MEDICINES
are not like
other products...

Let's talk about our medicines

With the EDQM,
Council of Europe

edqm 50 years/ans
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
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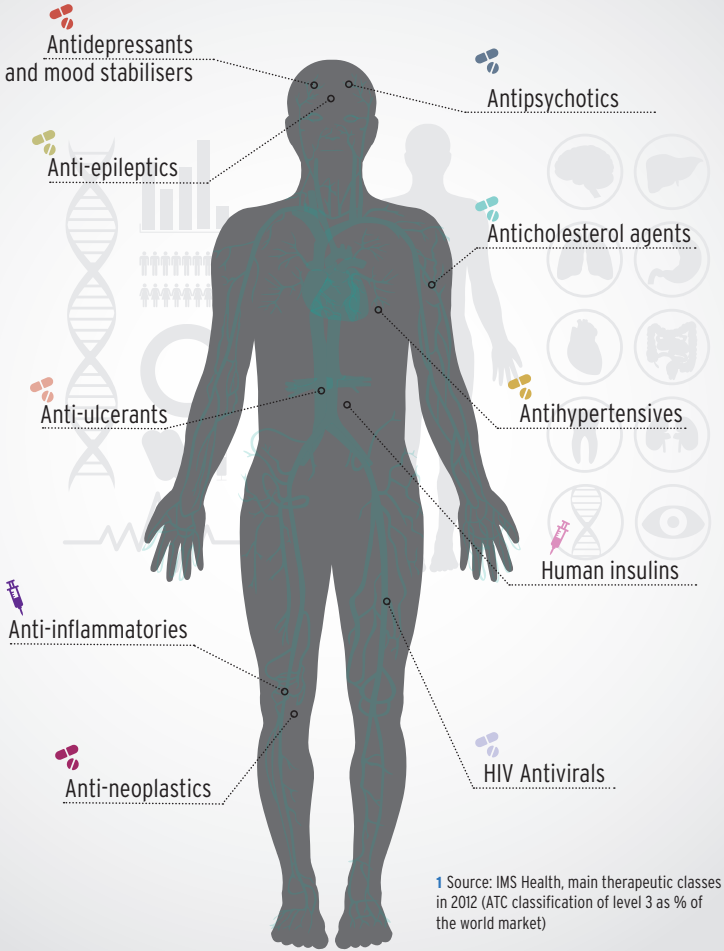
The most used medicines in the world
according to their therapeutic class (by value) [1]



1 Source: IMS Health, main therapeutic classes in 2012 (ATC classification of level 3 as % of the world market)

Whether we receive anticholesterol agents, antihypertensive medicines, antibiotics or even vaccines, we expect our medicines to be safe, effective and of high quality, no matter where we buy them in Europe and regardless of their ingredients. These expectations are justified since they directly concern our health. How can we be sure of the quality, safety and efficacy of our medicines in today's context of globalisation and the threat of counterfeit (falsified) medicines?

To face these challenges, the strict regulatory and legislative framework established by the European public health authorities must constantly evolve and be adapted.

European member states of the Council of Europe have been working since 1964 to elaborate common quality standards (the European Pharmacopoeia) that are mandatory for medicines and their ingredients. In addition to their work on the European Pharmacopoeia, the member states have also become strongly committed to other activities since 1994: yearly programmes for the market surveillance of medicines, the evaluation of the quality of raw materials, and more recently specific programmes to combat counterfeit (falsified) medicines.

Answers to frequently asked questions

1. How can I be sure that I'm taking a high-quality medicine?

Legal systems are in place for the manufacture and supply of medicines, covering every step in the lifecycle of a medicine from its conception to its distribution; this is the only way to guarantee the quality of medicines and prevent you from receiving counterfeit (falsified) medicines. This applies regardless of whether the medicines are dispensed from a pharmacy or from points of sale authorised by the competent national authorities.

Medicines must therefore be **constantly** under the control of each competent national authority. This ensures the quality of the medicine (composition and conditions for manufacturing, storage and distribution). Medicines can only be dispensed by **a pharmacist or another competent person**. Regardless of whether a medicine requires a prescription or not, it must always **be dispensed by a competent professional** who will also make sure that the medicine is compatible with any other medicines/treatments that you may be taking. You thus benefit from the advice of a **professional specialised in medicines**.

2. Why can't I buy a prescription medicine directly without involving a health professional?

Never forget, a medicine is an active substance: it contains one or more active ingredients to effectively treat or prevent a disease. Its activity also means that it may have side effects (adverse reactions). They should not be considered to be harmless. Medicines available only upon presentation of a medical prescription are called prescription medicines: they must be prescribed by a physician or another health professional. A prescription is based on an assessment of your needs during a medical appointment, taking into consideration your medical record and any other chronic treatments that you may be taking.

3. How are medicines manufactured?

The final quality of a medicine depends on the quality of the raw materials that make up the medicine, and also the quality of the process to manufacture the finished product. Specific regulations apply to the manufacture of medicines, which takes place under the responsibility of the head pharmacist or other competent professional, who is accountable for each batch that is produced.

According to European regulations, before the production of a medicine can begin, the quality of the raw materials making up the medicine must be demonstrated in a technical file submitted as part of the Marketing Authorisation (MA) application. If the substance is described in the European Pharmacopoeia, it must comply with the European quality standards in force. Its manufacturer can apply for a certificate of suitability to the quality standards of the European Pharmacopoeia through the Certification Procedure of the European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe. This certificate attests that the substance from this source, produced according to the process described in the application file, can be suitably controlled by the European Pharmacopoeia quality standard. This certificate can then be used in each MA application for a medicine containing this substance.

4. How are our medicines controlled in practice?

Medicines are subjected to many controls throughout their lifecycle. For example, manufacturers must comply with specific standards for manufacturing called "good manufacturing practice" (GMP). Each batch of medicine is tested by the manufacturer. In addition, European countries organise market surveillance programmes in their territories to test the quality of commercialised medicines.

These countries also work together at the European level via the European network of Official Medicines Control Laboratories (OMCLs); they have been collaborating in this area of activity since 1994. These activities are financed jointly with the European Union. These public laboratories are at the forefront of quality control testing of medicines on a daily basis and are also involved in investigations into suspected fraud or counterfeit (falsified) medicines.

5. Who does what in Europe for the quality and safety of medicines?

The EDQM is responsible for the elaboration of obligatory quality standards for medicines and their ingredients. These standards are published in an official reference work called the European Pharmacopoeia. Through its European Network of Official Medicines Control Laboratories (OMCLs), the EDQM also organises programmes for market surveillance of medicines commercialised and distributed in Europe. The Council of Europe is also involved in finding ways to fight more effectively against the counterfeiting (falsification) of medicines through the elaboration of common approaches at the European level and of legal instruments such as the MEDICRIME Convention. The European Union establishes regulations in the pharmaceutical area governing the development, marketing and testing of medicines as well as post-marketing surveillance of adverse reactions (pharmacovigilance). The competent national authorities, such as the Agence Nationale du Médicament et produits de santé (ANSM) in France or the Agenzia Italiana del Farmaco (AIFA) in Italy, control the quality of medicines marketed in their territories.

In addition, at the European level, common programmes have been set up to make more effective use of the specific expertise of the various competent national authorities via a co-operative and harmonised approach.

The member states participate jointly in these European programmes of activities and they ensure access at the national level to high-quality, safe and effective medicines through their general health policies.

Some answers to your questions ...

6. Is there a common "European" quality for all our medicines?

The quality of our medicines is harmonised throughout Europe by a book called the "European Pharmacopoeia".

It is used as a reference by all professionals involved in the manufacture and control of medicines on a daily basis. Since its creation in 1964, the European Pharmacopoeia has been contributing to making high-quality medicines accessible. In 2014, 37 European countries are participating in this work. The EDQM not only oversees the elaboration of the European Pharmacopoeia through an international convention but also implements a programme for the evaluation of the quality of raw materials for pharmaceutical use and programmes for market surveillance of medicines. The European Union refers to this work in its legislation, and the national health authorities ensure that the standards are applied.

7. What is Europe doing to fight against the growing problem[2] of counterfeiting (falsification) of medicines?

The first approach explored by Europe is to reinforce existing legislation.

The MEDICRIME Convention of the Council of Europe is the first available legal instrument that can be used to prosecute and punish those involved in the distribution and sales of counterfeit (falsified) medical products that endanger public health.

The EDQM is also involved in multisector training programmes for customs, police and health authorities to develop common, effective investigative procedures.

Other possible approaches have been explored by the European Union, such as the reinforcement of regulations to prevent counterfeit (falsified) medicines from being introduced into the legal supply chain, for example, by introducing security devices that enable individual boxes of medicines to be authenticated and identified[3].

All of these new measures will enable practices in all the member states to be harmonised. They provide a guarantee of the quality and integrity of medicines and consolidate the fight against the introduction of counterfeit (falsified) medicines into the medicines supply chain.

2 Source : WHO World Malaria Report 2011 &2 Gaurvika Nayyar, Joël Breman, Paul Newton, and James Herrington, "Poor-quality anti-malarial drugs in southeast Asia and sub-Saharan Africa". The Lancet Infectious Diseases. Vol. 12, No 6, pp. 488-496, June 2012
3 Source : Directive 2011/62/UE

Good habits that should be picked up

A FEW STATISTICS

- It is estimated that in the future **34%** of medicines in the world will **be produced in Asia**[4]
- About **10 000 medicines** currently marketed **in France**[5]
- It is estimated that **3 500 active substances** are used in medicines in France[5]
- **And 14 500 pharmaceutical products** are on the market in countries such as **France**[5].

4 Source : Study: Active Pharmaceutical Ingredient (API) Market Trends, Competitive Landscape and Global Forecasts (2011-2016), published by marketsandmarkets.com (www.marketsandmarkets.com)
5 Source : ANSM list (www.ansm.sante.fr)

You can:
Become involved in your health:

→ **Buy your medicines** only from legal points of sale that are authorised by the public health authorities and which therefore are suitably controlled (see page 13).

→ **Always be alert** when you take a medicine: check the packaging and the appearance and form of the medicine itself. Do not hesitate to contact your pharmacist or competent health professional if you have any doubts: certain counterfeit products have been quickly spotted by patients, which enabled the public health authorities to respond promptly.

→ **Be careful when you buy products on the Internet.** Even if more and more official pharmacies now sell products through the Internet, this is also the case for fraudulent companies hiding behind a facade of respectability and legality! Such companies may jeopardise your health. Do not hesitate to check suppliers on the Internet sites of the competent authorities (see page 13).

A FEW STATISTICS

- The use of **generic medicines** is growing. In 2012 the generics market corresponded to **23 % of the market for reimbursable medicines in France compared with over 60% in Germany, Poland and the United Kingdom**[6].
- **A file submitted for application for Marketing Authorisation** (MA) may consist of up to **100 000 pages**[7].
- and contain up to **15 gigabytes of data**[7] for an electronic application file for Marketing Authorisation (MA).

6 Source: ANSM report, Les médicaments génériques : des médicaments à part entière. December 2012

7 Source: Les cahiers de l'ordre national des pharmaciens (Study: La qualité de la chaîne du médicament à l'heure de la mondialisation, des rumeurs à l'information) - (www.ordre.pharmacien.fr/ Communications/ Rapports-Publications-ordinales/La-qualite-de-la-chaine-du-medicament)

ADDRESSES AND USEFUL LINKS

It should be pointed out that the sale of medicines is regulated and that only professionals are authorised to import medicines from countries outside the European Union.

THE NATIONAL COMPETENT AUTHORITIES AND THE ORGANISATIONS RESPONSIBLE FOR MEDICINES IN EUROPE ARE LISTED BELOW:

AUSTRIA

Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH (AGES): **www.ages.at**
Österreichische Apothekerkammer: **www.apotheker.or.at**

BELGIUM

Agence Fédérale des Médicaments et des Produits de Santé: **www.fagg-afmps.be**
Orde der Apothekers: **www.ordredespharmaciens.be**

BULGARIA

Bulgarian Drug Agency (BDA): **www.bda.bg**
Български фармацевтичен съюз **www.bd**

CROATIA

Agency for Medicinal Products and Medical Devices (ALMP): **www.almp.hr**
Hrvatska Ljekarnicka Komora: **www.hljk.hr**

CYPRUS

Ministry of Health: **www.moh.gov.cy**
Παγκύπριος Φαρμακευτικός Σύλλογος (ΠΦΣ): **www.cpa.org.cy**

CZECH REPUBLIC

Ministry of Health: **www.mzcr.cz**
State Institute for Drug Control: **www.sukl.cz**
Ceská lékárnická komora: **www.lekarnici.cz/**

DENMARK

Danish medicines Agency (DKMA): **www.dkma.dk**
Danish National Board of Health: **www.sst.dk**
Danmarks Apotekerforening: **www.apotekerforeningen.dk**

ESTONIA

National Medicines Agency: **www.ravimiamet.ee**
Eesti Apteekide Ühendus: **www.eestiapteek.ee**

FINLAND

Finnish medicines Agency: **www.fimea.fi**
Suomen Apteekkariliitto / Finlands Apotekareförbund: **www.apteekkariliitto.fi/**

FRANCE
Ministère des Affaires Sociales et de Santé: www.santé.gouv.fr
Agence nationale de sécurité du médicament et des produits de santé: www.ansm.sante.fr
Ordre National des Pharmaciens: www.ordre.pharmacien.fr/

GERMANY
Bundesinstitut fur Arzneimittel und Medizinprodukte (BfArM): www.bfarm.de
Paul-Ehrlich-Institute: www.pei.de

GREECE
National Organisation for Medicines (EOF): www.eof.gr

HUNGARY
National Institute of Pharmacy (OGYI): www.ogyi.hu
Magyar Gyógyszerész Kamara: www.mgyk.hu/

ICELAND
Icelandic medicines Agency (IMA): www.lyfjastofnun.is ou www.imca.is

IRELAND
Irish Medicines Board - Irish Medicines Board (IMB): www.imb.ie

ITALY
Istituto Superiore di Sanità (ISS): www.isst.it
Federazione Ordini Farmacisti Italiani (FOFI): www.fofi.it/

LATVIA
State Agency of Medicines (ZVA): www.zva.gov.lv

LITHUANIA
State Medicines Control Agency of Lithuania (VVKT): www.vvkt.lt

LUXEMBOURG
Luxembourg Ministry of Health: www.ms.public.lu
Syndicat des Pharmaciens Luxembourgeois a.s.b.l.: www.pharmacie.lu/

MALTA
Medicines Authority: www.gov.mt / www.medicinesauthority.gov.mt
Kamra ta`l-Ispizjara ta` Malta: spizjar@waldonet.net.mt

NETHERLANDS
Medicines Evaluation Board (MEB): www.cbg-meb.nl
Netherlands National Institute for Public Health and the Environment (RIVM): www.rivm.nl

NORWAY
Norwegian Medicines Agency: www.noma.no

POLAND
The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products: www.urpl.gov.pl
Naczelna Izba Aptekarska: www.nia.org.pl/

PORTUGAL
Autoridade Nacional do Medicamento e Produtos da Saúde (INFARMED): www.infarmed.pt
Ordem dos Farmacêuticos: www.ordemfarmaceuticos.pt/

ROMANIA
National Medicines Agency: www.anm.ro
Colegiului Farmacistilor din Romania: www.colegfarm.ro/

SERBIA
Medicines and Medical Devices Agency of Serbia (ALIMS): www.alims.gov.rs

SLOVAK REPUBLIC
State Institute for Drug Control: www.sukl.sk
Slovenská Lekárnická Komora: www.slek.sk/

SLOVENIA
Public Agency for Medicinal Products and Medical Devices (JAZMP): www.jazmp.si
Lekarniška Zbornica Slovenije: www.lzs.si

SPAIN
Spanish Agency for Medicines and Health Products : www.aemps.es
Consejo General de Colegios Oficiales de Farmaceuticos España: www.portalfarma.com/

SWEDEN
Medical Products Agency (MPA): www.mpa.se

SWITZERLAND
Swissmedic: www.swissmedic.ch

UNITED KINGDOM
Medicines and Healthcare Products Regulatory Agency: www.mhra.gov.uk
Royal Pharmaceutical Society of Great Britain: www.rpsgb.org.uk/

MEDICINES & HEALTH CARE

How does the Council of Europe work?

The programmes of activities of the European Directorate for the Quality of Medicines & HealthCare are implemented by various commissions, steering committees and groups of experts.

THE EUROPEAN PHARMACOPOEIA COMMISSION

The Commission was set up **in 1964** in accordance with the Convention on the Elaboration of a European Pharmacopoeia. In 2013, it has **37 states and the European Union** as members. They decide on the work programme and **define the quality requirements** for our medicines and their ingredients **by appointing national experts** who are qualified to contribute to the elaboration of these standards.

More than **2500 quality standards have already been adopted** and implemented. They are **revised regularly** to keep up with technical and scientific progress in the areas of manufacture and control. The European Pharmacopoeia, now in its **8th Edition**, is a reference work that is essential to public health. It is intended for professionals in the area of medicines who use it regularly.

STEERING COMMITTEE OF THE CERTIFICATION PROCEDURE

This procedure was set up within the EDQM in 1994. The aim of the procedure is **to assess whether the methods for manufacturing and testing raw materials** for pharmaceutical use comply with the requirements of the European Pharmacopoeia. At present, **850** substances for pharmaceutical use are covered in this way. Since the creation of the procedure, more than **3 500** certificates have been granted and **283** inspections of manufacturing sites have been carried out.

EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES (OMCLs)

The network was set up 1994, and now **67** laboratories from more than **30** European countries participate in its activities. The work is coordinated by the EDQM. The role of this network is **to ensure the consistent quality of medicines marketed** in the member states and to contribute to the mutual recognition of the results of quality control testing of medicines by these states. The OMCL network is also responsible for organising the **testing of blood products, vaccines** and European Union centrally authorised products.

These activities are not public and involve the national and European authorities. The OMCL network also **participates in investigations** into **counterfeit (falsified) medicines**. In 2012, **600** medicines were tested, 10 000 certificates were granted under the batch release procedure for biological products (such as vaccines) and **300** reports were established on counterfeit (falsified) or illegal products. These activities are financed jointly with the European Union.

PHARMACEUTICAL PRACTICES AND COUNTERFEITING

The European Committee on Pharmaceuticals and Pharmaceutical Care **supervises the programmes of activities** of its subordinate committees, which are responsible for a number of missions, namely: the classification of medicines as regards their supply, quality and safety standards for pharmaceutical practice and care and minimising public health risks posed by counterfeiting (falsification) of medical products and related crimes.

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The Council of Europe is the main organisation for the protection of human rights on the continent. 28 out of its 47 member states are also members of the European Union. All the member states of the Council of Europe have signed the European Convention on Human Rights, a treaty intended to protect human rights, democracy and the rule of law.

The Big Family - 03 88 41 33 33

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