcium and colecalciferol, sequential	M05BB04	NE
Risperidone - Oral administration - Parenteral administration: depot i.m.	N05AX08	 II III
Ritanserin	N06AX Not yet determined	NE
Ritiometan	R01AX05	NE
Rivaroxaban	B01AX06	0
Rivastigmine	N06DA03	II
Rizatriptan	N02CC04	II
Rociverine	A03AA06	NE
Rocuronium bromide	M03AC09	III
Rofecoxib	M01AH02	NE
Roflumilast	R03DX07	0
Romiplostim (subcutaneous via)	B02BX04	I
Ronifibrate	C10AB07	NE
Ropinirole	N04BC04	II
Ropivacaine	N01BB09	III
Rosa bengal sodium	S01JA02	NE
Rosiglitazone	A10BG02	0
Rosuvastatin	C10AA07	0
Rotigotin	N04BC09	II
Roxatidine	A02BA06	I
Rufinamide	N03AF03	II
Rupatadine	R06AX28	I
Rutoside	C05CA01	0
Rutoside, combinations	C05CA51	0
S	**ATC CODE**	**CATEGORISATION labelling**
Saccharated iron oxide	B03AC02	0
Saccharated iron oxide	B03AB02	NE
Saccharomyces boulardii	A07FA51	0
Sacrosidase	A16AB06	NE
Salbutamol	R03AC02 R03CC02	0
Salbutamol and other drugs for obstructive airway diseases	R03AK04	Depending on the medicine in combination
Salicylamide	N02BA05	NE
Salicylamide , combinations with psycholeptics	N02BA75	NE
Salicylamide, combinations excl. Psycholeptics	N02BA55	NE
Salicylic acid	D01AE12	0
Salicylic acid	S01BC08	NE
Salicylic acid preparations	D02AF	0
Salmeterol	R03AC12	0
Salmeterol and other drugs for obstructive airway diseases	R03AK06	Depending on the medicine in combination
Salsalate	N02BA06	NE
Sapropterin	A16AX07	0

Saruplase	B01AD08	NE
S-atenol	C07AB11	NE
Saccharated iron oxide	B03AB02	NE
Saxagliptin	A10BH03	I
Scopolamine - Oral and rectal administration - Parenteral administration	A04AD01	 I II
Scopolamine	N05CM05 S01FA02	NE
Scopolamine, combinations	A04AD51	NE
Selegiline	N04BD01	I
Selenium compounds	D11AC03	0
Selenium sulfide	D01AE13	NE
Senega	R05CA06	0
Senna glycosides	A06AB06	0
Senna glycosides, combinations	A06AB56	0
Seratrodast	R03DX06	NE
Serobarbital	N05CA06	NE
Sertaconazole	D01AC14	0
Sertindole	N05AE03	NE
Sertraline	N06AB06	I
Sevoflurane	N01AB08	III
Sibutramine	A08AA10	NE
Silicone products	D02AA	0
Silicones	A03AX13	0
Silver	D08AL30	NE
Silver compounds	S01AX02	NE
Silver nitrate	D08AL01	0
Silver sulfadiazine	D06BA01	0
Silver sulfadiazine, combinations	D06BA51	0
Silymarin	A05BA03	0
Simfibrate	C10AB06	NE
Simvastatin	C10AA01	0
Simvastatin and acetylsalicylic acid	C10BX01	NE
Simvastatin and ezetimibe	C10BA02	0
Sitagliptin	A10BH01	I
Sitaxentan	C02KX03	I
Sobrerol	R05CB07	NE
Sodium acetate	B05XA08	0
Sodium apolate	C05BA02	0
Sodium aurothiomalate	M01CB01	0
Sodium aurothiosulfate	M01CB02	NE
Sodium bicarbonate	B05CB04 B05XA02	0
Sodium borate	S01AX07	NE
Sodium chloride	A12CA01 B05CB01 B05XA03	0
Sodium chloride, hypertonic	S01XA03	0
Sodium citrate	B05CB02	0
Sodium edetate	S01XA05	0
Sodium feredetate	B03AB03	0
Sodium fluoride	A01AA01 A12CD01	0
Sodium fluoride, combinations	A01AA51	NE
Sodium glycerophosphate	B05XA14	0
Sodium hypochlorite	D08AX07	NE

sodium Monofluorophosphate	A01AA02	NE
Sodium monofluorophosphate	A12CD02	0
Sodium perborate	A01AB19	0
Sodium phenylbutyrate	A16AX03	I
Sodium phosphate	A06AG01 B05XA09	0
Sodium phosphate	A06AD17	NE
Sodium picosulfate	A06AB08	0
Sodium picosulfate, combinations	A06AB58	0
Sodium propionate	S01AX10	NE
Sodium salicilate	N02BA04	NE
Sodium selenate	A12CE01	0
Sodium selenite	A12CE02	0
Sodium sulfate	A12CA02 A06AD13	0
Sodium tartrate	A06AD21	NE
Sodium tetradecyl sulfate	C05BB04	0
Soft paraffin and fat products	D02AC	0
Sorbitol	B05CX02	0
Sorbitol	A06AD18 A06AG07	NE
Sotalol	C07AA07	I
Sotalol and thiazides	C07BA07	I
Sotalol, combination	C07AA57	I
Spaglumic acid	S01GX03	I
Spaglumic acid	R01AC05	NE
Sparteine	C01BA04	NE
Spirapril	C09AA11	I
Spironolactone	C03DA01	I
Stannous fluoride	A01AA04	NE
Stanozolol	A14AA02	0
Stem cells from umbilical cord blood	B05AX04	NE
Stepronin	R05CB11	NE
Sterculia	A06AC03	0
Sterculia, combinations	A06AC53	NE
Stiripentol	N03AX17	NE
Stramoni preparations	R03BB03	NE
Streptokinase	B01AD01	0
Streptokinase, combinations	B06AA55	NE
Streptomycin	A07AA04	0
Streptomycin, combinations	A07AA54	NE
Strontium ranelate	M05BX03	0
Styramate	M03BA04	NE
Succinylsulfathiazole	A07AB04	NE
Sucralfate	A02BX02	0
Sufentanil	N01AH03	NE
Sulbentine	D01AE09	NE
Sulbutiamine	A11DA02	0
Sulconazole	D01AC09	NE
Sulfacetamide	S01AB04	NE
Sulfadicramide	S01AB03	NE
Sulfafena	S01AB05	NE
Sulfafurazole	S01AB02	NE
Sulfaguanidine	A07AB03	NE
Sulfamerazine	D06BA06	NE
Sulfamethizole	B05CA04 D06BA04	NE

	S01AB01	
Sulfanilamide	D06BA05	0
Sulfasalazine	A07EC01	0
Sulfathiazole	D06BA02	0
Sulfinpyrazone	M04AB02	NE
Sulfur	D10AB02	0
Sulfur compounds	D11AC08	0
Sulglicotide	A02BX08	NE
Sulindac	M01AB02	I
Suloctidil	C04AX19	NE
Sulodexide	B01AB11	0
Sulpiride	N05AL01	II
Sultiame	N03AX03	NE
Sultopride	N05AL02	NE
Sumatriptan	N02CC01	II
Suprofen	M01AE07	NE
Suxamethonium	M03AB01	III
Suxibuzone	M01AA90 M02AA22	NE
Syrosingopine and diuretics	C02LA09	NE
T	**ATC CODE**	**CATEGORISATION labelling**
Tacalcitol	D05AX04	0
Tacrine	N06DA01	NE
Tacrolimus - Intravenous administration - Oral administration - Topical use	L04AD02 D11AH01	 III II 0
Tafluprost	S01EE05	I
Talastine	R06AB07	NE
Talbutal	N05CA07	NE
Talinolol	C07AB13	NE
Tars	D05AA	NE
Tasosartan	C09CA05	NE
Taurolidine	B05CA05	NE
Tazarotene	D05AX05	0
Tedisamil	C01BD06	NE
Tegaserod	A03AE02	NE
Telmisartan	C09CA07	I
Telmisartan and amlodipine	C09DB04	I
Telmisartan and diuretics	C09DA07	I
Temazepam	N05CD07	III
Temocapril	C09AA14	NE
Tenecteplase	B01AD11	0
Tenidap	M01AX23	NE
Tenitramine	C01DA38	NE
Tenoxicam	M01AC02	I
Terbinafine	D01AE15	0
Terbinafine	D01BA02	0
Terbutaline	R03AC03 R03CC03	0
Terbutaline, combinations	R03CC53	NE
Terfenadine	R06AX12	I
Tertatolol	C07AA16	I
Tetrabenazine	N07XX06	NE
Tetracaine	C05AD02 D04AB06	0

Tetracaine	S01HA03	NE
Tetraciane (anesthetic, local)	N01BAO3	0 to III Depending on the route of administration
Tetracycline	A01AB13 D06AA04	0
Tetracycline	S01AA09 S02AA08 S03AA02	NE
Tetragalacturonic acid hydroxymethylester	B02BC03	NE
Tetrazepam	M03BX07	II
Tetryzoline	S01GA02	I
Tetryzoline	R01AA06 R01AB03	NE
Tetryzoline, combinations	S01GA52	NE
Thebacone	R05DA10	II
Thenalidine	D04AA03 R06AX03	NE
Thenalidine, combinations	R06AX53	NE
Theobromine	C03BD01 R03DA07	NE
Theobromine, combinations	R03DA57	NE
Theodrenaline	C01CA23	NE
Theophylline - Oral administration - Parenteral administration	R03DA04	 0 I
Theophylline and adrenergics	R03DB04	Depending on medicine in combination
Theophylline, combinations excl. psycholeptics	R03DA54	NE
Theophylline, combinations with psycholeptics	R03DA74	NE
Thiamine (vit B1)	A11DA01	0
Thiazinam	R06AD06	NE
Thiethylperazine	R06AD03	II
Thiocolchicoside	M03BX05	II
Thiomersal	D08AK06	0
Thiopental	N01AF03 N05CA19	III
Thiopropazate	N05AB05	NE
Thioproperazine	N05AB08	NE
Thioridazine	N05AC02	NE
Thonzylamine	D04AA01 R01AC06 R06AC06	NE
Thrombin	B02BD30	0
Thrombin (with human fibrinogen)	B02BC06	0
Thrombocytes	B05AX02	NE
Tiabendazole	D01AC06	NE
Tiadenol	C10AX03	0
Tiagabine	N04AG06	II
Tianeptine	N06AX14	NE
Tiapride	N05AL03	II
Tiaprofenic acid	M01AE11	I
Tibezonium iodide	A01AB15	NE
Ticlatone	D01AE08	NE
Ticlopidine	B01AC05	0
Tidiacic arginine	A05BA07	NE
Tiemonium iodide	A03AB17	NE

Tiemonium iodide and analgesics	A03DA07	NE
Tienilic acid	C03CC02	NE
Tilactase	A09AA04	NE
Tilidine	N02AX01	NE
Tiludronic acid	M05BA05	0
Timepidium bromide	A03AB19	NE
Timolol	C07AA06 S01ED01	I
Timolol - amiloride - hydrochlorothiazide	C07DA06	NE
Timolol and thiazides	C07BA06	I
Timolol, combinations Timolol+brinzolamide (Azarga)	S01ED51	I
Timolol, thiazide and other diuretics	C07DA06	I
Tinzaparin	B01AB10	0
Tioclomarol	B01AA11	NE
Tioconazole	D01AC07	0
Tioctic acid	A16AX01	NE
Tiopronin	R05CB12	NE
Tiotixene	N05AF04	NE
Tiotropium bromide	R03BB04	I
Tioxolone	D10AB03	NE
Tipepidine	R05DB24	NE
Tiracizine	C01EB11	NE
Tiratricol	D11AX08	NE
Tirilazad	N07XX01	NE
Tirofiban	B01AC17	0
Tiropramide	A03AC05	NE
Tisopurine	M04AA02	NE
Titoqualine	R06AX21	NE
Tixocortol	A07EA05 R01AD07	NE
Tixocortol, combinations	R01AD57	NE
Tizanidine	M03BX02	II
Tobramycin - Drops - Oinment	S01AA12	 0 I
Tocainide	C01BB03	NE
Tocofersolan (paediatric patients)	A11HA08	0
Tocopherol (vit E)	A11HA03	0
Tofisopam	N05BA23	NE
Tolazamide	A10BB05	NE
Tolazoline	C04AB02 M02AX02	NE
Tolbutamide	A10BB03	I
Tolcapone	N04BX01	II
Tolciclate	D01AE19	NE
Tolfenamic acid	M01AG02	I
Tolmetin	M01AB03 M02AA21	NE
Tolnaftate	D01AE18	0
Toloxatone	N06AG03	NE
Tolperisone	M03BX04	NE
Tolpropamine	D04AA12	NE
Tolrestat	A10XA01	NE
Tolvaptan	C03XA01	I
Tonics	A13A	0
Topiramate	N03AX11	II

Torasemide	C03CA04	0
Tosylchloramide sodium	D08AX04	NE
Tramadol	N02AX02	III
Tramadol, combinations	N02AX52	NE
Tramazoline	R01AA09	0
Trandolapril	C09AA10	I
Trandolapril and verapamil	C09BB10	I
Tranexamic acid	B02AA02	0
Tranylcypromine	N06AF04	II
Trapatepine	N04AA12	NE
Trapidil	C01DX11	NE
Travoprost	S01EE04	I
Trazodone	N06AX05	III
Trepibutone	A03AX09	NE
Treprostinil	B01AC21	NE
Tretinoin	D10AD01	0
Tretinoin, combinations (with erythromycin, topical use)	D10AD51	0
Tretoquinol	R03AC09 R03CC09	NE
Triamcinolone	A01AC01 A07EA D07AB09 D07XB02 R01AD11	0
Triamcinolone	R03BA06 S01BA05 C05AA12	NE
Triamcinolone and antibiotics	D07CB01	0
Triamcinolone and antiinfectives	S02CA04	0
Triamcinolone and antiseptics	D07BB03	NE
Triamterene	C03DB02	0
Triazolam	N05CD05	III
Tribenoside	C05AX05	NE
Tribenoside	C05CX01	0
Tribromometacresol	D01AE03	NE
Trichlormethiazide	C03AA06	NE
Trichlormethiazide and potassium	C03AB06	NE
Trichlormethiazide and potassium-sparing agents (spironolactone)	C03EA02	NE
Trichloroethylene	N01AB05	NE
Triclofos	N05CM07	NE
Triclosan	D08AE04 D09AA06	0
Tridihexethyl	A03AB08	NE
Trifluoperazine	N05AA05	NE
Trifluoperazine	N05AB06	III
Trifluperidol	N05AD02	NE
Trifluridine	S01AD02	NE
Triflusal	B01AC18	0
Trihexyphenidyl	N04AA01	II
Trimazosin	C02CA03	NE
Trimebutine	A03AA05	0
Trimetazidine	C01EB15	I
Trimethadione	N03AC02	NE
Trimethyldiphenylpropylamine	A03AX30	NE
Trimipramine	N06AA06	II

Trioxysalen	D05AD01 D05BA01	NE
Tripelennamine	D04AA04	0
Tripelennamine	R06AC04	NE
Triprolidine	R06AX07	III
Triticum (wheat fibre)	A06AC07	NE
Troglitazone	A10BG01	NE
Trolnitrate	C01DA09	NE
Trolnitrate, combinations	C01DA59	NE
Tromantadine	D06BB02	0
Trometamol	B05BB03	0
Trometamol (only in combination)	B05XX02	NE
Tropenzilone and analgesics	A03DA01	NE
Tropicamide	S01FA06	III
Tropicamide, combinations	S01FA56	III
Tropisetron	A04AA03	0
Trospium and analgesics	A03DA06	NE
Troxerutin	C05CA04	0
Troxerutin, combinations	C05CA54	0
Troxipide	A02BX11	NE
Trypsin	D03BA01	0
Trypsin	B06AA07	NE
Trypsin, combinations	M09AB52	NE
Tryptophan	N06AX02	NE
Tuaminoheptane	R01AA11 R01AB08	NE
Tubocurarine	M03AA02	III
Tulobuterol	R03AC11	NE
Tulobuterol	R03CC11	NE
Tyloxapol	R05CA01	NE
Tymazoline	R01AA13	NE
Tyrothricin	D06AX08 R02AB02	0
Tyrothricin	S01AA05	NE
U	**ATC CODE**	**CATEGORISATION labelling**
Ubidecarenone	C01EB09	I
Ulobetasol	D07AC21	NE
Undecylenic acid	D01AE04	NE
Undecylenic acid, combinations	D01AE54	NE
Unoprostone	S01EE02	NE
Urapidil	C02CA06	I
Urate oxidase	M04AX01	NE
Urokinase	B01AD04	0
Ursodeoxycholic acid	A05AA02	0
V	**ATC CODE**	**CATEGORISATION labelling**
Valdecoxib	M01AH03	NE
Valerian	N05CM09	I
Valnoctamide	N05CM13	NE
Valproic acid - Oral administration - Parenteral administration	N03AG01	 II III
Valpromide	N03AG02	NE
Valsartan	C09CA03	I

Valsartan and aliskiren	C09DX02	NE
Valsartan and amlodipine	C09DB01	I
Valsartan and diuretics	C09DA03	I
Valsartan, amlodipine and hydrochlorothiazide	C09DX01	I
Vancomycin	A07AA09	NE
Varenicline	N07BA03	I
Various (Antiinfectives and antiseptics for local oral treatment)	A01AB11	0
Various (Antiseptics)	R02AA20	NE
Various (Other agents for local oral treatment)	A01AD11	NE
Various (Other nasal preparations)	R01AX10	NE
Various (Other topical products for joint and muscular pain)	M02AX10	NE
Various combinations (Iron in other combinations)	B03AE10	0
Various combinations (Other anti-acne preparations for topical use)	D10AX30	NE
Vecuronium	M03AC03	III
Velaglucerase alfa	A16AB10	I
Venlafaxine	N06AX16	II
Veralipride	N05AL06	NE
Verapamil	C08DA01	I
Verapamil, combinations	C08DA51	I
Veratrum	C02KA01	NE
Veratrum and diuretics	C02LK01	NE
Verteporfin	S01LA01	III
Vidarabine	S01AD06	NE
Vigabatrin	N03AG04	II
Vildagliptin	A10BH02	I
Viloxazine	N06AX09	NE
Viminol	N02BG05	NE
Vinbarbital	N05CA09	NE
Vinburnine	C04AX17	I
Vincamine	C04AX07	I
Vinpocetine	N06BX18	NE
Vinyl ether	N01AA02	NE
Vinylbarbital	N05CA08	NE
Virginiamycin	D06AX10	NE
Visnadine	C04AX24	NE
Vitamins	B05XC	0
Vitamin B-complex, plain	A11EA	0
Vitamin B1 in combination with vitamin B6 and/or vitamin B12	A11DB	0
Vitamin B-complex with vitamin C	A11EB	0
Vitamin B-complex with minerals	A11EC	0
Vitamin B-complex with anabolic steroids	A11ED	0
Vitamin B-complex, other combinations	A11EX	0
Vitamins, other combinations	A11JC	0
Vitamins with minerals	A11JA	0
Voglibose	A10BF03	NE
Von Willebrand factor and coagulation factor VIII in combination	B02BD06	0
W	**ATC CODE**	**CATEGORISATION labelling**
Warfarin	B01AA03	0
X	**ATC CODE**	**CATEGORISATION**

		labelling
Xaliproden	N07XX03	NE
Xamoterol	C01CX07	NE
Xantinol nicotinate	C04AD02	NE
Xenon	N01AX15	NE
Xenysalate	D11AC09	NE
Ximelagatran	B01AE05	NE
Xipamide	C03BA10	0
Xylometazoline	R01AA07	0
Xylometazoline	R01AB06 S01GA03	NE
Xylometazoline, combinations	S01GA53	NE
Z	**ATC CODE**	**CATEGORISATION labelling**
Zafitlukast	R03DC01	0
Zaleplon - after 12h	N05CF03	III I
Ziconotide	N02BG08	III
Zimeldine	N06AB02	NE
Zinc acetate	A16AX05	0
Zinc bandage with supplements	D09AB02	0
Zinc bandage without supplements	D09AB01	0
Zinc chloride	B05XA12	0
Zinc compounds	S01AX03	NE
Zinc gluconate	A12CB02	NE
Zinc preparations	C05AX04	0
Zinc products	D02AB	0
Zinc protein complex	A12CB03	NE
Zinc sulphate	A12CB01	0
Zipeprol	R05DB15	NE
Ziprasidone - Oral administration - Parenteral administration: i.m.	N05AE04	 II III
Zofenopril	C09AA15	I
Zofenopril and diuretics	C09BA15	I
Zoledronic acid	M05BA08	I
Zolimidine	A02BX10	NE
Zolmitriptan	N02CC03	II
Zolpidem - after 8h	N05CF02	III II
Zomepirac	M01AB04	NE
Zonisamide	N03AX15	II
Zopiclone	N05CF01	III
Zotepine	N05AX11	NE
Zucapsaicin	M02AB02	NE
Zuclopenthixol - Oral administration - Parenteral administration: depot i.m.	N05AF05	 II III

6. The DRUID Patient-oriented information

Within DRUID WP4, medicines were categorized following DRUID criteria on medicines and driving. Furthermore, DRUID WP4 partners have produced patient-oriented information for each one of the medicines categorized.

The aim of producing this patient-oriented information is to help physicians and pharmacists (and other health professionals) in providing appropriate information to their patients. It is true that Patient Information Leaflets contain some sort of information regarding driving. However, DRUID WP4 partners considered that it is also quite important that health professionals provide further information for medicines and driving to their patients.

Tables 15 to 29 show some examples of patient-oriented information concerning the DRUID categorisation of the evaluated medicines. We have tried, in each table, to put an example of each of the DRUID categories (0, I, II, III, multiple categorisation and depending on medicine in combination), pointing out the different presentations or the different routes of administration.

The complete list with all the medicines from each ATC group and the patient-oriented information is shown in the annexes of this deliverable of each ATC group categorized (Annexes 2 to 17).

Table 15: Example of information to the patient and Categorisation and labelling of some available A-ALIMENTARY TRACT AND METABOLISM MEDICINES on driving.

A ALIMENTARY TRACT AND METABOLISM	ACTIVE SUBSTANCE	CATEGORY LABELLING	INFORMATION FOR THE PATIENT
A02BA01	Cimetidine	I	- Advise your patient not to drive if he/she experiences side-effects that can impair his/her driving abilities (e.g. dizziness) particularly during the first day of treatment, and not to drive as long as side-effects persist.
A02BA02	Ranitidine	I	
A02BA03	Famotidine	I	
A02BA04	Nizatidine	I	
A02BA06	Roxatidine	I	
A03BA01	Atropine	III	- Inform the patient that this medication may cause dilated pupils with loss of accommodation and photophobia and increased intraocular pressure and headache, mental confusion or excitement (especially in the elderly), drowsiness, which may impair their ability to drive. - Advise the patient not to drive until the next visit after start of treatment and also to be careful in other situations (e.g. using machinery and working at heights) - Advise the patient not to drink alcohol or use other psychoactive substances when taking this medicine.
A10AB01	Insulin (human)	I	- Advise your patient to take precautions to avoid hypoglycaemia, this may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or operating machinery), and not to drive as long as side-effects persist. - If your patient have frequent episodes or if he/she find it hard to recognise hypoglycaemia. The advisability of driving should be considered in these circumstances. - Advise your patient not to drink alcohol nor use any psychoactive substances when taking this medication
A10AB02	Insulin (beef)	I	
A10AC03	Insulin (pork)	I	
A10AC04	Insulin lispro	I	
A10AC30	Combinations (Insulins)	I	
A10BD02	Metformin and sulfonamides	I	- Advise your patient to take precautions to avoid hypoglycaemia, this may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or operating machinery), and not to drive as long as side-effects persist. - If your patient has frequent episodes or if he/she find it hard to recognise hypoglycaemia. The advisability of driving should be considered in these circumstances. - Advise your patient not to drink alcohol nor use any psychoactive substances when taking this medication
A10BD03	Metformin and rosiglitazone	0	- No special advice

Table 16: Example of information to the patient and Categorisation and labelling of some available B - BLOOD AND BLOOD FORMING ORGANS MEDICINES on driving.

B BLOOD AND BLOOD FORMING ORGANS	**ACTIVE SUBSTANCE**	**CATEGORY LABELLING**	**INFORMATION FOR THE PATIENTS**
B01AC11	Iloprost (for inhalation use)	II	- Inform your patient that the medication can cause side effects that impair driving abilities (down blood pressure and may cause dizziness or light-headedness). Do not drive or operate any tools or machines if you feel these effects of low blood pressure. - Advise the patient not to drive for the first few days of treatment until any effects on the individual have been determined and also to be careful in other situations (e.g. using machinery and working at heights)
B02BX01	Etamsylate	0	- No special advice
B02BX04	Romiplostim (subcutaneous via)	I	- Advise your patient not to drive if he/she experiences side-effects that can impair his/her driving abilities (e.g. dizziness, paraesthesia, etc.) and not to drive as long as side-effects persist.
B03XA01	Erythropoietin (epoetin alfa, beta, theta)	0	- No special advice
B03XA02	Darbepoetin alfa	0	- No special advice
B03XA03	Methoxy polyethylene glycol-epoetin beta	0	- No special advice

Table 17: Information to the patient based on the categorisation and labelling of the C - CARDIOVASCULAR SYSTEM MEDICINES on driving.

CATEGORY LABELLING	INFORMATION FOR THE PATIENT
0	- No special advice.
I	- Advise your patient not to drive if he/she experiences side-effects that can impair his/her driving abilities (e.g. dizziness, fatigue, hypotension, decreased attention, etc.) and not to drive as long as side-effects persist. - Advise your patient not to drink alcohol nor use any psychoactive substances when taking this medication.
II	- Inform your patient that the medication can cause side effects that impair driving abilities (e.g. dizziness, drowsiness, hypotension, fatigue, etc.). - Advise your patient not to drive for the first few days of treatment and to be careful in other situations, as well (e.g. operating machinery and working at heights). - Advise the patient not to drink alcohol nor use any psychoactive substance when taking this medicine.

Table 18: Example of information to the patient and Categorisation and labelling of some available D - DERMATOLOGICALS MEDICINES on driving.

D DERMATOLOGICALS	ACTIVE SUBSTANCE	CATEGORY LABELLING	INFORMATION FOR THE PATIENTS
D05BA02	Methoxsalen	0	No special advice
D05BB02	Acitretin	I	- Advise your patient not to drive if he/she experiences side-effects that can impair his/her driving abilities (blurred or decreased night vision) and not to drive as long as side-effects persist. - Advise your patient not to drink alcohol nor use any psychoactive substances when taking this medication.
D06AA02	Chlortetracycline	0	- No special advice
D06AA03	Oxytetracycline	0	- No special advice
D07AA02	Hydrocortisone	0	- No special advice
D07AA03	Prednisolone	0	- No special advice
D10AD01	Tretinoin	0	- No special advice
D10AD03	Adapalene	0	- No special advice
D10BA01	Isotretinoin - Oral administration - Topical use	 II 0	- Inform your patient that the medication can cause side effects that impair driving abilities (e.g., decreased night vision in some cases was sudden, visual and neurological disturbances etc.) - Advise your patient not to drive for the first few days of treatment and to be careful in other situations, as well (e.g. operating machinery and working at heights). - Advise the patient not to drink alcohol nor use any psychoactive substance when taking this medicine.
D11AX19	Alitretinoin - Oral administration - Topical use	 I 0	- Advise your patient not to drive if he/she experiences side-effects that can impair his/her driving abilities (blurred or decreased night vision) and not to drive as long as side-effects persist. - Advise your patient not to drink alcohol nor use any psychoactive substances when taking this medication.

Table 19: Example of information to the patient and Categorisation and labelling of some available M - MUSCULOSKELETAL SYSTEM MEDICINES on driving.

M MUSCULOSKELETAL SYSTEM	ACTIVE SUBSTANCE	CATEGORY LABELLING	INFORMATION FOR THE PATIENTS
M01AB01	Indometacin	I	- Inform the patient that the medication can cause side effects that impair driving and that reaction time can also be reduced without experiencing side effects. - Advise the patient also to be careful in other situations than driving (e.g. using machinery and working at heights) - Advise the patient to avoid any alcohol or other psychoactive substances during the treatment.
M01AB02	Sulindac	I	
M01AB05	Diclofenac	I	
M01AB08	Etodolac	I	
M01AB11	Acemetacin	I	
M01AB15	Ketorolac	I	
M01AB16	Aceclofenac	I	
M01AB51	Indometacin, combinations	I	
M01AB55	Diclofenac, combinations	I	
M03AA01	Alcuronium	III	- Advise the patient not to drive or operate machinery until the effects of the anaesthetic, and the immediate effects of surgery have passed. - Advise the patient (and explain to caregivers) not to drink any alcohol 24 hours after anaesthesia
M03AA02	Tubocurarine	III	
M03AA04	Dimethyltubocurarine	III	
M03AC01	Pancuronium	III	
M03AC02	Gallamine	III	
M03AC03	Vecuronium	III	
M03BA01	Phenprobamate	II	- Inform the patient about the effects of the medicine on reaction time and that the medication can cause side effects that impair driving (dizziness, drowsiness, sleepiness, blurred/double vision and reduced alertness) - Advise the patient not to drive for the first few days of treatment or until the next visit after the start of treatment and also to be careful in other situations (e.g. using machinery and working at heights) - Advise the patient not to drink alcohol or use other psychoactive substances when taking this medicine. - One time (occasional) use: inform your patient that his/her response is reduced. Advise your patient not to drive then.
M03BA02	Carisoprodol	II	
M03BA03	Methocarbamol	II	
M03BA04	Styramate		
M03BA05	Febarbamate	II	
M03BA51	Phenprobamate, combinations excl. psycholeptics	II	
M03BB02	Chlormezanone	II	
M03BB03	Chlorzoxazone	II	
M03BB52	Chlormezanone, combinations excl. psycholeptics	II	
M04AC01	Colchicine	0	- No special advice
M05BA02	Clodronic acid	0	- No special advice

Table 20: Example of information to the patient and Categorisation and labelling of some available N01- ANESTHETICS MEDICINES on driving.

<table>
<tr><th>N01 ANESTHETICS</th><th>ACTIVE SUBSTANCE</th><th>CATEGORY LABELLING</th><th>INFORMATION FOR THE PATIENT</th></tr>
<tr><td>N01A</td><td>Anesthetics, general</td><td></td><td></td></tr>
<tr><td>N01AB06</td><td>Isoflurane</td><td>III</td><td rowspan="8">- Advise the patient (and explain to caregivers), in the event an early discharge is envisaged following general anaesthesia, not to drive or operate machinery during the first 24 hours after anaesthesia.
- Advise the patient (and explain to caregivers) not to drink any alcohol 24 hours after anaesthesia</td></tr>
<tr><td>N01AB07</td><td>Desflurane</td><td>III</td></tr>
<tr><td>N01AB08</td><td>Sevoflurane</td><td>III</td></tr>
<tr><td>N01AF03</td><td>Thiopental</td><td>III</td></tr>
<tr><td></td><td>Fentanyl</td><td>III</td></tr>
<tr><td>N01AH02</td><td>Alfentanil</td><td>III</td></tr>
<tr><td>N01AH06</td><td>Remifentanil</td><td>III</td></tr>
<tr><td>N01AX01</td><td>Droperidol</td><td>III</td></tr>
<tr><td>N01B</td><td>Anesthetics, local</td><td></td><td></td></tr>
<tr><td>N01BA02</td><td>Procaine</td><td rowspan="20"></td><td rowspan="20">Categorisation, labelling and information to the patient depending of the route of administration

0

Topic administration (skin, mucous)

I

Infiltration (dental anaesthesia)
Intrarticular, intrabursal, tendon sheath administration, etc..
- Advise the patient not to drive or operate machinery until the effect of the anaesthesia and the immediate effects of surgery are passed.

II

Ocular administration:
- Advise at the patient that their sight may become blurred, and not to drive or operate machinery during the first 24 hours after using local anesthetics.

III

Regional anaesthesia (nerve-block, intravenous regional anaesthesia).
Spinal /Epidural
- Advise the patient (and explain to caregivers), in the event an early discharge is envisaged following regional / epidural / spinal anaesthesia, not to drive or operate machinery during the first 24 hours after anaesthesia.
- Advise the patient (and explain to caregivers) not to drink any alcohol 24 hours after anaesthesia</td></tr>
<tr><td>N01BA03</td><td>Tetracaine</td></tr>
<tr><td>N01BA05</td><td>Benzocaine</td></tr>
<tr><td>N01BA52</td><td>Procaine combinations</td></tr>
<tr><td>N01BB01</td><td>Bupivacaine</td></tr>
<tr><td>N01BB02</td><td>Lidocaine</td></tr>
<tr><td>N01BB03</td><td>Mepivacaine</td></tr>
<tr><td>N01BB04</td><td>Prilocaine</td></tr>
<tr><td>N01BB09</td><td>Ropivacaine</td></tr>
<tr><td>N01BB10</td><td>Levobupivacaine</td></tr>
<tr><td>N01BB20</td><td>Combinations</td></tr>
<tr><td>N01BB51</td><td>Bupivacaine combinations (with adrenalina)</td></tr>
<tr><td>N01BB52</td><td>Lidocaine combinations</td></tr>
<tr><td>N01BB53</td><td>Mepivacaine combinations (with epinephrine)</td></tr>
<tr><td>N01BB54</td><td>Prilocaine combinations (with lidocaine)</td></tr>
<tr><td>N01BB58</td><td>Articaine combinations</td></tr>
<tr><td>N01BX03</td><td>Phenol:</td></tr>
<tr><td>N01BX04</td><td>Capsaicin</td></tr>
</table>

Table 21: Example of information to the patient and Categorisation and labelling of some available N02 - ANALGESICS MEDICINES on driving.

N02 ANALGESICS	ACTIVE SUBSTANCE	CATEGORY LABELLING	INFORMATION FOR THE PATIENT
N02AA01	Morphine - Oral administration - Parenteral admin.	III III	- Inform the patient that the medication can cause side effects that impair driving and that reaction time can also be reduced without experiencing side effects. - Advise the patient (and explain to caregivers) not to drive until the next visit after start of treatment or after changes in dosage. - Advise the patient also to be careful in other situations than driving (e.g. using machinery and working at heights) - Advise the patient to strictly follow the prescribed doses and the intake scheme. - Advise the patient to avoid any alcohol or other psychoactive substances during the treatment. - Opiate cessation can also cause behavioral changes and requires follow-up and counseling.
N02AA03	Hydromorphone	III	
N02AA05	Oxycodone	III	
N02AA08	Dihydrocodeine	III	
N02AB03	Fentanyl - Oral administration - Parenteral admin. - Transdermal admin.	III III III	
N02AE01	Buprenorphine - Oral administration - Parenteral admin. - Transdermal admin.	III III III	
N02BA01 A01AD05 B01AC06	Acetylsalicylic acid	0	- No special advice.
N02BE01	Paracetamol	0	- No special advice.
N02BG06	Nefopam	II	- Advise the patient (and explain to caregivers) not to drive during the first days of treatment. - Inform the patient that the medication can cause side effects that impair driving and that reaction time can also be reduced without experiencing side effects. - Advise the patient also to be careful in other situations than driving (e.g. using machinery and working at heights) - Advise the patient to strictly follow the prescribed doses and intake scheme.. - Advise the patient to avoid any alcohol or other psychoactive substances during the treatment.
N02CA52	Ergotamine, combinations excl. psycholeptics	I	- Inform the patient that the medication can cause side effects that impair driving and that reaction time can also be reduced without experiencing side effects. - Advise the patient also to be careful in other situations than driving (e.g. using machinery and working at heights) - Advise the patient to avoid any alcohol or other psychoactive substances during the treatment.

Table 22: Example of information to the patient and Categorisation and labelling of some available N03 - ANTIEPILEPTIC MEDICINES on driving.

N03 ANTIEPILEPTIC	ACTIVE SUBSTANCE	CATEGORY LABELLING	INFORMATION FOR THE PATIENT
N03AA02	Phenobarbital - Oral administration - Parenteral administration	III III	**Advise the patient not to drive.** - Advise the patient to take the medicine as prescribed by the physician. - Advise the patient not to stop taking the medicine suddenly, and to inform the physician – doctor if he/she should do so. - Advise the patient not to drink alcohol while taking this medication.
N03AA03	Primidone	III	**Advise the patient not to drive.** - Advise the patient to take the medicine as prescribed by the physician. - Advise the patient not to stop taking the medicine suddenly, and to inform the physician – doctor if he/she should do so. - Advise the patient not to drink alcohol while taking this medication. **Essential tremor** - Advise the patient not to drive
N03AB02	Phenytoin - Oral administration - Parenteral administration	III III	**Advise the patient not to drive.** - Advise the patient to take the medicine as prescribed by the physician. - Advise the patient not to stop taking the medicine suddenly, and to inform the physician – doctor if he/she should do so. - Advise the patient not to drink alcohol while taking this medication. **Trigeminal neuralgia** - Advise the patient not to drive.
N03AE01	Clonazepam - Oral administration - Parenteral administration	II III	**Advise the patient not to drive during the first days of treatment as well as after dose increases.** - Advise the patient to take the medicine as prescribed by the physician. - Advise the patient not to stop taking the medicine suddenly, and to inform the physician – doctor if he/she should do so. - Advise the patient not to drink alcohol while taking this medication
N03AX16	Pregabalin	II	**Advise the patient not to drive during the first days of treatment as well as after dose increases.** - Advise the patient to take the medicine as prescribed by the physician. - Advise the patient not to stop taking the medicine suddenly, and to inform the physician – doctor if he/she should do so. - Advise the patient not to drink alcohol while taking this medication. **Neuropathic pain; Generalised Anxiety Disorder** - Advise the patient not to drive during the first days of treatment as well as after dose increases.

Table 23: Example of information to the patient and Categorisation and labelling of some available N04 - ANTIPARKINSON MEDICINES on driving.

N04 ANTIPARKINSON	ACTIVE SUBSTANCE	CATEGORY LABELLING	INFORMATION FOR THE PATIENT
N04AA02	Biperiden - Oral administration - Parenteral administration	II III	- Advise the patient (and explain to caregivers) not to drive during the first days of treatment
N04BA02	Levodopa and decarboxylase inhibitor Levodopa+carbidopa Levodopa+benserazide	II	- Advise the patient (and explain to caregivers) not to drive during the first days of treatment. - Inform patients that unwanted effects are seen rapidly during the dosage adjustment period. - Advise the patient (and explain to caregivers) not to drive at all if suffering from "sleep attacks". - Advise the patient (and explain to caregivers) not to drive at all if suffering from severe fluctuations in mobility "("on-off" phenomena).
N04BB01	Amantadine	I	- Advise the patient (and explain to caregivers) not to drive during the first days of treatment. - Some central nervous system unwanted effects (like confusion) are more common when amantadine is administered concurrently with anticholinergic agents.
N04BD01	Selegiline	I	**Monotherapy:** - Advise the patient (and explain to caregivers) not to drive during the first days of treatment. **In adjunct therapy with levodopa:**
N04BD02	Rasagiline	I	- Advise the patient (and explain to caregivers) not to drive during the first days of treatment. - Inform patients that unwanted effects are seen rapidly during the dosage adjustment period. - Advise the patient (and explain to caregivers) not to drive at all if suffering from "sleep attacks". - Advise the patient (and explain to caregivers) not to drive at all if suffering from severe fluctuations in mobility "("on-off" phenomena).

Table 24: Example of information to the patient and Categorisation and labelling of some available N05 - PSYCHOLEPTICS MEDICINES on driving.

N05 PSYCHOLEPTICS	ACTIVE SUBSTANCE	CATEGORY LABELLING	INFORMATION FOR THE PATIENT
N05AA01	Chlorpromazine - Oral administration - Parenteral administration	 III III	- Inform the patient about the effects of the medicine on reaction time and that the medication can cause side effects that impair driving (dizziness, drowsiness, sleepiness, blurred/double vision and reduced alertness) - Advise the patient not to drive until the next visit after start of treatment and also to be careful in other situations (e.g. using machinery and working at heights) - Advise the patient not to drink alcohol when taking this medicine. - In short-term use (eg intractable hiccup, nausea and vomiting) inform your patient that his/her response is still reduced for approximately 24 hours. Advise the patient not to drive then.
N05AB02	Fluphenazine	II	- Inform the patient about the effects of the medicine on reaction time and that the medication can cause side effects that impair driving (dizziness, drowsiness, sleepiness, blurred/double vision and reduced alertness) - Advise the patient not to drive for the first few days of treatment or until the next visit after the start of treatment and also to be careful in other situations (e.g. using machinery and working at heights) - Advise the patient not to drink alcohol when taking this medicine.
N05AD01	Haloperidol - Oral administration - Parenteral administration	 II III	- Inform the patient about the effects of the medicine on reaction time and that the medication can cause side effects that impair driving (dizziness, drowsiness, sleepiness, blurred/double vision and reduced alertness) - Advise the patient not to drive for the first few days of treatment or until the next visit after the start of treatment and also to be careful in other situations (e.g. using machinery and working at heights) - Advise the patient not to drink alcohol when taking this medicine. - In short-term use (eg intractable hiccup, nausea and vomiting), inform your patient that his/her response is still reduced for approximately 24 hours. Advise the patient not to drive then.
N05AH04	Quetiapine - start of treatment - continuation treatment	 III II	**Start of treatment:** - Inform the patient about the effects of the medicine on reaction time and that the medication can cause side effects that impair driving (dizziness, drowsiness, sleepiness, blurred/double vision and reduced alertness) - Advise the patient not to drive until the next visit after start of treatment and also to be careful in other situations (e.g. using machinery and working at heights)

			- Advise the patient not to drink alcohol when taking this medicine. **Continuation treatment:** - Inform the patient about the effects of the medicine on reaction time and that the medication can cause side effects that impair driving (dizziness, drowsiness, sleepiness, blurred/double vision and reduced alertness) - Advise the patient not to drive for the first few days of treatment or until the next visit after the start of treatment and also to be careful in other situations (e.g. using machinery and working at heights) - Advise the patient not to drink alcohol when taking this medicine.
N05BA01	Diazepam - Oral administration - Parenteral administration - Other routes	 III III III	- Inform the patient about the effects of the medicine on reaction time, that the medication can cause side effects that impair driving (dizziness, drowsiness, sleepiness, blurred/double vision and reduced alertness) and that reaction time can also be reduced without experiencing side effects. - Advise the patient not to drive until the next visit after start of treatment and also to be careful in other situations (e.g. using machinery and working at heights) - Advise the patient not to drink alcohol or use other psychoactive substances when taking this medicine. - One time (occasional) use: inform your patient that his/her response is still reduced for approximately 3 days to one week. Advise your patient not to drive then.
N05BA09	Clobazam	II	- Inform the patient about the effects of the medicine on reaction time and that the medication can cause side effects that impair driving (dizziness, drowsiness, sleepiness, blurred/double vision and reduced alertness) - Advise the patient not to drive for the first few days of treatment or until the next visit after the start of treatment and also to be careful in other situations (e.g. using machinery and working at heights) - Advise the patient not to drink alcohol or use other psychoactive substances when taking this medicine. - One time (occasional) use: inform your patient that his/her response is still reduced for approximately 3 days to one week. Advise your patient not to drive then.

Table 25: Example of information to the patient and Categorisation and labelling of some available N06A - ANTIDEPRESSANT MEDICINES on driving.

N06A ANTIDEPRE-SSANT MEDICINES	ACTIVE SUBSTANCE	CATEGORY LABELLING	INFORMATION FOR THE PATIENT
N06AA21	Maprotiline - Oral administration - Parenteral administration	II III	- Inform your patient about the effects of the medication on reaction time as well as that the medication can cause side-effects that impair driving abilities (e.g. dizziness, drowsiness, sleepiness, blurred vision, etc.). - Advise your patient not to drive for the first few weeks of treatment or until the next visit and to be careful in other situations, as well (e.g. operating machinery and working at heights). - Advise your patient not to drink alcohol nor use any other psychoactive substance when taking this medication. - In case of short-term use of the medication, advise your patient not to drive because his/her driving skills are still impaired for approximately 24 hours.
N06AB03	Fluoxetine	I	- Inform your patient about the effects of the medication on reaction time as well as that the medication can cause side-effects that impair driving abilities (e.g. dizziness, drowsiness, sleepiness, blurred vision, etc.). - Advise your patient not to drive if he/she experiences side-effects that can impair his/her driving abilities. - Advise your patient not to drive as long as side-effects persist. - Advise your patient not to drink alcohol nor use any other psychoactive substance when taking this medication.
- N06AX03	- Mianserin	- III	- Inform your patient about the effects of the medication on reaction time as well as that the medication can cause side-effects that impair driving abilities (e.g. dizziness, drowsiness, sleepiness, blurred vision, etc.). - Advise your patient not to drive until the next visit and to be careful in other situations, as well (e.g. operating machinery and working at heights). - Advise your patient not to drink alcohol nor use any other psychoactive substance when taking this medication. - In case of short-term use of the medication, advise your patient not to drive because his/her driving skills are still impaired for approximately 24 hours.

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Table 26: Example of information to the patient and Categorisation and labelling of some available N06B - PSYCHOSTIMULANT and N06D – ANTI-DEMENTIA MEDICINES on driving.

N06B PSYCHOSTIMU-LANT MEDICINES	**ACTIVE SUBSTANCE**	**CATEGORY LABELLING**	**INFORMATION FOR THE PATIENT**
N06BA02	Dexamafetamine	II	- Inform your patient about the effects of the medication on reaction time as well as that the medication can cause side-effects that impair driving abilities (e.g. dizziness, drowsiness, sleepiness, blurred vision, etc.). - Advise your patient not to drive for the first few weeks of treatment or until the next visit and to be careful in other situations, as well (e.g. operating machinery and working at heights). - Advise your patient not to drink alcohol nor use any other psychoactive substance when taking this medication. - In case of short-term use of the medication, advise your patient not to drive because his/her driving skills are still impaired for approximately 24 hours.
N06BA04	Methylphenidate	II	
N06BA05	Pemoline	I	- Inform your patient about the effects of the medication on reaction time as well as that the medication can cause side-effects that impair driving abilities (e.g. dizziness, drowsiness, sleepiness, blurred vision, etc.). - Advise your patient not to drive if he/she experiences side-effects that can impair his/her driving abilities. - Advise your patient not to drive as long as side-effects persist. - Advise your patient not to drink alcohol nor use any other psychoactive substance when taking this medication.
N06D ANTIDEMENTIA MEDICINES	**ACTIVE SUBSTANCE**	**CATEGORY LABELLING**	**INFORMATION FOR THE PATIENT**
N06DA02	Donepezil	II	- Inform your patient (and explain his/her caregiver) about the effects of the medication on reaction time as well as that the medication can cause side-effects that impair driving abilities (e.g. dizziness, drowsiness, sleepiness, blurred vision, etc.). - Advise your patient (and explain his/her caregiver) not to drive for the first few weeks of treatment or until the next visit and to be careful in other situations, as well (e.g. operating machinery and working at heights). - Advise your patient (and explain his/her caregiver) not to drink alcohol nor use any other psychoactive substance when taking this medication.

			- In case of short-term use of the medication, advise your patient (and explain his/her caregiver) not to drive because his/her driving skills are still impaired for approximately 24 hours. - Driving with this treatment should require an approval by driving licence administration.
N06DX02	Ginkgo biloba	0	- No special advice.

Table 27: Example of information to the patient and Categorisation and labelling of some available N07 - OTHER NERVOUS SYSTEM MEDICINES on driving.

N07 OTHER NERVOUS SYSTEM DRUGS	**ACTIVE SUBSTANCE**	**CATEGORY LABELLING**	**INFORMATION FOR THE PATIENT**
N07AA01	Neostigmine - Oral administration - Parenteral administration	 II III	- Advise the patient (and explain to caregivers) not to drive during the first days of treatment. - The treatment can impair patient's vision especially by night.
N07AX01	Pilocarpine - Oral administration - Ophthalmic eye drops/ Gel	 II II	- Advise the patient (and explain to caregivers) not to drive during the first days of treatment. - The treatment can impair patient's vision especially by night and may require an ophthalmological advice.
N07BA01	Nicotine - Oral and nasal administration	0	- The treatment has to be used according to the recommended dose to avoid side effect on driving. - Smoking cessation can also cause behavioural changes.
N07BA03	Varenicline	I	- Advise the patient (and explain to caregivers) not to drive during the first days of treatment and after changes in doses. - The treatment has to be used according to the recommended dose. - Advise the patient about possibles effects on behavior. - Smoking cessation can also cause behavioural changes.
N07BB01	Disulfiram	II	- Advise the patient (and explain to caregivers) not to drive during the first days of treatment and after changes in doses. - Advise the patient to strictly follow the prescribed doses and treatment procedures and to avoid any alcohol or other psychoactive substances during the treatment. - Alcohol cessation can also cause behavioural changes and requires follow-up and counselling. - Driving with this treatment should require an approval by driving licence administration.
N07BC02	Methadone - Oral administration: - Parenteral administration:	 II III	- Advise the patient (and explain to caregivers) not to drive during the first days of treatment and after changes in doses. - Advise the patient to strictly follow the prescribed doses, the treatment and delivery procedures and to avoid any alcohol or other psychoactive substances during the treatment. - Opiate cessation can also cause

			behavioural changes and requires follow-up and counselling. - Driving with this treatment should require an approval by driving licence administration.
N07BC51	Buprenorphine, combinations (buprenorphine+naloxone)	III	- Advise the patient (and explain to caregivers) not to drive during the first days of treatment and after changes in doses. - Advise the patient to strictly follow the prescribed doses, the treatment and delivery procedures and to avoid any alcohol or other psychoactive substances during the treatment. - Opiate cessation can also cause behavioural changes and requires follow-up and counselling. - Driving with this treatment should require an approval by driving licence administration.

Table 28: Example of information to the patient and Categorisation and labelling of some available R - RESPIRATORY SYSTEM MEDICINES on driving.

R RESPIRATORY SYSTEM MEDICINES	**ACTIVE SUBSTANCE**	**CATEGORY LABELLING**	**INFORMATION FOR THE PATIENT**
R01AA03	Phedrine	0	- No special advice.
R01AD05	Budesonide	0	- No special advice.
R01BA02	Pseudoephedrine	I	- Inform the patient about the effects that the medicine can have on reaction time and that the medication can cause side effects that impair driving (anxiety, restlessness, termor, insomnia) - Advise the patient not to drive when this side effects occur and also to be careful in other situations (e.g. using machinery and working at heights) - Advise the patient not to drink alcohol or use other psychoactive substances when taking this medicine.
R01BA52	Pseudoephedrine, combinations + loratadine + triprolidine	 I III	+ loratadine - Inform the patient about the effects that the medicine can have on reaction time and that the medication can cause side effects that impair driving (anxiety, restlessness, tremor, insomnia, dizziness, fatigue) - Advise the patient not to drive when this side effects occur and also to be careful in other situations (e.g. using machinery and working at heights) - Advise the patient not to drink alcohol or use other psychoactive substances when taking this medicine. + triprolidine - Inform the patient about the effects of the medicine on reaction time and that the medication can cause side effects that impair driving (anxiety, restlessness, tremor, insomnia, drowsiness) - Advise the patient not to drive until the next visit after start of treatment and also to be careful in other situations (e.g. using machinery and working at heights) - Advise the patient not to drink alcohol or use other psychoactive substances when taking this medicine.
R03DA04	Theophylline **Oral administration **Parenteral administration	 0 I	Oral: - No special advice Parenteral: - Inform the patient about the effects that the medicine can have on reaction time and that the medication can cause side effects that impair driving (insomnia, confusion, anxiety, vertigo, dizziness, tremor, visual disturbances) - Advise the patient not to drive when this side effects occur and also to be careful in other situations (e.g. using machinery and

			working at heights) - Advise the patient not to drink alcohol or use other psychoactive substances when taking this medicine.
R06AA02	Diphenhydramine	III	- Inform the patient about the effects of the medicine on reaction time and that the medication can cause side effects that impair driving (dizziness, drowsiness, blurred vision and reduced alertness) - Advise the patient not to drive until the next visit after start of treatment and also to be careful in other situations (e.g. using machinery and working at heights) - Advise the patient not to drink alcohol or use other psychoactive substances when taking this medicine.
R06AX19	Azelastine	I	- Inform the patient about the effects that the medicine can have on reaction time and that the medication can cause side effects that impair driving (drowsiness, somnolence) - Advise the patient not to drive when this side effects occur and also to be careful in other situations (e.g. using machinery and working at heights) - Advise the patient not to drink alcohol or use other psychoactive substances when taking this medicine.
R06AX22	Ebastine	I	

Table 29: Example of information to the patient and Categorisation and labelling of some available S - SENSORY ORGANS MEDICINES on driving.

S SENSORY ORGANS	ACTIVE SUBSTANCE	CATEGORY LABELLING	INFORMATION FOR THE PATIENTS
S01AA01	Chloramphenicol	General rule Drops: 0 Oinment: I	- Inform the patient that as with any ocular medication, if transient, blurred vision occurs at application. - Advise the patient that he/she should wait until his/her vision clears before driving or using machinery.
S01AA16	Rifamycin		
S01AA17	Erytromycin		
S01AX13	Ciprofloxacin		
S01AX17	Lomefloxacin		
S01BB01	Hydrocortisone and mydriatics	Depending on the mydriatic in combination	Depending on the mydriatic in combination
S01BB02	Prednisolone and mydriatics		
S01EA03	Apraclonidine	II	- Inform the patient that this ocular medication may cause fatigue and/or drowsiness, blurred and/or abnormal vision which may impair the ability to drive or operate machinery, especially at night or in reduced lighting. - Advise the patient that he/she should wait until these symptoms have cleared before driving or using machinery.
S01EA04	Clonidine	II	
S01EA05	Brimonidine	II	
S01EC02	Diclofenamide	I	- Inform the patient that as with any ocular medication, if transient, blurred vision occurs at application. - Advise the patient that he/she should wait until his/her vision clears before driving or using machinery.
S01EC04	Brinzolamide	I	
S01ED01	Timolol	I	
S01ED02	Betaxolol	I	
S01ED03	Levobunolol	I	
S01ED05	Carteolol	I	
S01FA01	Atropine	III	- Inform the patient that this ocular medication may cause transient blurring of vision or that he/she may suffer from photophobia and that this may impair their ability to drive under certain circumstances. Complete recovery from the effects of mydriatic anticholinergics may take up to 24 hours. - Advise the patients not to drive or operate hazardous machinery until 24 hours after receiving ocular medication (recovery occurs within 24 hours) or until vision is clear.
S01FA05	Homatropine	III	
S01FA06	Tropicamide	III	
S01FA56	Tropicamide, combinations	III	
S01FAP1	Atropine+escopolamine+phenylephrine	III	

7. Categorisation and labelling of medicines approved by the EMA january 2008-september 2010

In Task 4.3, we have also provided a classification/categorisation for the "new" medicines approved by the EMA from January 2008 to September 2010. Table 30 shows the new medicines approved by the EMA during this period.

The categorisation of these new medicines has been carried out using the methodology described in chapter 2.

The medicines in ATC groups G, J, L, V, as well as medicines ATC (code not yet assigned), have been categorized as an exercise according to DRUID criteria, even though no patient-oriented information has been produced for these medicines and they have not been included in the alphabetical list

Table 30: Categorisation and labelling of "new" medicines approved by EMA from January 2008 to September 2010

ATC	ACTIVE SUBSTANCE	INVENTED NAME	CATEGORY	LABELLING
A ALIMENTARY TRACT AND METABOLISM				
A03AE04	Prucalopride	RESOLOR	I	I
A06AH01	Methylnaltrexone bromide	RELISTOR	0	0
A10BD07	Sitagliptin and 850 mg of metformin hydrochloride.	JANUMET/VELMETIA /EFFICIB	I	II
A10BH03	Saxagliptin	ONGLYZA	I	I
A10BX02	Repaglinide	ENYGLID	I	I
A10BX07	Liraglutide	VICTOZA	I	I
A11HA08	Tocofersolan	VEDROP (from birth to 16 or 18 years of age)	0	0
A16AB10	Velaglucerase alfa	VPRIV	I	I
A16AX07	Sapropterin dihydrochloride	KUVAN	0	0
B BLOOD AND BLOOD FORMING ORGANS				
B01AC22	Prasugrel	EFIENT	0	0
B01AC30	Clopidogrel + acido acetilsalicilico	DUOCOVER/DUOPLAVIN	0	0
B01AE07	Dabigatran etexilate (as mesilate)	PRADAXA	0	0
B01AX06	Rivaroxaban	XARELTO	0	0
B02BC	Human fibrinogen / human thrombin	EVICEL	0	0
B02BX04	Romiplostim	NPLATE	I	I
B02BX05	Eltrombopag olamine	REVOLADE	0	0
B03XA01	Epoetin theta	BIOPIN	0	0
C CARDIOVASCULAR SYSTEM				
C01EB18	Ranolazine	LATIXA (RANEXA)	I	I
C01EB19	Icatibant - acetate	FIRAZYR	I	I
C01EB21	Regadenoson	RAPISCAN	NE (not	NE (not

			SmPC published)	SmPC published)
C02KX02	Ambrisentan	VOLIBRIS	I	I
C03XA01	Tolvaptan	SAMSCA	I	I
C09DX01	Valsartan/Amlodipine besylate/ hydrochlorothiazide	DAFIRO HTC	I	I
C09XA52	Aliskiren hemifumarate / hydrochlorothiazide	RASILEZ HCT	0	0
C10AD52	Nicotinic acid / Laropiprant	TREDAPTIVE/TREVACLYN/PELZONT	I	I
G GENITO URINAY SYSTEM AND SEX HORMONES				
G03GA06	Follitropin beta,	FERTAVID	0	0
G03GA09	Corifollitropin alfa	ELONVA	I	I
G03XC02	Bazedoxifene	COMBRIZA	I	I
G04BE08	Tadalafil	ADCIRCA	I	I
G04CA04	Silodosin	SILODYX	I	I
J ANTIINFECTIVES FOR SYSTEMIC USE				
J01DF01	Aztreonam	CAYSTON	0	0
J01DH04	Doripenem monohydrate	DORIBAX	0	0
J02AX05	Micafungin (as sodium).	MYCAMINE	0	0
J05AG04	Etravirine	INTELENCE	I	I
J06BA02	Human normal immunoglobulin (IVIg)	PRIVIGEN	I	I
J06BB04	Human hepatitis B immunoglobulin	ZUTRECTA	0	0
J07AH	Meningococcal Group A, C, W-135 and Y Coniugate Vaccine	MENVEO	I	I
J07AL52	Streptococcus pneumoniae polysaccharide serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F each conjugated to a carrier protein (Pneumococcal vaccine)	SYNFLORIX (indicated for children from 6 weeks up to 2 years of age)	NE (Only paediatric patients)	NE (Only paediatric patients)
J07BA02	Japanese Encephalitis vaccine, inactivated, adsorbed	IXIARO	I	I
J07BB02	Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) A/VietNam/1194/2004 NIBRG-14	PANDEMRIX	I	I
L ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS				
L01AC01	Thiotepa	TEPADINA	III	III
L01BC07	Azatizine	VIDAZA	III	III
L01CA05	Vinflunine ditartrate	JAVLOR	II	II
L01XC09	Catumaxomab	REMOVAB	II	II
L01XC10	Ofatumumab	ARZERRA	I	I
L01XE07	Lapatinib	TYVERB	I	I
L01XE10	Everolimus	AFINITOR	I	I
L01XE11	Pazopanib	VOTRIENT	I	I

L01XX31	Gefinitib	IRESSA	I	I
L02BX02	Degarelix	FIRMAGON	I	I
L03AB08	Interferon beta-1b	EXTAVIA	II	II
L03AX14	Histamine dihydrochloride	CEPLENE	II	II
L03AX15	Mifamurtide	MEPACT	II	II
L03AX16	Plerixafor	MOZOBIL	I	I
L04AA13	Leflunomide	LEFLUNOMIDE WINTHROP	I	
L04AA06	Mycophenolate mofetil	MYCLAUSEN		
L04AA27	Fingolimod	GILENYA		
L04AB05	Certolizumab pegol	CIMZIA	I	I
L04AB06	Golimumab	SIMPONI	I	I
L04AC04	Canakinumab	ILARIS	I	I
L04AC05	Ustekinumab	STELARA	I	I
L04AC07	Tocilizumab	ROACTEMRA	I	I
L04AC08	Rilonacept	RILONACEPT REGENERON	II	II
L04AX02	Thalidomide	THALIDOMIDE CELGENE	III	III
M MUSCULO-SKELETAL SYSTEM				
M04AA03	Febuxostat	ADENURIC	I	I
M05BC02	Eptotermin alfa	OPGENRA	0	0
M05BX04	Denosumab	PROLIA	I	I
N NERVOUS SYSTEM				
N01BX04	Capsaicin	QUTENZA	0	0
N03AF04	Eslicarbazepin	EXALIEF	II	II
N03AX18	Lacosamide	VIMPAT	II	II
N05CF04	Eszopiclone	LUNIVIA	NE (not SmPC published)	NE (not SmPC published)
N06AX22	Agomelatine	VALDOXAN/ THYMANAX	II	II
N07XX05	Amifampridine	FIRDAPSE	II	II
R RESPIRATORY SYSTEM				
R03AC18	Indacaterol maleate	OSLIF BREEZHALER	0	0
R03DX07	Roflumilast	DAXAS	0	0
S OPHTHALMOLOGICALS				
S01ED51	Brinzolamide / timolol	AZARGA	I	I
V VARIOUS				
V03AB35	Sugammadex	BRIDION	II	II
V03AE02	Sevelamer (carbonate)	RENVELA	0	0
V09HA03	Besilesomab	SCINTIUM	0	0
ATC CODE NO YET ASSIGNED				
ATC code not yet assigned	Ulipristal acetate	ELLAONE	I	I
ATC code not yet assigned	Dronedarone	MULTAQ	I	I
ATC code	Lasofoxifene	FABLYN	0	0

not yet assigned				
ATC code not yet assigned	Characterised viable autologous cartilage-forming cells expanded in vivo expressing specific marker proteins	CHONDROCELECT	II	II

NE: Not evaluted

8. Conflict of interests

The authors of the study declare there is no conflict of interest