EUROPEAN PARLIAMENT

DIRECTORATE-GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT A
ECONOMIC AND SCIENTIFIC POLICY

Economic and Monetary Affairs

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# Note on the Pharmaceutical Package for the EP Information offices (EPIOs)

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## Abstract

The Pharmaceutical Package in this document refers to the initiatives taken by the European Commission under the "Communication on the future of the single market in pharmaceuticals for human use", setting out the EC's vision for the sector. It comprises three pieces of legislation put forward to the European Parliament on different aspects of medicinal products. The proposals cover: information to patients on prescription medicines, pharmacovigilance, and patient safety and falsified medicines. These legislative proposals have a direct impact on public health, as well as connections with internal market and industrial policies. In the European Parliament the Committee on Environment, Public Health and Food Safety-ENVI is leading these reports. The committees on the Internal Market-IMCO and Industry, Research & Energy-ITRE are responsible for opinions. This note provides a general overview of the present situation on public health policy and pharmaceutical products in the EU, taking into account its degree of implementation and impact. The note presents the three proposals from a public health perspective with regards to their present state of advancement inside the legislative process. Finally it mentions the main stakeholders for these subjects. The note includes an annex with the key officials responsible for this policy area in the EU institutions.



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## DISCLAIMER

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# LIST OF ABBREVIATIONS

| | |
|---|---|
| **ATMP** | Advanced Therapy Medicinal Products |
| **ECDC** | European Centre for Disease Prevention and Control |
| **ECHI** | European Community Health Indicators |
| **EMEA** | European Medicines Agency |
| **ENCR** | European Network of Cancer Registries |
| **ESS** | European Statistical System |
| **EUACRD** | EU Advisory Committee on Rare Diseases |
| **EUROCHIP** | European Cancer Health Indicator Project |
| **EWRS** | Early Warning and Response System |
| **HIV/AIDS** | Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome |
| **IHR** | International Health Regulations |
| **OECD** | Organisation for Economic Cooperation and Development |
| **PRPG** | Public Health Preparedness and Response Planning Group |
| **SARS** | Severe Acute Respiratory Syndrome |
| **WHO** | World Health Organization |

# 1. HEALTH AND PHARMACEUTICALS IN THE EU

The primary responsibility for protection of health and in particular for organising healthcare systems remains at Member States level. However, the EU plays an important role in improving public health, preventing and managing diseases, mitigating sources of danger to human health and fostering cooperation between Member States on health issues. The EU has a comprehensive Health Policy with the Health Strategy "Together for Health", the Community Programme to support projects at EU level and in Member States, and a body of secondary legislation. The institutional set-up to support effective implementation includes the Directorate General for Health and Consumer Protection (DG SANCO) and specialised agencies.

In title XIV Public Health, Article 168, the Lisbon Treaty (ex Article 152 TEC) stipulates that: "a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities". This objective is to be achieved through Community support to Member States' activities and by fostering cooperation between Member States. The Council can adopt legislative measures setting quality standards for blood, organs and substances of human origin, measures in the veterinary and phytosanitary fields, and other incentives designed to protect and improve human health, except harmonisation of the national law.

Because of the multi-disciplinary and horizontal character of health, other Community policies can have protection of health as their objective (e.g. Environmental policy, Article 174(1)), and measures pertinent to public health can be adopted under other provisions of the Treaty (e.g. free movement of persons, internal market, culture, etc.).

Historically, EU Health policy focused on health and safety issues with the objective of ensuring the high quality of medicinal products, ensuring the safety of blood, tissues and organs for transplantation, and protecting EU citizens from the threat of communicable diseases including epidemics and pandemics. While these remain valid objectives, new challenges including the ageing EU population, novel health threats, and scientific and technological developments in the health sectors require that the objectives of current EU Health Policy be much broader and more holistic.

Current Health Policy is based on the principle that the good health of the EU population is a precondition for meeting the basic EU objectives of prosperity, solidarity and safety. All citizens should have access to universal, quality health care, including preventive healthcare, and healthcare should be patient-centred and based on scientific evidence. To ensure social cohesion, inequalities in health both between and within Member States should be reduced. Because of the multidisciplinary character of health issues, EU Health Policy has to be well coordinated with other policies, and new partners such as the private sector and civic society must be involved.

The three strategic objectives of EU Health Policy are:

- Fostering good health – to prevent diseases and promote healthy lifestyles by addressing the issue of nutrition, physical activity, alcohol, tobacco and drug consumption, environmental risks and injuries. With the ageing population the specific health needs of older people will require more attention;

- Protecting citizens from health threats – to improve surveillance and preparedness for epidemics and bioterrorism and build capacity to respond to new health challenges such as the climate change;

- Supporting dynamic health systems – to help healthcare systems in Member States to respond to the challenges of ageing populations, rising citizens' expectations and the mobility of patients and health professionals.

The general framework for the EU health policy is based on the Health Strategy "Together for Health" adopted in 2007, setting a policy framework for Community actions in the field of health. The 2nd Community Programme, 2008-2013, serves to support the implementation of the strategy.

The 1st Community Programme in the field of Public Health 2003-2008, with a budget of EUR 312 million, supported more than 300 projects.

The European Centre for Disease Prevention and Control (ECDC) was established to coordinate activities in surveillance, early warning and response related to communicable diseases.

With the aim of fostering good health the EU has specific actions at two different groups of topics: healthy lifestyles, with subjects such as Tobacco, Nutrition and physical activity, Alcohol and Drugs; and Non-communicable diseases, with subjects such as Cancer and Rare diseases. Actions oriented at protecting citizens from health threats include Health security, Communicable diseases, Anti-microbial resistance and HIV/AIDS. The EU provides support for dynamic health systems and particularly in the domain of Blood, Tissue, Cell and Organ Donation and Transplantation.

A comprehensive system for authorisation, classification and labelling of medicinal products is in place to ensure both safety and efficacy of products and devices and allows free movement of these products in the internal market (Directive 2001/83/EC and Regulation (EC) 726/2004). Specific legislation was adopted on advance therapy (Regulation (EC) 1394/2007), paediatric medicinal products (Regulation (EC) 1901/2006) and orphan drugs (Regulation (EC) 141/2000). The directive on clinical trials (2001/20/EC) specifies the requirements for investigations in humans for the purpose of authorisation procedure for new drugs. The European Medicines Agency (EMEA) was established to provide scientific input in the area of evaluation of the quality, safety and efficacy of medicinal products.

A body of EC legislation was adopted to specify the essential requirements medical devices have to fulfil in order to be placed on the market, and the procedure for assessment of conformity with these requirements, as well as conditions for clinical investigation and for the packaging and labelling of medical products. The legislation includes Directive 90/385/EEC on Active Implantable Devices, Directive 93/42/EEC on Medical Devices, Directive 98/79/EEC on In Vitro Diagnostic Medical Devices, and Directive 2007/47/EC amending Directives 90/385/EEC and 98/79/EEC.

# The role of the European Parliament

Parliament has consistently promoted the establishment of a coherent public health policy and a policy on pharmaceuticals that would take into account both the public health interest and the industrial aspects. It has also actively sought to strengthen and promote health policy through numerous opinions, questions to the Commission and own-initiative reports on issues including:

- EU Health Strategy;
- Environmental health;
- Health information and statistics;
- Health and safety at work;
- Health determinants and promotion of healthy life styles including tobacco control, alcohol, nutrition and physical activity; injuries and road safety;
- Illicit drugs;
- Cancer, rare diseases, cardiovascular disease, rheumatic diseases and other non-communicable diseases;
- Communicable diseases and preparedness for pandemic influenza;
- HIV/AIDS;
- Physical factors including electromagnetic fields;
- E-health and telemedicine;
- Cross-border healthcare;
- Patient safety and protection against healthcare associated infection;
- Safety and quality of blood, tissues and organs;
- Availability of organs for transplantation and ethical issues related to human egg cells;
- International cooperation in health and integration of health in EU development aid;
- Medicinal products;
- Medical devices.
- Alternative therapies

# Policy topics of relevance to pharmaceuticals

## Antimicrobial Resistance

Antimicrobial agents are natural or synthetic substances that kill or inhibit the growth of micro-organisms, including pathogenic bacteria, viruses, fungi and parasites. Antimicrobial agents have been used for decades to treat and prevent infectious diseases and infections. Common treatment procedures such as surgery, transplants or chemotherapy cannot be performed without potent antibiotics.

The use (and often misuse, such as unnecessary prescriptions) of microbial agents is linked to an increasing prevalence of micro-organisms that have acquired resistance to one or more antimicrobial agents. Antimicrobial resistance poses a threat to public health, may prolong the suffering of patients, increases healthcare costs and has subsequent economic implications for society.

Based on surveillance data, the situation in Europe shows a general increasing trend in resistance to antibiotics used in outpatient and ambulatory care. There is a significant geographical difference, with low resistance in northern countries and high resistance in southern countries. This correlates with the pattern of antibiotics use, whereby southern countries use higher volumes of broad-spectrum antibiotics with consumption being some three times higher than in northern countries.

Antimicrobial resistance has been monitored at European level since 1999, when the European Antimicrobial Resistance Surveillance System was established following the adoption of the Decision on epidemiological surveillance[1] (see also chapter 6.1). In 2001, the Commission adopted a Strategy against antimicrobial resistance[2]. Several projects on this topic have been funded by the Community programmes.

The fight against antimicrobial resistance is part of the "protection against health threat" objective of the Health Strategy "Together for Health"[3].

Current policy objectives are to prevent the spread of resistant strains and to ensure that antibiotics are only used when they are needed for effective treatment. The policy has four pillars, identified below.

- Surveillance - monitoring the evolution of antimicrobial resistance and the effects of interventions through the establishment and strengthening of accurate surveillance systems for antimicrobial resistance in the human and the veterinary sector, and for the consumption of antimicrobial agents.
- Prevention – control of communicable diseases and infections to reduce the need for the use of antimicrobial agents. This includes prudent use of antimicrobial agents, entailing the need for improved product information for authorised antibacterial medicinal and veterinary products, and the promotion of education for health professionals and the general public.
- Research and product development – improving the understanding of the molecular mechanisms behind antimicrobial resistance, and support for the development of new classes of antimicrobial agents and alternative treatments, including vaccines and strategies to reduce the spread of infections. The development of rapid diagnostics and susceptibility tests that would facilitate prudent use of antibiotics.
- International cooperation – consultation and co-operation at EU and Member States level with relevant international organisations and non-EU countries to ensure effective strategies to tackle antimicrobial resistance. This includes the fight against counterfeit medicine as it contributes to the spread of antimicrobial resistance.

Following the publication of the Community strategy on antimicrobial resistance the Council adopted the Recommendation on the prudent use of antimicrobial agents (see below).

In 2008, the Council adopted the Council Conclusions on Antimicrobial Resistance in which it concluded that antimicrobial resistance was still growing in Europe and represents a global health problem. The Conclusions reiterated the main elements of the policy laid down in the Health Strategy and the Council Recommendation on the prudent use of antimicrobial agents. It stressed the importance of further improving surveillance and coordination between health care, veterinary and agriculture sectors. The Conclusions call for better control of multi-drug resistant tuberculosis.

[1] Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community
[2] Communication from the Commission on a Community Strategy against antimicrobial resistance (COM(2001)333 final)
[3] White paper - Together for Health: A Strategic Approach for the EU 2008-2013 (COM(2007)630 final)

Since its establishment, the European Centre for Disease Prevention and Control (ECDC) has run a programme on antimicrobial resistance. The Centre coordinates relevant surveillance networks, collects, analyses and disseminates epidemiological data on antimicrobial resistance, provides guidance on prevention and control of multi-drug-resistant bacteria, and organises courses and awareness-raising campaigns.

The 2nd Public Health Programme[1] continues to support projects in line with the Community antimicrobial resistance policy. For example, in 2009 projects focusing on the development of protocols and monitoring of the rational use of antibiotics are eligible for funding.

Council Recommendation on the prudent use of antimicrobial agents in human medicine (2002/77/EC) recommended that Member States establish or strengthen surveillance systems on antimicrobial resistance and the use of antimicrobial agents, in order to gather reliable data on the spread of resistance and on the prescription and use of antimicrobial agents.

It further recommended that Member States implement measures to support the prudent use of antimicrobial agents and contribute to limiting the spread of communicable diseases, in particular by:

- restricting systemic antibacterial agents to prescription-only use;
- setting guidelines for the use of other antimicrobial agents;
- developing principles and guidelines on good practice for the management of communicable diseases, to maintain the effectiveness of antimicrobial agents. These include assessing clinical and microbiological criteria for diagnosis of infections and optimising choice of drug, dosage and duration of the treatment;
- establishing and implementing control systems on the marketing of antimicrobial agents to ensure compliance with principles and guidelines on the prudent use of antimicrobial agents;
- implementing hygiene and infection control standards in institutions (hospitals, child care facilities, nursing homes etc.); and
- encouraging national immunisation programmes to progressively eliminate vaccine preventable diseases;

The recommendation also encouraged awareness raising measures, in particular the education and training of health professionals on the problem of antimicrobial resistance and informing the general public of the importance of prudent use of antimicrobial agents. The latter is to be achieved by:

- encouraging realistic public expectations for prescription of antimicrobial agents;
- launching information initiatives involving the patients on the importance of interventions to reduce the unnecessary use of antimicrobial agents; and
- highlighting the value of basic hygiene and of vaccination.

The Council further recommended that the Commission and Member States cooperate in a number of key areas. These include the development of indicators and guidelines on good practice for the prudent use of antimicrobial agents and the further development of European surveillance and exchange of information. An additional area for cooperation is research, in particular research initiatives focusing on the mechanism of antimicrobial resistance, intervention strategies in hospitals and communities, diagnostic tools and tests, modalities of prevention and treatment of infections, alternatives to antimicrobial agents and new surveillance methods.

[1] Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13)

A final area for cooperation is the evaluation and, if necessary, update of the product information (SPC) for antibacterial medicinal products particularly related to indications, dosage and prevalence of resistance.

Seven years after the adoption of the Council Recommendation, not all elements are implemented properly by all Member States. While Member States maintain responsibility for the implementation of the Recommendation, the Commission could facilitate implementation by providing standards and good practice guidelines for some elements where compliance with the recommendation is weak, e.g. inter-sectoral coordination, prescribing practices, infection control, and the accreditation of health establishments.

## Healthcare Associated Infections

There is growing awareness and concern about the preventable harm to patients that is caused by healthcare itself, for example by errors in diagnosis, failure to act on test results, prescribing or administering the wrong medicine or the failure of medical equipment. Infections in hospitals are a particular problem that receives considerable media and political attention.

It is estimated that in EU Member States between 8-12% of patients admitted to hospitals suffer from adverse events. National studies show alarming rates of adverse events, for example in the UK in 1999 there were 400 deaths or serious injuries related to medical devices and 10,000 serious adverse reactions to medicinal products, while in 2005 9.3% of Spanish hospital patients suffered from adverse events, almost half of which were preventable. More than 4 million patients suffer from healthcare-associated infections in the EU every year. These infections are often difficult to treat due to antimicrobial resistance of the micro-organisms causing these infections.

Some aspects of patients' safety have been addressed at EU level in past. The safety of medicinal products including pharmacovigilance is covered by legislation on pharmaceuticals. In addition, there is legislation to ensure safety of blood, human tissue and cells and organs for transplantation. Several projects focusing on patients' safety have been funded by the Community programmes.

The Health Strategy "Together for Health"[1] identified patients' safety as one of the priorities for Community action. The Working Group on Patient Safety of the High Level Group on Health Services and Medical Care brings together the Commission and representatives of Member States to discuss policy in this area. The Commission published its Communication on Patient Safety[2] outlining the future Community action.

Concerning healthcare-associated infections, the European Centre for Disease Prevention and Control (ECDC) operates a surveillance and early warning network and assists Member States in responding to this problem.

Several projects in Member States are supported by Community funding, including the Improving Patients Safety in Europe project aimed at improving capacity for the surveillance and control of healthcare-associated infections and the European Network for Patient Safety which facilitates cooperation between all stakeholders involved in patient safety.

[1] White paper - Together for Health: A Strategic Approach for the EU 2008-2013 (COM(2007)630 final)
[2] Communication from the Commission to the European Parliament and the Council on patient safety, including the prevention and control of healthcare-associated infections (COM(2008)836 final)

Council Recommendation of 9 June 2009 on patients' safety, including the prevention and control of healthcare associated infections recommends that Member States:

- support the establishment and development of national policies and programmes;
- involve patient organisations in policy development and disseminate information to patients on risks and measures to reduce these risks;
- strengthen reporting and learning systems;
- promote the education and training of the healthcare workforce on patient safety;
- adequately classify and measure patient safety in cooperation with the Commission;
- share knowledge, experience and best practices;
- establish national strategies for healthcare-associated infections in order to:
  - implement prevention and control measures;
  - enhance prevention and control at the level of individual healthcare establishments;
  - strengthen surveillance at national and regional level and at the level of healthcare establishments;
  - improve education and training at Member State level and at the level of healthcare establishments;
  - improve information given to patients;
  - support research; and
- establish an inter-sectoral mechanism for the implementation of national strategies and for information exchange and coordination with the Commission, the ECDC and other Member States.

In its legislative resolution[1] the European parliament proposed several modifications to the aforementioned Commission proposal for Council recommendation on Patients' Safety. These proposals identify missing elements and potential for improvement, including that:

- the national patients safety policies should take into account specific needs of older people who are more susceptible to diseases;
- Member states should consider targets for placing specialised staff in hospital to attain the recommended ratio of one infection control nurse per 250 beds;
- Member States should set a target to reduce adverse events by 20% by 2015;
- health authorities should share information on malpractice and negligence by healthcare staff;
- Member States should provide adequate education and training for the use of medical devices aimed at prevention of health risks;
- Member States should provide effective risk assessment mechanisms to identify additional conditions of patients that require additional precaution; and
- Member States should protect healthcare staff through vaccination, routine screening, post-exposure prophylaxis, etc.

## Medicinal products

The placing on the market of medicinal products as well as their classification and labelling were regulated in the EU from 1965 onwards. The essential aim of regulating medicinal products was to safeguard public health. At the same time, great disparities between Member States' legislation dealing with these products hindered their trade in the internal market. The regulation of medicinal products was scattered over separate directives, each dealing with specific medicinal products, such as radiopharmaceuticals or homeopathic medicinal products, or with other aspects such as labelling requirements.

[1] European Parliament legislative resolution of 23 April 2009 on the proposal for a Council recommendation on patient safety, including the prevention and control of healthcare associated infections

An increasing number of EU citizens have been demanding information on medicinal products, independently from healthcare professionals. This is in a context where 5% of hospital admissions are due to an adverse drug reaction (ADR), which is also the fifth most common cause of hospital death. These ADR are sometimes only detected after a medicine has been authorised on the market. Pharmacovigilance rules are therefore necessary for the protection of public health in order to prevent, detect and assess adverse effects of medicinal products. At the same time, there is an alarming increase in the EU of medicinal products which are falsified in relation to their identity, history or source and may contain sub-standard or falsified ingredients, or no ingredients or ingredients in the wrong dosage, including active ingredients. Falsified products pose a major threat to both patients and industry, and there are strong concerns in the public and amongst policy makers about the steady increase of these products detected in the EU in recent years.

The emergence of new techniques has also created challenges for the regulation of medicinal products. Advanced therapy medicinal products are a relatively new kind of medical products or pharmaceuticals based on novel treatments including gene therapy, cell therapy or tissue engineering. They have great potential for developing new treatments for a variety of diseases, such as cancer or Alzheimer. An absence of initiative to regulate these products at EU level led again to a scattered approach and great differences in regulation from one Member State to another.

In 2004, the European Medicines Agency (EMEA) was established[1], and given responsibility for the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. The EMEA is an EU body coordinating the scientific resources of the Member States and is responsible for providing the scientific research enabling the evaluation of the quality, safety and efficacy of medicinal products. It provides scientific input to the application of EU legislation in this field and to the subsequent centralised authorisation procedure.

In 2001, directive 2001/83/EC was adopted, establishing a Community code relating to medicinal products for human use and regulating placing on the market, classification and labelling of all medicinal products in the EU. This directive codified and amended the existing patchwork of Directives, dated from between 1960 and 1995 into one comprehensive piece of legislation. The code was amended a number of times in the following years to take new developments into account.

The EU Health Strategy “Together for Health” does not explicitly address any health-related aspects of medicinal products in the EU. Nevertheless, the Strategy touches upon issues which indirectly affect pharmaceuticals policy in the EU. For instance, the Strategy notes that patients are becoming more involved in decision-making related to their health.

Building on this and in response to the concerns identified above, in December 2008 the Commission adopted the Pharmaceutical Package, including a Communication and three legislative proposals. The Communication is entitled “Safe, Innovative and Accessible Medicines: a renewed vision for the pharmaceutical sector”[2], and states that patients have a right to more quality information on available medicines, the grounds on which they have been authorised and how they are monitored.

[1]The EMEA replaced the former European Agency for the Evaluation of Medicinal Products.
[2]COM(2008)666

Together with this Communication, the Commission proposed three new legislative packages in the area of medicinal products. The first legislative proposal includes a Directive[1] and a Regulation[2], both aimed at creating access for citizens to reliable information on medicinal products. The second proposal includes a Directive[3] and a Regulation[4] and tackles the issue of pharmacovigilance, the mechanism for monitoring the safety of medicinal products by allowing for the suspension or withdrawal of an authorisation. The third proposal includes a Directive[5] that addresses the threats posed by fake medicines. These legislative proposals have been submitted to the European Parliament and the Council. Within the European Parliament, rapporteurs were assigned to the various dossiers, but time constraints prevented further progress being made.

In 2005, the European Commission proposed a Regulation on Advanced Therapy Medicinal Products (ATMP). This Regulation amended the 2001 code relating to medicinal products and the mandate of the EMEA in order to adapt the existing legal framework to these new developments in the area of medicinal products. The proposal was part of the 2005 Community Work Programme and aimed to bridge the legal gap in the EU's legal framework dealing with medicinal products. The objective of the Commission was to guarantee, on the one hand, a high level of health protection for European patients, and on the other hand, to harmonise market access and free movement of these products in the EU.

Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use (as amended by Directive 2004/27/EC) requires Member States to adopt implementation measures transposing each requirement of the Directive. The code contains nearly all aspects relating to medicinal products as well as some specific requirements for certain types of medicinal products.

- The Directive aims at improving the free movement of medicinal products in the EU market, by avoiding duplication of the evaluation tests for authorisation in each Member State, while at the same time guaranteeing public health protection within the EU. For that purpose, it refers to the principle of mutual recognition of products placed on the market in the EU, i.e. in the case where one Member State has authorised a product following the evaluation standards and test methods of the Directive, that product should then also be allowed access to the markets of the other Member States, respecting certain minimal procedural rules.
- In order to achieve a general level of protection and harmonised authorisation procedures, the Annexes to the directive set out the analytical, pharmacotoxicological and clinical standards and protocols to be followed in the testing of medicinal products.
- For manufacturing or import of these medicinal products, a separate authorisation procedure was established, including detailed rules for the manufacturing process.

[1] Proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use COM/2008/0663 final

[2]Proposal for a Regulation of the European Parliament and of the Council amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency COM/2008/0662 final

[3] roposal for a Directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use COM/2008/0665 final

[4] Proposal for a Regulation of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency COM/2008/0664 final

[5]Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source COM/2008/0668 final

- The Directive also specifies the packaging and labelling requirements for medicinal products placed on the market in the EU. The packaging requirements consist, among others, of the obligation to include a summary of the product characteristics on the package. The labelling requirements include, for instance, the name of the manufacturer and the person holding the authorisation to place the product on the EU market as well as the expiry date.
- The Directive classifies medicinal products and determines which products should be subject to medical prescriptions in the Member States.
- Rules on publicity and advertising of medicinal products are set, both for the general public and for persons qualified to prescribe or supply these products, in order to avoid misleading advertising.
- The Directive requires that Member States make certain information accessible to the public. This information includes, for instance, the assessment report, the reasons for not disclosing some documents on grounds of confidentiality, and the product characteristics.
- The Code includes specific requirements for herbal medicinal products, homeopathic medicinal products and radiotherapeutic medicinal products. For instance, a simplified procedure is established for traditional herbal medicinal products.

- It is important to note that the Directive does not regulate issues such as pricing of the medicinal products or the organisation of the social security schemes of the Member States.

Some medicinal products, however, were made subject to a Community-level authorisation procedure. This procedure is set out in Regulation (EC) 726/2004 of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. Other products are subject to the authorisation procedure of Directive 2001/83.

The Community-level authorisation procedure applies to specific medicinal products mentioned in Annex I to the Regulation, such as some biotechnologically developed products (i.e. by means of recombinant DNA technology) or medicinal products containing a new active substance not previously authorised on the EU market designed to treat cancer, diabetes, acquired immune deficiency syndrome, neurodegenerative disorder, auto-immune diseases and viral diseases. The procedure also applies to orphan medicinal products.

The Regulation deals with similar aspects of the marketing of these medicinal products on the EU market, such as authorisation to be placed on the market, classification, packaging and labelling.

Secondly, the Regulation established the EMEA, which replaced the previous agency dealing with evaluation and authorisation of these specific medicinal products.

The Clinical Trials Directive 2001/20/EC regulates investigations in humans to carry out research on, or corroborate results of, medicinal products under investigation. The clinical trials used within the authorisation procedure mentioned above must comply with the requirements of this Directive.

Regulation (EC) No 1394/2007 of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 establish specific rules for novel medicinal products based on gene therapy, cell therapy and tissue engineering. These novel medicinal products have, for example, been developed for the treatment of certain types of cancer, to prevent amputations or as skin substitutes.

The Regulation was proposed to create a harmonised regulatory framework for these products, of which some were regulated as medicinal products in the EU while others were not. The divergent national approaches to authorisation, evaluation, classification and labelling were considered an obstacle to the free circulation of these products within the EU and hindered patients´ access to these products. In addition, the legislation was developed to remedy a lack of legal certainty that existed on this issue due to the absence of a comprehensive explicit piece of legislation dealing with these products.

The Regulation is a *lex specialis*, containing a number of specific provisions for advanced therapy medicinal products. While the provisions of Directive 2001/83/EC and Regulation 2004/726 remain applicable, the specific provisions of the Advanced Therapy Medicinal Products Regulation apply add a number of additional guarantees or specifically tailored provisions dealing with these products.

It is important to note that the Regulation does not interfere with Member States' policies and legislation relating to the use of specific types of human cells, such as embryonic stem cells or animal cells.

A number of legal instruments adopted in the area of medicinal products deal with specific issues, such as products for children and orphan medicinal products or clinical tests.

Regulation (EC) No 1901/2006 of 12 December 2006 on products for paediatric use established specific guarantees for medicinal products for children. This Regulation does not amend the existing authorisation procedure, but introduces additional requirements for medicinal products for children.

Regulation (EC) 141/2000 on orphan medicinal products aims at giving incentives for research, development and marketing of orphan medicinal products. These orphan medicinal products are intended to treat very serious conditions that are rare in the EU. As these products were not sufficiently developed under normal market conditions, the Regulation was adopted to create additional incentives for their development.

As indicated in the section above, a Pharmaceutical Package has been proposed by the Commission to address access to information on medicinal products, pharmacovigilance and counterfeit medicinal products.

The first legislative proposal consists of a Proposal for a directive amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC, and a Proposal for a Regulation amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Regulation (EC) No 726/2004.

The proposed legislation harmonises the information that marketing authorisation holders are allowed to disseminate, as well as the quality standards for such information, with the aim of ensuring that the information is of high quality and non-promotional.

It also determines the authorised channels for disseminating information, in order to exclude unsolicited means of dissemination, and requires Member States to establish monitoring systems to ensure compliance and enforce these provisions. The Member States are left to determine the most appropriate monitoring mechanisms, with a general rule that monitoring should take place after the dissemination of information (with certain exceptions).

Finally, the legislation establishes rules for the dissemination of information through websites to take account of the cross-frontier nature of information provided over the Internet and to facilitate cooperation between Member States and avoid duplication of monitoring.

The second legislative proposal of the package consists of a Proposal for a Directive amending, as regards pharmacovigilance, Directive 2001/83/EC and a Proposal for a Regulation amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004.

There are six key elements to this legislative proposal:

- It aims at clarifying and codifying the tasks and responsibilities of involved parties in the legislation. A new scientific committee, the Pharmacovigilance Risk Assessment Advisory Committee, responsible for pharmacovigilance, is created within the EMEA.
- Transparency and communication will be improved through the strengthening of the Eudravigilance database, which should become the single point for the receipt of pharmacovigilance information for medicinal products authorised in the Community. Communication on major new or changing safety issues will be coordinated either through the legislation or through the EMEA. A European medicines safety web-portal will be set up by the EMEA.
- It simplifies the existing pharmacovigilance obligations of the marketing authorisation holders by creating a "Pharmacovigilance system master file", which requires only key elements of the pharmacovigilance system in the marketing authorisation application.
- It requires a risk management system for each medicinal product to be newly authorised in the Community (or for existing products on the basis of safety concerns), which should be proportionate to the identified risks, potential risks, and the need for additional information on the medicinal product.
- It simplifies adverse reaction reporting rules by providing that all adverse reaction data are reported by marketing authorisation holders and Member States directly to the Eudravigilance database. It ensures that companies report medication errors that result in an adverse reaction to the relevant competent authorities and makes clear the legal basis for patients to report suspected adverse drug reactions.
- It guarantees regulatory follow-up of assessments of periodic safety update reports, to ensure a clear link between pharmacovigilance evaluations and the review and updating of marketing authorisations in the Community.

The Proposal for a Directive amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source addresses the risk of falsified medicinal products entering the legal supply chain.

The proposal would serve to amend Directive 2001/83/EC as follows:

- To include obligations for players other than wholesale distributors who act in the distribution chain (for example, by auctioning products).
- To provide the Commission with a legal basis to render obligatory specific safety-features on the packaging of prescription medicines and to prohibit, in principle, the manipulation of safety-features on packaging by actors working “in-between” the manufacturer and the user.
- To set up obligatory audits of wholesale distributors and strengthen the requirements for imports of active pharmaceutical ingredients from third-countries in cases where it cannot be established that the regulatory framework in the respective third country ensures a sufficient level of protection of human health regarding the quality of products exported to the EU. To strengthen the rules for inspections and increase transparency around these inspections.

The existing legal framework provides a comprehensive framework for all aspects relating to medicinal products in the EU. In addition, specific pieces of legislation regulate precise areas of the EU medicinal products policy.

It will be important to follow up on emerging technologies developing medicinal products in the EU in order to adapt the legal framework as was done for advanced therapy medicinal products.

Given the importance of alternative therapies such as homeopathy and acupuncture in some Member States, it may be relevant for the EU framework on medicinal products to be extended to include products associated with these therapies. The use of such alternative therapies across the EU is heterogeneous, with some Member States imposing bans, whilst other Member States provide reimbursement for treatment under their health systems.

In addition, the more limited markets for products associated with these techniques make industry less inclined to invest in research and development, despite promising results from some treatments. There may be a role for the EU bodies to promote research in cases where evidence has been found of successful treatments with alternative therapies in order to fully explore possibilities.

# 2. CHALLENGES AND DESIRABLE SCENARIOS

## Integration of Health and Pharmaceuticals Policies

The theme of "Health in All Policies" under Article 152 of the Treaty, the EU is obliged to ensure that all Community actions and activities contribute towards a high level of health protection.[1] Key issues include:

- Ensuring that other sectors understand how health impacts upon their sector and developing good relations to ensure cooperation
- Facilitating partnerships with academia, industry, NGOs and the media
- Implementing the "Health in All Policies" approach in external policies, such as development, international relations and trade.[2]

In view of the experiences of the past, the policy guidelines set by the treaties and specific pieces of legislation and with a critical attitude towards the present situation, the European Commission and the European Parliament should ask themselves:

- What mechanisms have been established to ensure the horizontal integration of health into all policies?
- In what ways have Health Impact Assessments been integrated into other policies?
- Are health indicators used as a factor in the assessment of official development assistance?
- To what extent the industrial policies concerning medicinal products are well aligned with the public health priorities?
- Is the EU creating an environment that allows alternative therapies to develop?

## Anti-Microbial Resistance

Although the rise of antibiotics in the first part of the 20th Century was a major breakthrough in disease treatment, in recent years resistance to pharmaceuticals, both antibiotics and other anti-microbial has increased. Specific issues include:

- Anti-microbial resistant infections in hospitals.
- A lack on incentives for pharmaceutical companies to develop new antibiotics.
- Irrational drug use, which promotes the rise of anti-microbial resistance.
- Coordinating surveillance of antimicrobial resistance across Member States.

Current initiatives include the Hospitals in Europe Link for Infection Control through Surveillance (HELICS)[3] and the European Antimicrobial Resistance Surveillance System (EARSS)[4]

In view of the experiences of the past, the policy guidelines set by the treaties and specific pieces of legislation and with a critical attitude towards the present situation, the European Commission and the European Parliament should ask themselves:

- What is the EU doing to support current surveillance initiatives and is this sufficient and appropriate?
- What is the EU doing to create incentives for the development of new antibiotics?

[1] http://ec.europa.eu/health/ph_overview/other_policies/health_other_policies_en.htm
[2] EU Health Strategy White Paper
[3] http://ec.europa.eu/health/ph_threats/com/networks/network_helic.
[4] http://ec.europa.eu/health/ph_threats/com/networks/network_earss...

- What could the EU do to eliminate antibiotics from the food chain, with the aim or suppressing one of the main environmental pressures leading to the appearance of anti-microbial resistances?
- What is being done to facilitate implementation of the Council Recommendation on the prudent use of anti-microbial agents?

Possible policy and legislative measures:

- Assistance to Member States in creating sufficient guidelines on rational use of pharmaceuticals; strengthening the role of the EMEA
- Funding for research into new antibiotics.
- Further banning of antibiotics in animal breeding, and in any step of the production, conservation or storage of food products.

## Healthcare Associated Infections

Patient safety is concerned with protecting patients from unnecessary harm or potential harm associated with healthcare.[1] In 2005, a working group was set up under the High Level Group on Health Services and Medical Care through which the European Commission aims to facilitate and support its Member States in their work and activities. Its members also include the World Health Organization (primarily through the World Alliance on Patient Safety), the Council of Europe, the OECD and European associations of patients, doctors, nurses, pharmacists, dentists and hospitals.

The European Commission and the European Parliament should ask themselves:
- How can the needs of older people who are more susceptible to disease be taken into account under national patients safety policies?

Possible policy and legislative measures:
- Funding research into healthcare related harm and infections acquired in hospital.
- Harmonising quality of care standards across Member States.
- Systems for information sharing on malpractice and negligence by healthcare staff.

## Medicinal Products

The EU is committed to providing a high level of protection, competitiveness and innovation in the field of public health. This includes guaranteeing access to affordable medicines, ensuring that medicines are safe and effective, and improving the quality and dissemination of information on pharmaceuticals. It also aims to improve cooperation between the pharmaceutical industry, healthcare stakeholders and EU countries.[2] The EC is very active in addressing many of these issues. However, some challenges remain. Specifically:

- Medicines associated with alternative therapies are as yet not included in the legislative framework.
- Ensuring the competitiveness of the European pharmaceutical sector, which is part of the aim of the Pharmaceutical Forum.
- Access, availability and affordability of pharmaceuticals differs across member states[3].

1 http://ec.europa.eu/health-eu/care_for_me/patient_safety/index_en.htm
[2] http://ec.europa.eu/health-eu/care_for_me/medicines_and_treatment/index_en.htm
[3] Lalis, G. Does fostering pharmaceutical innovation and competiveness benefit the European patient?. Eurohealth 14 (4) 3-6.

In view of the experiences of the past, the policy guidelines set by the treaties and specific pieces of legislation and with a critical attitude towards the present situation, the European Commission and the European Parliament should ask themselves:

- Is the EU considering extending the legislation on medicinal products to include medicines associated with alternative therapies?
- What kinds of mechanisms could the EU introduce to promote funding for independent research into new medicinal products that is motivated by protecting human health rather than by profit?

Possible policy and legislative measures:

- Review regulatory policies for children's medicines.[1]
- Continue to support the work of the Pharmaceutical Forum.
- Review regulations on marketing costs and create incentives for reducing R&D costs and to promote the use of generics[2].
- Support programmes to increase the level of information available to the citizen on the prudent use of medicines, with the aim of promoting responsible behaviour and empowering the individual in partnership with health practitioners.
- Encourage the recovery of traditional healing practices, particularly those concerning medicinal herbs and homemade remedies.

[1] http://ec.europa.eu/enterprise/pharmaceuticals/paediatrics/medchild_en.htm
[2] ibid

# 3. IMPLEMENTATION REVIEW

## The Health Programme

**Legal Act:** Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008)

The Commission carried out an interim evaluation of the Community Health Programme 2003-2008, involving the evaluation of the programme by an independent consultant. In its report to the European Parliament and the Council[1], the Commission made a number of conclusions regarding the Programme.

Regarding the value of the programme, stakeholders considered the results of projects relevant for them and for EU citizens. Special benefits mentioned in interviews were network creation, exchange of knowledge and good practices, Europe-wide cooperation and capacity building. All project participants and stakeholders supported European intervention in public health. The EU action was found to interlink national policies and actions thus helping to coordinate and support national measures.

In terms of the grant procedures, surveys found that the selection process was considered transparent and objective, and that only projects relevant to the objectives of the Programme were funded. However, project leaders found the project administration complex and bureaucratic and the application procedure long and burdensome. Project, monitoring was considered adequate.

At the same time, there was mixed feeling about coordination with other Community programmes. The best interaction was perceived by project leaders in the area of bioterrorism, health systems and pharmaceuticals.

Regarding the future of projects, less than half of project leaders thought that their project would be sustainable when the Community funding stops. They suggested that sustainability could be achieved through the use of project outputs, dissemination, continued collaboration and networking, and additional funding.

As such, the overall assessment of the programme was positive. Specific recommendations from improvement included that priorities should be developed through a needs-driven process, since current priorities may not reflect the actual needs of stakeholders and EU citizens. In addition, innovative proposals should be encouraged and results better disseminated, since the projects are known to the “inner circle” of stakeholders but not those all who could benefit are informed and involved. Regarding procedural aspects, the application procedure should be simplified and the number of proposals for evaluation should be limited by indirect, closed or informal competition.

[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Interim evaluation of the implementation of the Public Health Programme (2003-2008) (COM(2008)484 final)

The independent consultant who evaluated the Programme also proposed to redefine priorities, to monitor project activities against the objectives of the programme and not only against those of the project, and to disseminate the results through tailored messages to public health community.

## Antimicrobial Resistance

**Legal Act:**
Council Recommendation on the prudent use of antimicrobial agents in human medicine (2002/77/EC)

The Commission evaluated the implementation of the Council Recommendation in its report to the Council and Parliament[1]. The report focused on the prudent use of antimicrobial agents in human medicine (the aspects related to veterinary medicine were not addressed in the report).

The report concluded that most Member States had in place a national system for surveillance of antimicrobial agents' use and antibiotics consumption. Surveillance of resistance was less developed partly because of privacy issues. The coordination with veterinary surveillance was missing especially in new Member States.

Most Member States introduced measures to improve prescribing practices but continuous feedback to prescribers is lacking.

Although selling antimicrobial agents without prescription is often considered as inappropriate, Member States were not able to estimate proportion of antimicrobial agents sold without prescription.

Most countries had national guidance for use of antimicrobial agents for surgical prophylaxis and for treatment of common infectious diseases.

Most countries had national programmes for hospital hygiene and infection control in place, some of those requiring infection control committees and nurses in hospital and nursing homes. However, often infection control is not a part of accreditation of these health establishments.

Health professionals do not always receive training in appropriate use of antimicrobial agents during their studies. They usually receive this training in continuing education.

Most countries performed a campaign to raise awareness of the issue although these campaigns were primarily focused on professionals.

[1] Report from the Commission to the Council on the basis of member states' reports on the implementation of the Council recommendation (2002/77/EC) on the prudent use of antimicrobial agents in human medicine (COM(2005)684 final)

# Medicinal products

The many Directives and Regulations dealing with pharmaceuticals in the EU have been implemented at Community level through implementing regulations and guidelines.

EudraLex, the comprehensive EU database on medicinal products includes specific guidelines to ensure a correct implementation of the legislation.

- Volume 1 – EU pharmaceutical legislation for medicinal products for human use
- Volume 2 - Notice to applicants and regulatory guidelines for medicinal products for human use
- Volume 3 - Scientific guidelines for medicinal products for human use
- Volume 4 – Guidelines for good manufacturing practices for medicinal products for human and veterinary use
- Volume 8 - Maximum residue limits
- Volume 9 – Guidelines for pharmacovigilance for medicinal products for human and veterinary use
- Volume 10 – Guidelines for clinical trial

**Legal Act:**

The Regulations are directly applicable in the Member States and have been developed in these and other guidelines that elaborate more practical requirements relating to their implementation. Public consultations were held by the Commission to obtain input from stakeholders on the guidelines. For instance, one of the latest public consultations held by the Commission requested input from stakeholders on the guidelines for implementing the Regulation on products for paediatric use.

The Commission also held public consultations on the implementation of some of the Regulations, such as on traditional herbal medicinal products. The public consultation on the simplified procedure applicable to these traditional herbal medicinal products investigated the possibility of extending this procedure to other categories of medicinal products. The 2007 Communication adopted on the basis of the results of the public consultation concluded that it was too early to fully assess the application of the simplified procedure only 18 months after the start of its implementation. However, the Commission also noted that an extension of the scope of the Directive to other medicinal products, such as traditional Chinese medicinal products, could be considered in the long run, on the condition of having a long tradition of safe use.

The Regulation on products for paediatric use requires Member States to adopt incentives and reward mechanisms to achieve the objectives of the Regulation. A 2008 Commission inventory of the incentives adopted shows that a majority of Member States have put such reward schemes of incentives in place. The incentives vary from financial grants to taxation incentives or the establishment of expert networks.

Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use.

The implementation of Directive 2001/83/EC as well as the amendments introduced by Directive 2004/27/EC was the subject of a number of disputes and infringement procedures before the European Court of Justice. Nevertheless, it should be noted that the overall transposition of both Directives was effective.

In July and September 2008, the ECJ condemned Lithuania and Poland for failing to fulfil the requirements of Article 6(1) of Directive 2001/83/EC. In November 2007, France was condemned by the ECJ for failing to transpose Directive 2004/24/EC which amends Directive 2001/83/EC.

In 2007, the ECJ adopted judgments against Ireland, the Czech Republic, Spain and the Netherlands for failure to transpose the amendments to the Community Code (Directive 2001/83/EC) introduced by Directive 2004/27/EC.
Other disputes concerned the application of the Directive and its authorisation requirement to a specific product or precise procedural requirements.

On the basis of public stakeholder consultations, some necessary modifications to the Directive were identified, namely on pharmacovigilance. These modifications are part of the legislative package on pharmaceuticals currently under discussion in the European Parliament.

The Clinical Trials directive 2001/20/EC

A report on the implementation of the Clinical Trials Directive published in 2007 concluded that some obstacles related to differences in implementation and administrative practice of this Directive had not yet been overcome. For instance, problems seem to arise with regard to a common interpretation of the definitions in the Directive, which create differences between Member States. As many clinical trials involve more than one site in multiple Member States, these differences seem to create difficulties for complying with the requirements of the Directive.

In September 2005, the Netherlands was condemned by the ECJ for failing to transpose the requirements of Directive 2001/20/EC on clinical trials.

# 4. INFORMATION TO PATIENTS ON MEDICINES

Below are the technical details of the parliamentary procedure concerning the information to patients on prescription medicines.

Reference: COD/2008/0255

Full Title:
Medicinal products for human use: information on products subject to medical prescription (amend. Regulation (EC) No 726/2004, Community procedures)

Legal Basis: TFEU 114-p1 ; TFEU 168-p4

Dossier of the committee ENVI/7/00156

Subject(s) 4.20.04 pharmaceutical products and industry
4.60.02 consumer information, publicity, labelling

Stage reached: Awaiting Parliament decision, 1st reading/single reading

Commission/Council (summary):
initial legislative document
EC COM(2008)0662 C6-0517/2008 10/12/2008
EP: draft report by the committee responsible
EP PE439.412 10/03/2010

Forecasts:
28/09/2010 EP: report scheduled for adoption in committee, 1st or single reading
06/12/2010 Council: debate or examination expected
14/12/2010 EP plenary sitting (indicative date)

Environment, Public Health and Food Safety (responsible)
Fjellner, Christofer, PPE - Rapporteur

Industry, Research and Energy (opinion)
Chatzimarkakis, Jorgo, ALDE

Internal Market and Consumer Protection (opinion)
Correia De Campos, António Fernando, S&D

**COD/2008/0255 : 10/12/2008 - Commission/Council: initial legislative document**

PURPOSE: to promote public health in the Community by establishing harmonised rules on the provision of information on medicinal products subject to medical prescription.

PROPOSED ACT: Directive of the European Parliament and of the Council.

BACKGROUND: Directive 2001/83/EC on the Community code relating to medicinal products for human use provides for a harmonised framework on advertising of medicines at Community level, the application of which remains a responsibility of Member States. This legislation prohibits the advertising to the general public of medicines subject to prescription.

However, neither the Directive nor Regulation (EC) No 726/2004 include detailed provisions on information on medicinal products, providing only that certain information supply activities are exempted from the advertising provisions. Therefore, Community legislation does not prevent Member States from establishing their own approaches regarding the provision of information on medicinal products as long as the above mentioned rules on advertising are respected. In addition, the boundaries between advertising and information, and therefore the field of application of the legislation's restrictions on advertising, are not interpreted consistently across the Community.

Pursuant to Directive 2001/83/EC, a Communication from the Commission to the European Parliament and the Council concerning the "Report on current practices with regard to the provision of information to patients on medicinal products" (see COD/1999/0134 under “Follow-up documents”) was adopted and submitted to the European Parliament and the Council on 20 December 2007. According to the Report, rules and practices on what information can be made available vary significantly among Member States. Moreover, divergences in terms of rules and practices on what information can be made available have a negative impact on legal certainty for marketing authorisation holders with cross-border activity.

CONTENT: the Commission proposes to amend Directive 2001/83/EC and Regulation (EC) No 726/2004 (see also COD/2008/0256) to address the gap in the current pharmaceutical legislation as regards the provision of information to the general public on prescription-only medicinal product for human use. The aim is to enhance the rational use of these medicines, while ensuring that the legislative framework continues to prohibit direct-to-consumer advertising of prescription-only medicines.

The main elements of the proposals can be summarised as follows:

- clarifying that the provision of information on prescription-only medicines directly to the public by marketing authorisation holders is allowed, without prejudice to the prohibition on advertising, provided that clearly defined conditions are fulfilled;
- establishing harmonised conditions on the content of information which marketing authorisation holders are allowed to disseminate (information approved by the competent authorities for granting marketing authorisation, whether used literally or presented in a different way, and other limited medicine-related information);
- establishing harmonised quality standards for such information, to ensure that it is of high-quality and non-promotional;
- determining the authorised channels of information provision, in order to exclude unsolicited means of dissemination;
- introducing the obligation for Member States to establish a monitoring system to ensure that the abovementioned provisions on content of information, quality standards and dissemination channels are complied with and ensure enforcement in case of non-compliance. The proposal leaves it up to the Member States to decide the most appropriate monitoring mechanisms, but lays down a general rule that monitoring should take place after dissemination of information, with certain exceptions (where prior approval would be necessary) in the case of certain modalities of information where the distinction between advertising and non-promotional information is more difficult to establish. For products authorised in accordance with Regulation (EC) No 726/2004, certain approval tasks are given to the European Medicines Agency;
- establishing specific monitoring rules for information disseminated through websites, to take account of the cross-border nature of information provided over the Internet and to allow Member State cooperation and avoid duplication of monitoring.

**30/11/2009 - Council's activities**
**(this is a common text to the whole of the pharmaceutical package):**

On the basis of progress reports, the Presidency informed the Council of the state of play in the negotiations on two parts of the "pharmaceutical package": preventing falsified medicines from entering into the legal supply chain of medicinal products and the strengthening and rationalising of the current pharmacovigilance system.

1) Concerning the draft directive on preventing the entry into the legal supply chain of falsified medicinal products, the working group reached tentative agreement on a number of technical aspects, including:

- the definition of "falsified medicinal products";
- the proposed definition of ''trading of medicinal products'' has been changed to ''brokering of medicinal products'' and amended, thereby clarifying which actors in the supply chain should be subject to the responsibilities of brokers. The proposed introduction of obligations for brokers aim to reinforce the traceability of medicinal products;
- a clarification of the relationship between the proposed new provisions in Directive 2001/83/EC and Community legislation on intellectual property rights.

Other elements of the proposal still need further discussion, notably with regard to the strengthening of controls of non active substances used in pharmaceuticals (excipients) and the proposed safety features aiming to render falsification more difficult.

The proposal includes provisions requiring the accreditation of third party auditors of Good Manufacturing Practices and Good Distribution Practices. A majority of delegations object to accreditation, since they maintain that such a system could result in a transfer of responsibility from manufacturers and importers as well as make enforcement by national competent authorities more difficult. The Presidency has therefore proposed to delete the provisions regarding accreditation from the text. Some delegations have expressed an interest in the possibility of establishing third party accreditation at a national level.

2) Concerning the proposals for a regulation and a directive on strengthening the EU system for the safety monitoring of medicinal products ("pharmacovigilance"), the working group reached tentative agreement on a number of questions including:

- a clarification of the relation between the proposed new provisions in Directive 2001/83/EC and Regulation (EC) 726/2004 on the one hand and the Community legislation on protection of personal data on the other hand;
- a strengthening of the role of the Pharmacovigilance Risk Assessment Committee (PRAC) in relation to the Committee for Medicinal Products for Human Use and to the Coordination Group set up by Article 27 of Directive 2001/83/EC (CMD), including an obligation for these last two bodies to explain any differences in opinion compared to the PRAC;
- a change in the composition of the PRAC and in the method for nominating the PRAC members so that all Member States will be represented;
- the inclusion of a requirement for the Agency, in collaboration with the Member States and the Commission, to draw up functional specifications for the Eudravigilance database which will take account of the role and experience of national competent authorities for pharmacovigilance. The new reporting obligations to Eudravigilance will not apply until these specifications are met and to this end a transitional period is envisaged;
- the legal status of CMD opinions and how they are implemented in Member States. Here, text redrafting proposals are under legal scrutiny.

The Working Party has continued to discuss other central provisions of the proposals, mainly in relation to the Community Procedure and Referrals, the Recording and Reporting of adverse reactions, the Periodic Safety Update Reports and the Post Authorisation Safety Studies.

A number of issues still require further examination, such as the recording and reporting of adverse reactions and the proposed list of medicinal products for human use under intensive monitoring.

At this stage, all delegations have a general scrutiny reservation on the entire proposal while the Danish, Maltese and United Kingdom delegations have parliamentary scrutiny reservations.

3) With regard to the third part of the "pharmaceutical package", the proposals for a regulation and a directive concerning information for the general public on medicinal products, the Presidency recalled the strong concerns of many Member States. The Commission made it clear that it is prepared to show flexibility in order to find a common basis for the future negotiations.

# 5. PHARMACOVIGILANCE

Below are the technical details of the parliamentary procedure concerning the pharmacovigilance initiative.

Reference: COD/2008/0260

Full Title:
Medicinal products for human use: pharmacovigilance of products (amend. Directive 2001/83/EC, Community code)

Legal Basis: TFEU 168-p4 ; TFEU 114-p1

Dossier of the committee ENVI/7/00153

Subject(s) 4.20.04 pharmaceutical products and industry
4.60.08 safety of products and services, product liability

Stage reached: Awaiting Parliament decision, 1st reading/single reading

Commission/Council (summary):
initial legislative document
EC COM(2008)0665 C6-0514/2008 10/12/2008
EP: draft report by the committee responsible
EP PE430.927 17/12/2009
EP: tabled legislative report, 1st reading or single reading
EP A7-0159/2010 02/06/2010

Forecasts:
21/09/2010 EP plenary sitting (indicative date)
06/12/2010 Council: political agreement on position expected

Environment, Public Health and Food Safety (responsible)
Mcavan, Linda, S&D - Rapporteur

Industry, Research and Energy (opinion)
Rivasi Michèle, Verts/ALE

Internal Market and Consumer Protection (opinion)
Turmes, Claude, Verts/ALE

**COD/2008/0257 : 10/12/2008 - Commission/Council: initial legislative document**

PURPOSE: to improve the functioning of Community rules on the pharmacovigilance of medicinal products for human use, with the overall objectives of better protecting public health, ensuring proper functioning of the internal market and simplifying the current rules and procedures.

PROPOSED ACT: Directive of the European Parliament and of the Council.

CONTENT: it is estimated that 5% of all hospital admissions are due to an adverse drug reaction, that 5% of all hospital patients suffer an adverse drug reaction and adverse drug reactions are the fifth most common cause of hospital death. Some adverse reactions will only be detected after a medicine has been authorised and the full safety profile of medicinal products can only be known once they have entered the market.

Community rules so far adopted have made a major contribution to the achievement of the objective that medicinal products authorised to be placed on the Community market are continuously monitored as regards their safety. However, in the light of the experience acquired and following an assessment by the Commission of the Community system of pharmacovigilance, it has become clear that new measures are necessary to improve the operation of the Community rules on the pharmacovigilance of medicinal products for human use.

Therefore, the proposals aim at the strengthening and rationalizing the Community pharmacovigilance system of medicinal products for human use through the amendment of the two legal acts governing this field, i.e. Directive 2001/83/EC (see COD/2008/0260) and Regulation (EC) No 726/2004. The specific objectives are:

- providing for clear roles and responsibilities for the key responsible parties and clear obligations against which they perform their roles;
- rationalising EU decision-making on drug safety issues;
- strengthening medicines safety transparency and communication;
- strengthening companies' pharmacovigilance systems;
- ensuring the proactive and proportionate collection of high quality data relevant to the safety of medicines through risk management and structured data collection;
- involving stakeholders in pharmacovigilance;
- simplification of the current Community pharmacovigilance procedures.

The key elements of the proposals can be summarised as follows:

Clear roles and responsibilities:

- the key tasks of the Agency in the area of pharmacovigilance are overall maintained, but the Agency's coordinating role at the centre of the Community pharmacovigilance system is reinforced;
- the Member States should remain core to the operation of pharmacovigilance in the Community, with increased cooperation and work-sharing mechanisms;
- the pharmacovigilance responsibilities of marketing authorisation holders are also clarified, in particular as regards the scope of the obligation of marketing authorisation holders to continuously monitor the safety of products to ensure that all information available is brought to the attention of the authorities;
- a new scientific committee responsible for pharmacovigilance is created within the Agency: the Pharmacovigilance Risk Assessment Advisory Committee. This Committee is intended to play a key role in the pharmacovigilance assessments in the Community;
- the mandate of the coordination group composed of Member States representatives is enhanced;
- the Community procedure for the assessment of serious safety issues for nationally authorised products is stream-lined through clear and binding initiation criteria for the Member States.

Transparency and communication in terms of drug safety issues:

- strengthening of the Eudravigilance database, which should become the single point of receipt of pharmacovigilance information for medicinal products for human use authorised in the Community;

- Community coordination of communication about safety issues and establishment of a European medicines safety web-portal;
- introduction of a new 'key information' section in the summary of the product characteristics and the package leaflet which accompany every medicinal product placed on the Community market.

Pharmacovigilance obligations of the marketing authorisation holder: the proposals simplify the requirement that a 'detailed description of the pharmacovigilance system' be submitted in marketing authorisation applications. In the marketing authorisation application, only key elements of the pharmacovigilance system should be submitted, but this is balanced with a requirement for companies to maintain a detailed pharmacovigilance system master file on site.

Risk management planning and non-interventional safety studies:

- the establishment of a risk management system for each medicinal product to be newly authorised in the Community (or for existing products on the basis of safety concerns), which should be proportionate to the identified risks, potential risks, and the need for additional information on the medicinal product;
- the establishment of harmonised guiding principles and a procedure for the supervision of non-interventional post-authorisation safety studies (i.e. safety studies of authorised products that are not clinical trials), in particular to ensure that they are non promotional, and the follow-up of any safety data generated in such studies.

Adverse drug reaction case reports: the proposals are intended to make reporting proportionate to risks, to empower patients to report their side effects, and to ensure that overdoses and medication errors are reported. The following has therefore been proposed:

- simplification of adverse reaction reporting by providing that all adverse reaction data are reported directly to the Eudravigilance database;
- requiring the Agency to assume the role of monitoring scientific literature by the Agency and to enter case reports of adverse effects into the Eudravigilance database;
- clarification of the definition of adverse drug reaction to make clear that companies report medication errors that result in an adverse reaction to the competent authorities for medicines and ensure that all the relevant Member State authorities share data;
- clarification of the legal basis for patients to report suspected adverse drug reactions.
- Periodic safety update reports and other safety related assessments: the proposals simplify periodic safety update report submission by industry and make it proportional to the knowledge about the safety/risk of the product. They introduce work-sharing mechanisms for the assessments, with a prominent role in all cases by the Pharmacovigilance Risk Assessment Advisory Committee, and faster updating of product information through the establishment of clear procedures.

## OPINION OF THE EUROPEAN DATA PROTECTION SUPERVISOR

On the proposal for a Regulation of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and on the proposal for a Directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Recall: on 10 December 2008, the Commission adopted two proposals relating to the amendment of the actual pharmacovigilance system. The general intention of the two proposals is to remedy these weaknesses and to improve and strengthen the Community pharmacovigilance system with the overall objective of better protecting public health, ensuring proper functioning of the internal market and simplifying the current rules and procedures (see COD/2008/0260). The overall operation of the current pharmacovigilance system relies on the processing of personal data. These data are included in the adverse drug reactions reporting and can be considered as data relating to health of the persons concerned since they reveal information about drug use and associated health problems.

Processing of such data is subject to strict data protection rules as laid down in Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data and Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Despite this, no reference to data protection is included in the current text of Regulation (EC) No 726/2004 and Directive 2001/83/EC, except for one specific reference in the Regulation. The EDPS regrets that data protection aspects are not considered within the proposed amendments and that he was not formally consulted on both proposals for amendments. The EDPS recommends that a reference to this opinion is included in the preamble of both proposals.

Content of the Opinion: this Opinion will first proceed with a simplified explanation of the system of pharmacovigilance in the EU as it follows from Regulation (EC) No 726/2004 and Directive 2001/83/EC in their present state. Subsequently, the necessity of processing of personal data in the context of pharmacovigilance will be analysed. After this, the proposals of the Commission for improving the current and envisaged legal framework will be discussed and recommendations will be made on how to ensure and improve the data protection standards.

Conclusions and recommendations: the EDPS takes the view that the lack of a proper assessment of the data protection implications of pharmacovigilance constitutes one of the weaknesses of the current legal framework set out by Regulation (EC) No 726/2004 and Directive 2001/83/EC. The current amendment of Regulation (EC) No 726/2004 and Directive 2001/83/EC should be seen as an opportunity to introduce data protection as a full-fledged and important element of pharmacovigilance.

A general issue to be addressed thereby is the actual necessity of processing personal health data at all stages of the pharmacovigilance process. As explained in this Opinion, the EDPS seriously doubts this need and urges the legislator to reassess it at the different levels of the process. It is clear that the purpose of pharmacovigilance can in many cases be achieved by sharing information on adverse effects which is anonymous in the meaning of the data protection legislation. Duplication of reporting can be avoided through the application of well structured data reporting procedures already at national level.

The proposed amendments envisage a simplified reporting system and a strengthening of the EudraVigilance database. The EDPS has explained that these amendments lead to increased risks for data protection, especially when it involves the direct reporting of patients to the EMEA or the EudraVigilance database.

In this respect, the EDPS:

– strongly advocates a decentralised and indirect reporting system whereby communication to the European web portal is coordinated through using the national web portals;

- emphasises that privacy and security should be part of the design and implementation of a reporting system through the use of web-portals ('privacy by design');
- underlines that once data concerning health about identified or identifiable natural persons is processed, the person responsible for such processing should comply with all the requirements of the Community data protection legislation.

More specifically, the EDPS recommends:

- to include a reference to this Opinion in the preamble of both proposals, to introduce in both Regulation (EC) No 726/2004 and Directive 2001/83/EC a recital stating the importance of data protection in the context of pharmacovigilance, with references to the relevant Community legislation;
- to introduce in Regulation (EC) No 726/2004 and Directive 2001/83/EC a new Article having a general nature which states that: (i) the provisions of Regulation (EC) No 726/2004 and Directive 2001/83/EC are without prejudice to the rights and obligations stemming from the provisions of Regulation (EC) No 45/2001 and Directive 95/46/EC respectively, with specific reference to Article 10 of Regulation (EC) No 45/2001 and Article 8 of Directive 95/46/EC respectively; (ii) identifiable health data shall only be processed when strictly necessary and parties involved should assess this necessity at every single stage of the pharmacovigilance process;
- to include in the proposed Article 24(2) of Regulation (EC) No 726/2004 a sentence stating that the accessibility of the EudraVigilance database shall be regulated in conformity with the rights and obligations stemming from the Community legislation on data protection;
- to add a paragraph to the proposed Article 24 stating that measures shall be put in place which ensure that the data subject can exercise his right of access to personal data concerning him as provided for by Article 13 of Regulation (EC) No 45/2001;
- to add to the proposed Article 101 of Directive 2001/83/EC a paragraph which states that in case of processing of personal data the individual shall be properly informed in accordance with Article 10 of Directive 95/46/EC;
- to include in the newly proposed Articles 25 and 26 of Regulation (EC) No 726/2004 and Article 106 of Directive 2001/83/EC, which deal with the development of a reporting system for adverse effects through the use of web- portals, an obligation to incorporate proper privacy and security measures at an even level across Member States, taking into account the basic principles of confidentiality, integrity, accountability and availability of data.

### 30/11/2009 - Council's activities

See the common text included in the previous chapter.

# 6. FALSIFIED MEDICINAL PRODUCTS

Below are the technical details of the parliamentary procedure concerning the counterfeit of falsified medicinal products initiative.

Reference COD/2008/0261

Full Title:
Medicinal products for human use: prevention of the entry into the legal supply chain of falsified medicinal products (amend. Directive 2001/83/EC)

Legal Basis TFEU 168-p4 ; TFEU 114-p1

Dossier of the committee ENVI/7/00148

Subject(s) 3.40.14 industrial competitiveness
4.20.04 pharmaceutical products and industry
4.60.02 consumer information, publicity, labelling
4.60.08 safety of products and services, product liability

Stage reached Awaiting Parliament decision, 1st reading/single reading

Commission/Council (summary):
initial legislative document
EC COM(2008)0668 C6-0513/2008 10/12/2008
EP: draft report by the committee responsible
EP PE430.883 07/01/2010
EP: tabled legislative report, 1st reading or single reading
EP A7-0148/2010 07/05/2010

Forecasts:
07/10/2010 EP plenary sitting (indicative date)
06/12/2010 Council: political agreement on position expected

Environment, Public Health and Food Safety (responsible)
Matias, Marisa, GUE/NGL

Industry, Research and Energy (opinion)
Sartori, Amalia, PPE

Internal Market and Consumer Protection (opinion)
Bastos, Regina, PPE

**COD/2008/0261 : 10/12/2008 - Commission/Council: initial legislative document**

PURPOSE: to prevent the entry into the legal supply chain of medicinal products which are falsified.

PROPOSED ACT: Directive of the European Parliament and of the Council.

BACKGROUND: there is an alarming increase in the EU of medicinal products which are falsified in relation to their identity, history or source. These products are, from the point of view of EU pharmaceutical legislation, illegal insofar as they do not comply with the Community rules for medicinal products. Moreover, the number of falsifications of innovative and life-saving medicines is increasing. In this way, in 2007, many thousand packs of falsified life-saving drugs reached patients in the EU.

The underlying causes for falsified medicinal products remaining undetected in the legal supply chain are manifold, but can be reduced to four aspects: (i) falsified medicinal products can not always be easily distinguished from originals; (ii) the distribution chain has become very complex and is only as strong as its weakest link; (iii) there are legal uncertainties as to the regime applicable to products introduced into the EU while allegedly not being placed on the market; (iv) lastly, already the active pharmaceutical ingredients (API) entering the manufacturing process may be a falsification of the original API.

The existing provisions of Directive 2001/83/EC are in some respects insufficient to address these concrete causes. In view of the time span between the proposal for amendments to Directive 2001/83/EC and their effective implementation, there is a clear need for the Commission to act now.

CONTENT: in order to address the risk of falsified medicinal products entering the legal supply chain, the Commission proposes a number of amendments to Directive 2001/83/EC.

These include:

- certain obligations for stakeholders other than wholesale distributors, who are involved in the distribution chain. These stakeholders are typically involved in the transactions without actually handling the products (for example, by auctioning or brokering products);
- a legal basis for the Commission to render obligatory specific safety-features (such as a serial number or a seal) on the packaging of prescription-medicines;
- a prohibition in principle of manipulating (i.e. removing, tampering with, or over-labelling) safety features on the packaging by stakeholders situated “in-between” the original manufacturer and the last stakeholder in the distribution chain (typically the pharmacist) or end user (doctor/patient);
- compulsory audits of wholesale distributors of medicinal products in order to ensure reliability of business partners;
- strengthened requirements for imports of API from third countries if it could not be established that the regulatory framework in the respective third country ensures a sufficient level of protection of human health for products exported to the EU;
- audits of manufacturers of API;
- stricter rules for inspections including increased transparency of inspection results through publication in the EudraGMP database managed by the EMEA.

**07/06/2010 - Council's activities**
**(see also text at the end of chapter 4)**

The Council took note of a presidency progress report on the state of play in the negotiations on the prevention of falsified medicines from entering into the legal supply chain of medicinal products (doc. 10469/10).

The presidency also provided the Council with oral information on the progress in the discussions on the strengthening of the current pharmacovigilance system (aimed at protecting patients from adverse reactions to medicinal products). With regard to the pharmacovigilance part of the pharmaceutical package, the presidency will endeavour to reach an agreement at first reading with the European Parliament before the end of June.

# 7. MULTIANUAL POLICY OVERVIEW

## Community Programme

| | Pre-2009 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | Post-2014 |
|---|---|---|---|---|---|---|---|---|
| Decision No 1350/2007/EC of the European Parliament and the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13) | | | | | | | | |
| External interim report | | | 31/12/10 | | | | | |
| Communication on the continuation of the programme | | | | 31/12/11 | | | | |
| External evaluation report | | | | | | | | 31/12/15 |

## Anti-microbial Resistance

| | Pre-2009 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | Post-2014 |
|---|---|---|---|---|---|---|---|---|
| Council Recommendation on the prudent use of antimicrobial agents in human medicine (2002/77/EC) | | | | | | | | |
| MS report to EC | 5/2/04 | On request by EC | | | | | | |

## Medicinal Products

| | Pre-2009 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | Post-2014 |
|---|---|---|---|---|---|---|---|---|
| Directive 2001/83/EC on the Community code relating to medicinal products for human use | | | | | | | | |
| Compliance | 30/10/05 | | | | | | | |
| Regulation (EC) 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. | | | | | | | | |
| Implementation/Compliance | 20/05/08 | | | | | | | |
| General report from the EC | | | | | | | 31/12/14 | |
| The Clinical Trials Directive 2001/20/EC | | | | | | | | |
| Implementation | 01/05/04 | | | | | | | |
| Regulation (EC) No 1394/2007 on advanced therapy medicinal products | | | | | | | | |
| Entry into force | 30/12/08 | | | | | | | |
| Compliance of products other than tissues on the market before 30/12/08 | | | | 30/12/11 | | | | |
| Compliance of tissue products on the market before 30/12/08 | | | | | 30/12/08 | | | |
| Regulation (EC) No 1901/2006 on products for paediatric use | | | | | | | | |
| Compliance | | 26/1/09 | | | | | | |
| Regulation (EC) 141/2000 on orphan medicinal products | | | | | | | | |
| EC Report on experience and public health benefits | 22/01/06 | | | | | | | |

# ANNEX 1: SELECTED STUDIES

## HEALTH STRATEGY AND HEALTH PROGRAMME

European Commission (2004), *Enabling Good Health for All, A reflection process for a new EU health strategy*, Brussels.

Suhrcke M., McKee M., Sauto Arce R., Tsolova S. and Mortensen J. (2005): *The contribution of health to the economy in the European Union*, Luxembourg.

Stahl, T. et al. (eds.) (2006): Health in all policies. Prospects and potentials. Helsinki: Ministry of Social Affaires and Health

Oortwijn, W. J. et al. (2007): Interim evaluation of the Public Health programme 2003-2008. Cambridge: RAND

## HEALTH CARE ASSOCIATED INFECTIONS

Conklin A., Vilamovska A.M., de Vries H., Hatziandreu E. (2008), *Improving Patient Safety in the EU. Assessing the expected effects of three policy areas for future action*, RAND, Cambridge.

Université Claude Bernard Lyon (2008), *Improving Patient Safety in Europe. Technical Implementation Report 2005-2008*, European Commission, Brussels.

## MEDICINAL PRODUCTS

Europe Economies (2008), *Policies to Combat Counterfeit Medicines*, Europe Economies, London.

Europe Economies (2008), *Safe Medicines through Parallel Trade*, Europe Economies, London.

European Medicines Agency (2007), *Report on the European Commission-EMEA conference on the operation of the clinical trials Directive*, European Medicines Agency, London.

European Commission (2006), *Report on the experience acquired as a result of the application of Regulation (EC) 141/2000 on orphan medicinal products*, SEC(2006) 832, Brussels.

Charles River Associates (2004), Innovation in Pharmaceuticals, Charles River Associates, London.

De Varax A., Letellier M. and Börtlein G. (2004), *Study on Orphan Drugs*, Phase I Overview of the conditions for marketing orphan drugs in Europe, Alcimed, Paris.

De Varax A., Letellier M. and Börtlein G. (2004), *Study on Orphan Drugs*, Phase II Considerations on the application of article 8.2 of EC regulation No. 141/2000 concerning orphan drugs, Alcimed, Paris.

# ANNEX 2: EXPLANATORY STATEMENTS OF THE REPORTS

In this section we include the Explanatory Statements of the three reports, as due to their length it resulted impractical to include them in full.

The references for the full documents are:

FJELLNER Report:
On information to the general public on medicinal products for human use subject to medical prescription.
2008/0255 (COD) - PE439.412v01-00 - 10-03-2010
www.europarl.europa.eu/oeil/file.jsp?id=5729442

MCAVAN Report:
On pharmacovigilance
A7-0159/2010 - PE430.927v03-00 - 02.06.2010
www.europarl.europa.eu/oeil/file.jsp?id=5729472

MATIAS Report:
On medicinal products which are falsified.
A7-0148/2010 - PE430.883v03-00 - 07.05.2010
www.europarl.europa.eu/oeil/file.jsp?id=5729252

## 1. INFORMATION TO THE PUBLIC ON MEDICINES

### EXPLANATORY STATEMENT

The Rapporteur welcomes the proposal by the Commission on information to patients on prescription-only medicines (COM(2008)0662-0663). The Parliament and patient organizations have been asking for such a proposal for a long time, in order to enable patients to better informed on the medicines they are prescribed and taking.

Increased access to quality information will contribute to achieving better health outcome for patients as better informed patients are more likely to continue necessary treatments and better understand decisions related to their treatment; so the proposal, if properly phrased and implemented, will bring an added value.

Therefore the objective of the proposal can not only be harmonisation of European legislation but also to improve health through improved health literacy. The pharmaceutical industry has an important role to play in promoting health literacy and good health, but their role must be clearly defined and their involvement strictly regulated, in order to avoid commercially driven overconsumption of pharmaceuticals.

There are many problems with the current legal framework and the situation within Europe when it comes to patients' access to information on prescription-only medicine. The differences in interpretations of the Directive by the Member States give patients in different parts of Europe different access to high quality information on pharmaceuticals. In some Member States patients lack easy access to even the most basic information about the pharmaceuticals they are prescribed. This is unacceptable and creates health inequalities within the Union.
Today's regulation is not adjusted to technical development and the possibilities and challenges created by Internet.

Patients in Europe already have infinite access to uncontrolled and often incorrect information about prescribed-only pharmaceuticals in a few seconds. The access to controlled and safe information about pharmaceuticals on internet though is very limited for most patients. This is especially a problem for those who need information in their mother tongue.

The current and different interpretation of the Directive by courts throughout Europe shows that there is a certain legal unclarity that creates uncertainty about how the Directive should be implemented and to whom it is applicable. This is also shown through the differences in the way different Member States have implemented the Directive. Therefore it is essential to create a increased clarity in the provisions.

Altogether it is therefore necessary to update the provisions regarding information about prescribed pharmaceuticals, and that new rules come into place soon.

The Rapporteur, however, raises several concerns about the Commission's proposal. This explanatory statement highlights the most important changes put forward in the draft reports.

- The Commission's proposal focuses on the pharmaceutical companies' right to disseminate information rather then the patients' right to access quality information. The Rapporteur therefore proposes to shift the focus of the proposal and to mandate pharmaceutical companies to provide certain information to the patients and thus, to put the "patients' right to know" into the centre of the legislation. The possibility to make information available to patients may not be used as an advertisement opportunity for the pharmaceutical companies; information should really serve patients' interests. The Rapporteur wishes to oblige pharmaceutical industry to make certain fundamental information on prescription-only pharmaceuticals available and easy accessible to European patients, e.g. summary of product specifications and package leaflets.

- The making available of information should be based on the "pull principle", i.e. information should be made available to those patients who are searching for information themselves. Thus the channels through which information is made available should be more carefully selected. While the role of internet is increasing, internet penetration and access varies considerably from one Member State to the other, not to mention the differences in internet literacy. For that reason information should be made available through more "traditional" channels as well e.g. correspondence.

- Concerning, though, the use of printed media as information channel the Rapporteur has reservations. Information in newspapers or magazines is available to everyone not only to those who are seeking for information themselves, i.e. patients are not protected from unsolicited information. The Rapporteur therefore proposes to delete the possibility to make information available by the pharmaceutical companies in newspapers, magazines and similar publications.

- The Rapporteur also wishes to make a clearer distinction between advertisement and information. Though Article 86 of the Directive sets the definition of advertising, and Article 88 (1) prohibits the advertisement of prescription-only medicines, for the sake of clarity it should underlined that no promotional material on prescription-only medicines could be made available.

– In order to avoid confusion, it has to be emphasised that the provisions of the Directive would apply to the pharmaceutical companies only and would not affect, under any circumstances, the right of either the press or patients and their organisations to express their views on certain medicines and treatment, as long as they are acting independently and not on behalf of, in the interest of, or upon instructions by the pharmaceutical companies. This is a regulation on the industry, and not a broader regulation that affects freedom of speech or the freedom of the press etc.

– In order to make patients' voice heard, patients' organisation should be actively involved into the implementation of the Directive and the Regulation. The Rapporteur welcomes the idea to have guidelines and a code of conduct drafted concerning the information which is made available to the patients, and wants the Commission to cooperate with patients' organisations when drafting those guidelines and code of conduct.

– There is a need to emphasise the important relationship between doctor and patient. The most important source of information about prescription-only medicines is, and should remain, the prescribing doctor. This relationship has a fundamental value and can only be supplemented by other channels of information.

– With regard to the scope of information the Rapporteur welcomes that the publicly accessible version of the assessment report is made public. He is, however, of the opinion that the pharmaceutical and pre-clinical tests and the clinical trials of the given medicines could also be made available. Given the commercial sensitivity of such information, pharmaceutical companies could not be mandated to publish this information, but as this information can be of value to patients and their organisation making available of the information should not be prohibited.

Putting the proposals into context, the Rapporteur underlines that information to patients on prescription-only medicines should be part of a wider "information to patients strategy" and a broader strategy of health literacy. Patients and everyone interested should be able to find accurate and unbiased information on healthy lifestyle, the prevention of illness and specific diseases, and various treatment options. This, however, goes beyond the scope of the current proposal and report. The Rapporteur though expects the Commission to present a new proposal in a near future as a part of such wider "information to patients strategy" and to complement this one.

# 2. PHARMACOVIGILANCE

## EXPLANATORY STATEMENT

Pharmacovigilance is the system used to monitor the safety of medicines after they have been authorised for public use. Pharmacovigilance plays an important role in public health. An estimated 197,000 deaths per year are caused by Adverse Drug Reactions (ADRs) in the EU). Clinical trials can miss side effects from drugs if they are rare, only appear after long-term use or involve interaction with other drugs. Most of us will be aware of the tragedy of the drugs Thalidomide in the 1960s and Viox more recently. There can therefore be no doubt that systems for tracking drug use, reporting on ADRs and looking for patterns (“signal detection”) are a priority for European public health policy.

Under current EU legislation, medicines can be authorised in two ways: a) through a central procedure where one application is made by a pharmaceutical company to the EMEA (European Medicines Agency) or b) through a system of mutual recognition where one country leads on the assessment of the new drug and coordinates with other Member States through mutual recognition. There is an obligation for certain kinds of new products to go through the centralised system e.g. Biotech, cancer, HIV, neurodegenerative drugs. Rules governing the centralised procedure are set out in EU Regulation 726/2004 and for the decentralised system in Directive 2001/83/EC. The Commission proposal to update the rules on pharmacovigilance therefore requires amendment of both pieces of legislation. Your rapporteur has similarly drafted amendments to both the Regulation and the Directive, but given the overlapping nature of the two pieces of legislation, the narrative below refers to both.

The essence of a good pharmacovigilance system is proper reporting of ADRs by healthcare professionals, companies and patients themselves and proper recording of these ADRs by the public authorities so that "signals" pointing to potential problems can be detected. These signals must then be followed up with action which can include changes to the way a medicine is prescribed, better information on how it is used or, where the nature of the ADR is severe, the withdrawal of the medicine altogether. The advantage of strengthening cooperation on pharmacovigilance at EU level is that the "pool" of reported ADRs is larger, meaning rarer patterns can be picked up more quickly, duplicate work on following up the same ADRs in different Member States can be avoided and unsafe medicines can be withdrawn quickly when required. "Signals" are picked up from spontaneous reports of ADRs to national competent authorities, from the periodic safety update reports (PSURs) that companies are required to present once a product is on the market and from expert review of medical research papers. The current system of pharmacovigilance in the EU has evolved in recent years to better coordinate work between Member States. A single Eudravigilance database which collects data is up and running and a working party meets to discuss issues. However, gaps in the current legislation mean that the approach is somewhat ad hoc and inconsistent.

The Commission therefore proposes changes to strengthen EU pharmacovigilance and rationalise procedures. Your rapporteur generally welcomes the Commission's approach but has strengthened its proposals in some areas. The following are, your rapporteur believes, the main points.

**1. Strengthened EU Committee on Pharmacovigilance:**

The rapporteur believes the Commission is right to replace the existing Pharmacovigilance working party with the Pharmacovigilance Risk Assessment Advisory Committee (PRAAC). Most experts agree that the existing working party system works in a rather ad hoc manner, focusing only on drugs authorised through the central procedure and lacking the status to ensure its findings are acted on by the Committee for Medicinal Products for Human Use (CHMP) which oversees the whole system. However, the rapporteur believes that the PRAAC 's role can be strengthened still by giving it the power to recommend action to the CHMP rather than simply providing advice to it and be extending its membership to one representative per Member State. To reinforce the transparency of the work of the PRAAC, your rapporteur also proposes that two additional representatives be appointed to represent patients and healthcare professionals, as is the case with other EMEA Committees.

**2. The role of Member States in the system:**

Your rapporteur believes that Member States must remain key players in the EU pharmacovigilance system. As proposed by the Commission, the competent authority(CA) in each Member State should continue to act as the clearing house for all spontaneous reporting of ADRs and healthcare professionals and patients should continue to report ADRs to their CA and not directly to Eudravigilance (the EU database of ADRs). The rapporteur understands the concerns of Member States at the Commission proposal to allow a company to make a single report to Eudravigilance on an ADR rather than to every Member State (see point 2). She believes that Member States must be immediately informed if a company reports an ADR which happened on its territory to the Eudravigilance database and suggests that a system to alert relevant Member States simultaneously be established.

**3. The role of companies in the system:**

Several useful changes are proposed which affect companies. The rapporteur particularly welcomes proposals which ensure better follow up and coordination of the assessments of ADRs by preventing duplicate work in different Member States. She therefore supports direct reporting to Eudravigilance by companies (with the safeguards in point 3) and the work-sharing mechanisms for follow-up to Periodic Safety Reports coordinated through the PRAAC.

**4. The role of Healthcare professionals:**

Your rapporteur supports measures to encourage healthcare professionals to voluntarily report ADRs to their competent authority and wants to strengthen their role in informing and encouraging patients to report.

**5. The role of patients:**

Patients are key to “signal detection” of ADRs. Your rapporteur supports proposals to encourage the “informed patient” and strongly supports the new provisions to allow direct patient reporting of ADRs, though she believes this should be to competent authorities and not companies. At present, only a few Member States accept direct reporting but where it exists, the system has not overburdened the competent authority. The informed patient also needs to know when they are taking new drugs .The rapporteur therefore also supports the proposal for Intensively Monitored Products and believes the system should not only inform patients who are prescribed a new product but encourage them to report ADRs. She has tabled a number of amendments to improve information on the Patient Information Leaflet (PIL) to that effect.

**6. The Patient Information Leaflet (PIL):**

A number of stakeholders are unhappy with the proposal by the European Commission to include the “black box” with essential information on the PIL. Your rapporteur understands those concerns, in particular that what is essential to one patient may not be essential to all patients. However, she also feels that the current PIL is not satisfactory from a patient point of view and that there needs to be a clearer indication of the main features of the drug for patients . It is possible that the best solution would be to remit this problem to a general review of the PIL For this reason, she has not tabled any amendments herself to the Commission proposals .

**7. The reporting of ADRs:**

The new system proposes that all ADRs (and not just serious ones) are reported to the Eudravigilance database by Competent Authorities and Companies. This means that information on all ADRs will, for the first time, be centralised in one place in the EU. This can be a valuable research tool for all. The Commission needs to ensure, however, that Eudravigilance is able to cope with the surge of information and by putting systems in place so that the most serious ADRs are clearly flagged up. If all ADRs are recorded on Eudravigilance, the rapporteur sees the logic of cutting back on the requirement by companies to provide line by line reporting of ADRs in PSURs . Instead of just presenting raw data, companies will be required instead to analyse the ADRs and present summaries of their findings. This makes sense, particularly since the rapporteur has learned that competent authorities have often been overwhelmed by the sheer volume of PSURS they have received in the past, with the result that many have gone unread. The speed with which ADRs are reported to Eudravigilance is of paramount importance for patient safety. The rapporteur is therefore concerned to hear that both companies and Member States have failed to meet the current requirement to report ADRs within 15 days. However, Member States are by far the worst "offenders": 5% of company reports were late compared with 50% of Member State reports. The Rapporteur has therefore sought to include provisions to ensure better compliance mechanisms.

**8. Urgent action or "Community procedure" :**

Your rapporteur welcomes the inclusion of clearer provisions for when an urgent procedure is triggered. Member States need to work quickly together to act when a serious ADR occurs.

**9. Transparency:**

Your rapporteur welcomes the proposals to bring more transparency to the EU pharmacovigilance system. She welcomes the expansion of the web portal and the use of public hearings to gather evidence about ADRs. She believes public hearings should not only be used in the case of urgent action, but could also be useful tools for normal pharmacovigilance and has therefore proposed an amendment along these lines.

## 3. FALSIFIED MEDICINAL PRODUCTS

### EXPLANATORY STATEMENT

The Commission's proposal on the prevention of falsified medicines entering the supply chain highlights a concern which is getting higher and higher on the agenda of the European citizens: the quality and safety of the medicinal products they are consuming. Therefore the Rapporteur welcomes the Commission proposal to combat falsified medicines as a necessary step to respond to this rising health threat and to better ensure patients' safety.

**The problem**

The impact assessment by the Commission (SEC(2008)2674) mentions inter alia the following very alarming observations:

– A sharp increase in seizures of falsified medicines by customs (2.7 million medicinal products at EU custom borders in 2006 and 2.5 million in 2007; an increase of 384% compared to 2005)

– A trend from the falsification of 'lifestyle' medicines to life-saving medicines, including medicines to treat cancer and heart disease, psychiatric disorders and infections. Treatment with such falsified medicines can have fatal consequences.

– A trend towards targeting the classical supply chain. Besides the internet, the licensed distribution chain is increasingly targeted. Out of 13 Member States who had data, seven reported incidences of counterfeit medicinal products in the legal supply chain.

– It needs to be emphasised that, according to the expert group of the WHO, many countries in Africa, parts of Asia and Latin America have areas where more than 30% of the medicines on sale can be falsified. Policies to prevent falsified medicines on the European market should also have positive impacts in other regions of the world where the problem is even more prominent.

Patients need to be absolutely sure that the medicines they consume are really the medicines they expect it to be. The use of falsified medicines can result in therapeutic failure and can put lives at risk. Your Rapporteur therefore believes that the protection of public health against falsified medicines should be the main focus of the directive. This focus should not be troubled by other additional objectives.

The directive should not concern intellectual property and patent rights, which are already covered by other specific legislative frameworks.

**Double legal basis**

Your Rapporteur chooses to have a double legal basis for this directive. Falsifying of medicinal products is a criminal act that denies patients the necessary medical treatment and is harmful to their health, sometimes even leading to their death. Therefore the first and most important objective of the directive should be the protection of public health. This should be reflected in the legal basis on the directive. This is in line with the draft Convention of the Council of Europe which puts the focus on public health.

**Definitions and responsibilities**

To be able to better safeguard the distribution network for medicinal products it is crucial to have clear definitions on not only the scope, but also on the different actors in the supply chain. What is a falsified medicinal product? What is an active ingredient or an excipient? The Commission proposal does not provide the required clarity. The same applies for the definitions of the different actors in the chain of supply, clarifying their roles and responsibilities. It is essential to make a distinction between those actors who are already formally recognized - and which role is considered liable - and those who are outside that category, although being relevant to the liability of the distribution chain. Therefore it is important to make the distinction between traders and brokers, as well as to clarify their roles and responsibilities. The same applies for other actors, such as transporters or parallel traders. The directive should prevent confusion and should not allow any room for 'grey' areas. It should clearly identify which actors and under which conditions are able to operate in this domain. Clearer definitions will result in simpler implementation.

**Sanctions**

The falsification of medicinal products is not a minor offence. It is an organised criminal activity that puts human lives at risk. Sanctions against falsification should reflect this and should be equivalent to those typically applied for illegal acts related to narcotics. It is crucial to strengthen the relevant provisions on sanctions in the Commission's proposal.

**Safety features**

Member States make the distinction between prescription and non prescription medicines since prescription medicines result in higher risks for the patient either when falsified or when unduly taken. Therefore safety features must be mandatory for prescription medicines. It needs however to be recognised that medicines will only be falsified if there are economic reasons for doing so. Because of the low costs of generic medicinal products it is less profitable to falsify this group of medicines. Therefore your Rapporteur is of the opinion that, only if this is in accordance with the conclusions of a risk assessment, the performance criteria for the safety features can be waived for certain generic medicinal products or product categories. Your Rapporteur furthermore proposes to assess within five years after the entry info force of this directive whether safety features should also be mandatory for the so called over the counter medicines.

**Excipients**

When patients take medicinal products they do not only consume the active ingredients, but also the excipients. The consequences of the use of falsified excipients are well documented. Examples of severe consequences include the death of 89 people in 1995, and of, at least, 59 children in 1996 in Haiti, or the death of 30 children in India, in 1998. The Rapporteur therefore included the excipients in the draft report. The quality and authenticity of the falsified medicines should be verified.

**Internet sales**

The Commission proposal does not address internet sales, considering it as part of the illegal chain of supply. This does not reflect the fact that in some Member States internet sales are legalized. It is well known that internet represents one of the main routes for falsified medicinal products to enter the European market. Your Rapporteur chooses to include provisions in the draft report to deal with this important route. The first priority is to increase public awareness of the risks of buying medicinal products through the internet. Educational programmes to increase consumer awareness about the existence of falsified products and the risk of buying medicines from unauthorised channels should be put in place. The second priority is to ensure that patients can recognise those sites which are in compliance with the relevant legislation. A directive aiming at fighting the falsification of medicines, without dealing with internet, the most important route, is not explainable to the public. Addressing this route is one of the key issues in the draft report.

**Information and Reporting**

The creation of a network between the Commission, the European Medicines Agency and the competent authorities in Member States would help to have more data and a better understanding of the phenomenon so as to better tackle it. The Commission, European Medicines Agency and the competent authorities in the Member States shall report annually to this network on the actions they have undertaken.

**International cooperation**

Coordination between various national and international bodies involved in fighting falsified medicines is necessary. It's important to improve international collaboration and develop appropriate multilateral mechanisms that will enable importing countries to trigger investigations and identification of the actual source of counterfeit medicines entering their markets.

**Imports inspections**

This Directive focuses on the quality control of the import of medicinal products, since this is one of the key entry doors of falsified medicines to the European market. Therefore your Rapporteur considers it to be crucial to create an inspections system which is mainly based on the Good Manufacturing Practices already defined through international agreements. The already existing international cooperation, together with the experience in the Member States are key anchors for a strengthened efficient detection system of falsifications.

**Exports**

The Commission proposal does not address the control and distribution of falsified medicines to third countries. It is difficult to explain why we have stringent provisions for medicines that enter the European market in order to find the responsible actors if medicines are falsified, but no provisions for medicines which are exported to third countries in Africa, South America or Asia. This significantly weakens the possibility for Europe to insist on stronger international cooperation. The manufacturing and the distribution of medicines from the EU to third countries must obey the same criteria as applied for the import. This would strengthen our contribution to fight the criminal falsification of medicines in several third countries where, according to WHO estimates, the problem is very serious.

**Final remarks**

Within this directive several often contradictory interests are at the stake. For some actors the solution involves the reduction of intermediaries; others would prefer the maintenance of the already existing procedures without taking part in the sharing of responsibilities or costs. Some actors support the principle that this Directive should focus on the risks of the products; some support the focus on the risks of the chain. Your Rapporteur truly believes that the directive should take into account the different interests, but that it should focus on our common interest - patient safety. This is the guiding principle for the amendments in the draft report.

# ANNEX 3: MAIN STAKEHOLDERS

## 1. PROFESIONAL ORGANISATIONS

**Standing Committee of European Doctors.** CPME aims to promote the highest standards of medical training and medical practice in order to achieve the highest quality of health care for all patients in Europe. CPME is also concerned with the promotion of public health, the relationship between patients and doctors and the free movement of doctors within the European Union. CPME represents the National Medical Associations of 27 countries in Europe and works closely with the National Medical Associations of countries that have applied for EU membership as well as specialized European medical associations. It is an international, not for profit association under Belgian Law composed of the National Medical Associations of the European Union. To achieve its goals, CPME co-operates proactively with the Institutions of the European Union. Policies are being set both in answer to developments in Europe as well as by taking the lead in matters regarding the profession and patient care.

Statements from the CPME on the pharmaceutical package can be found on:
www.euractiv.com/en/health/eu-ease-drugs-ad-rules-upcoming-pharma-package/article-174648
and on the CPME website:
www.cpme.be

**PGEU**. The Pharmaceutical Group of the European Union is the European association representing community pharmacists. PGEU's members are the national associations and professional bodies of community pharmacists in 30 European countries including EU Member States, EU candidate countries and EFTA members. Through its members, PGEU represents around 400,000 community pharmacists contributing to the health of over 500 million people throughout Europe. It is estimated that over 46 million people visit the community pharmacies in the EU member states every day.

PGEU website is:
www.pgeu.org

## 2. INDUSTRY

**EFPIA** is the European Federation of Pharmaceutical Industries and Associations (EFPIA) representing the pharmaceutical industry operating in Europe. Through its membership of 31 national associations and 40 pharmaceutical companies, EFPIA is the voice on the EU scene of 2,200 companies.

EFPIA's position of the Pharmaceutical Package can be found at:

www.efpia.org/content/default.asp?PageID=574

## 4. ASOCIATIONS & PATIENTS ORGANISATIONS

**EPHA** is the European Public Health Alliance, an international non-profit association registered in Belgium. Membership is composed of not-for-profit organisations working on all aspects of public health. EPHA's mission is to promote and protect the health of all people living in Europe and to advocate for greater participation of citizens in health-related policy making at the European level.

EPHA releases its updated position on pharmacovigilance
www.epha.org/a/3725?var_recherche=pharma+pack
On 1 November 2009, EPHA released its updated position pharmacovigilance. The document brings the perspective of the public health community on this relevant policy dossier, further to a consultation of EPHA's membership. The position paper aims at inputting the debate in the European Parliament and Council on the Pharmacovigilance directive and regulation from the Pharmaceutical package.

Another article about EPHA's view on the pharmaceutical package can be found here:
www.epha.org/a/3313?var_recherche=pharma+pack

## 5. INTERNATIONAL ORGANISATIONS

**WHO Europe.** WHO is the authority responsible for public health within the United Nations system. The WHO Regional Office for Europe (WHO/Europe) is one of WHO's six regional offices around the world. It serves the WHO European Region, which comprises 53 countries, covering a vast geographical region from the Atlantic to the Pacific oceans. WHO/Europe collaborates with a range of public health stakeholders in the Region and globally, to ensure that coordinated action is taken to develop and implement efficient health policies and to strengthen health systems. Ms Zsuzsanna Jakab has been at WHO/Europe's helm since 1 February 2010, as WHO Regional Director for Europe. The WHO Europe and other partners run the European Observatory on Health Systems & Policies.

The EURO WHO website:
www.euro.who.int/en/home
The Observatory website:
www.euro.who.int/en/home/projects/observatory

# ANNEX 4: KEY CONTACT POINTS

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EUROPEAN PARLIAMENT

DIRECTORATE-GENERAL FOR INTERNAL POLICIES

# POLICY DEPARTMENT A
## ECONOMIC AND SCIENTIFIC POLICY

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**Note on the Pharmaceutical Package for the EP Information offices (EPIOs)**