Basic information

1999/0134(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Medicinal products for human use: Community code. Codification Amended by 2000/0323(COD) Amended by 2001/0253(COD) Amended by 2002/0008(COD) Amended by 2004/0217(COD) Amended by 2005/0227(COD) Amended by 2006/0295(COD) Amended by 2008/0045(COD) Amended by 2008/0260(COD) Amended by 2008/0261(COD) Amended by 2012/0025(COD) Amended by 2012/0266(COD) Amended by 2014/0256(COD) Amended by 2021/0431(COD) **Subject** 4.20.01 Medicine, diseases 4.20.04 Pharmaceutical products and industry	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
JURI Legal Affairs and Internal Market	BEYSEN Ward (ELDR)	06/03/2001

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health, Consumer Policy		

Council of the European Union

Council configuration	Meetings	Date
Competitiveness (Internal Market, Industry, Research and Space)	2371	2001-09-27

European Commission

Commission DG	Commissioner
Legal Service	

Key events

Date	Event	Reference	Summary

28/06/1999	Initial legislative proposal published	COM(1999)0315	Summary
23/07/1999	Committee referral announced in Parliament, 1st reading		
15/12/2000	Legislative proposal published	COM(2000)0830	Summary
26/06/2001	Vote in committee, 1st reading		
03/07/2001	Decision by Parliament, 1st reading	T5-0364/2001	Summary
27/09/2001	Act adopted by Council after Parliament's 1st reading		
06/11/2001	Final act signed		
06/11/2001	End of procedure in Parliament		
28/11/2001	Final act published in Official Journal		

Technical information

Procedure reference	1999/0134(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Codification
Legislative instrument	Directive
Amendments and repeals	Amended by 2000/0323(COD) Amended by 2001/0253(COD) Amended by 2002/0008(COD) Amended by 2004/0217(COD) Amended by 2005/0227(COD) Amended by 2006/0295(COD) Amended by 2008/0045(COD) Amended by 2008/0260(COD) Amended by 2008/0261(COD) Amended by 2012/0025(COD) Amended by 2012/0266(COD) Amended by 2014/0256(COD) Amended by 2021/0431(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095 Rules of Procedure EP 52-p1
Stage reached in procedure	Procedure completed

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Text adopted by Parliament, 1st reading/single reading		T5-0364/2001 OJ C 065 14.03.2002, p. 0021-0033 E	03/07/2001	Summary

European Commission

Document type	Reference	Date	Summary
	COM(1999)0315		

Initial legislative proposal		28/06/1999	Summary
Legislative proposal	COM(2000)0830	15/12/2000	Summary
Follow-up document	COM(2007)0862	20/12/2007	Summary
Follow-up document	SEC(2007)1740	20/12/2007	
Follow-up document	COM(2008)0584	29/09/2008	Summary
Follow-up document	COM(2015)0138	30/03/2015	Summary
Follow-up document	COM(2016)0498	08/08/2016	Summary
Follow-up document	SWD(2016)0284	08/08/2016	
Follow-up document	COM(2017)0135	22/03/2017	Summary
Follow-up document	COM(2021)0497	31/08/2021	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0933/1999 OJ C 368 20.12.1999, p. 0003	21/10/1999	
EU	Implementing legislative act	32003L0063 OJ L 159 27.06.2003, p. 0046-0094	25/06/2003	Summary

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Directive 2001/0083
OJ L 311 28.11.2001, p. 0067 Summary

Delegated acts

Reference	Subject

2015/2890(DEA)	Examination of delegated act
2014/2759(DEA)	Examination of delegated act
2021/2616(DEA)	Examination of delegated act
2021/3053(DEA)	Examination of delegated act
2021/2800(DEA)	Examination of delegated act
2021/2510(DEA)	Examination of delegated act

Medicinal products for human use: Community code. Codification

1999/0134(COD) - 03/07/2001 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted the proposal without debate.

Medicinal products for human use: Community code. Codification

1999/0134(COD) - 29/09/2008 - Follow-up document

The Commission presented its report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC, as amended by Directive 2004/24/EC, on specific provisions applicable to **traditional herbal medicinal products**.

Under Articles 16a to 16i of Directive 2001/83/EC, introduced by Directive 2004/24/EC, a specific registration procedure is to be used by the Member States for herbal medicinal products that meet the criteria for a traditional herbal medicinal product. Herbal medicinal products are defined as any medicinal product exclusively containing as active ingredients one or more herbal substances, one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations. Article 16i requires the Commission to submit a report to the European Parliament and to the Council concerning the application of the simplified registration procedure and including an assessment of the possible extension of traditional-use registration to other categories of medicinal products. This document was prepared in consultation with the European Medicines Agency and the Committee on Herbal Medicinal Products (HMPC) and was submitted for consultation to the Member States and interested parties. As a major source of information, the Commission welcomed the HMPC report of 31 October 2006 (Doc.Ref.EMEA/HMPC/187219/2006) presenting the views of the EMEA and the HMPC.

The report recalls that Directive 2004/24/EC was intended to address the specific situation of medicinal products that, despite their long tradition of use, do not fulfil the requirements for a marketing authorisation as set out in the Community pharmaceutical legislation. By introducing a simplified registration procedure with specific requirements, the Directive aimed to allow these products to be marketed under harmonised conditions and to ensure the protection of public health by making such products subject to the necessary guarantees of quality, safety and efficacy. During the public consultation on the draft of this report, numerous supportive views were expressed on the setting of harmonised safety standards for traditional products.

During the public consultation, some stakeholders referred to the experience with the application of the requirements of the simplified registration procedure. In particular, **the issue of genotoxicity data** needs careful consideration from a scientific and legal point of view. The requirement for genotoxicity data should be considered on a case by case basis in the framework of the simplified registration, because wrong interpretation of the legal requirements could possibly lead to the marketing of some products under another qualification that would not necessarily offer the same guarantees of quality, safety and efficacy. Such a result would be contrary to the public health and harmonisation objectives of Directive 2001/83/EC and Directive 2004/24/EC. In order to overcome this difficulty, **a case-by-case decision**, where specific concerns about safety exist, appears to be a proportionate and balanced approach and in line with the objectives of the Directive.

As regards the **possible extension of the scope of the Directive**, any such extension should be in line with the objectives of Directive 2004/24/EC, i.e. to have harmonised rules for the placing on the market of certain medicinal products with a long tradition of use but which do not generally satisfy the requirements for marketing authorisation, while ensuring the protection of public health by introducing specific requirements for proof of quality, safety and efficacy. In this regard, the European Commission is prepared to **consider extending the simplified registration procedure to products other than herbal substances with a long tradition of safe use**. This proposal received general support during the public consultation on the draft of this report. On the other hand, the key requirements of the simplified registration procedure, based on public health considerations, such as the limitation to products with 15 years use in the Community, to certain routes of administration and to products that do not need the supervision of a medical practitioner, should be maintained. For certain requirements, more experience is needed before any change to the system can be proposed.

The proposed extension would enable certain medicinal products from specific European or non-European medicine systems (such as — in alphabetical order — anthroposophic, Ayurvedic, Chinese, Kampo Korean, Mongolian, Thai, Tibetan Unani, or Vietnamese medicine), as well as **traditional products with a long-standing tradition** in the European Union (such as honey, royal jelly, propolis, fish oils, minerals, micro-organisms and other substances) to be eligible for the simplified registration procedure with a view to placing them on the market as traditional medicinal products.

Many of these products are present in the Community market, and their inclusion under the simplified registration procedure will introduce harmonisation in a sector where differences currently exist between Member States as regards classification and placing on the market and will increase the protection of public health since the quality, safety and efficacy of the products concerned will be assessed during the simplified registration procedure.

During the public consultation, proponents of **three traditional medical systems** using products with a long-standing tradition expressed support for the global regulation of their traditions within the EU: anthroposophic, Ayurvedic and traditional Chinese medicine. It was suggested that proof of the plausibility of efficacy should not be by medicinal product, but by therapeutic approach.

Medical traditions such as those mentioned above are based on a holistic approach, and the set of requirements for the simplified registration procedure under Directive 2004/24/EC is not appropriate for a global regulation of such medical practices. The regulation of such traditions would demand a different approach from that introduced by Directive 2004/24/EC. Therefore, **the Commission does not envisage extending the scope of the simplified registration procedure to cover traditional medical systems as such**. Nevertheless, independently of this report, the suitability of a **separate legal framework** for products of certain traditions should be assessed.

Medicinal products for human use: Community code. Codification

1999/0134(COD) - 28/06/1999 - Initial legislative proposal

PURPOSE: the legislative codification of a series of Council Directives dealing with medicinal products for human use. CONTENT: The new Directive will supersede the various Directives incorporated in it; their contentis fully preserved and they are brought together with only such formal amendments as are required by the codification exercise itself.

Medicinal products for human use: Community code. Codification

1999/0134(COD) - 20/12/2007 - Follow-up document

The Commission presented a report on the current practice with regard to the provision of information to patients on medicinal products, in accordance with Directive 2001/83/EC, as amended by Directive 2004/27/EC on the Community code relating to medicinal products for human use.
This report reviews the activities carried out by Member States concerning the provision of information on medicinal products in order to respond to the needs of patients/consumers under the applicable legislative framework. Particularly, the report addresses the use of the Internet on the provision of information and its role in improving access to information.

The basic content of the report is based on information provided by Member States, as well as information published in various literature sources and contributions from patient groups, health professional organisations and other stakeholders. The report also takes into account discussions within the Pharmaceutical Forum on Information to Patients. Within this overall framework and based on a thorough analysis the report considers in particular: (i) existing information mechanisms and technologies on an EU and Member States level; (ii) the needs of patients; (iii) the role of different stakeholders.

The main findings of the report are as follows:

(a) based on a common basic principle that advertising to the public is prohibited for prescription-only medicines, evidence shows that the rules and practices on what information can be available still vary significantly among Member States. This results in **unequal access of patients, and the public at large, to information** on medicinal products;
(b) at the same time, **patients have become more empowered and proactive** regarding the treatment of their illnesses. Information needs of patients as regards medicinal products range from information on adverse effects to information about efficacy of the medicine to treat the disease concerned, including also information about the costs and duration of treatments;
(c) in general, the **Internet** plays a central role for those who are seeking information, even though non-electronic tools are still relevant for large parts of the population (like the elderly, or patients with special needs).
(d) the **quality of information** is currently very variable, in particular in view of the Internet where the providers have no or limited accountability toward EU citizens. Mechanisms such as educating consumers, encouraging self-regulation of healthcare providers, evaluation of information by third parties and the use of different enforcement procedures can be potential tools for quality management of information;
(e) currently, **public authorities** play a central role in providing information. However, the information that they provide varies widely, thus creating inequalities in access to information about medicines throughout the EU;
(f) **national authorities** may not be in a position to fully address patients' needs in terms of the substance of information and the access via different means. In turn, the pharmaceutical industry possesses the key information on their medicines but this information can currently not be made available to patients and healthcare professionals throughout the EU.

The public consultation has provided an extensive set of contributions where views from the different sectors were expressed. Opinions expressed on the way forward converged as regards the need to: (i) improve information to patients, (ii) adopt common standards and quality criteria, (iii) distinguish between advertising and information, (iv) keep the ban on direct-to-consumer advertising on prescription-only medicines, and (v) recognise the Internet as an important information channel. Different views were expressed on how to improve provision of information to patients, on the role of the pharmaceutical industry and on the mechanisms to regulate and enforce applicable rules.

On the basis of the outcome of this consultation, the Commission intends to propose, to the European Parliament and the Council, amendments to the current rules on the provision of information to patients by the end of 2008. This proposal will put the interests of patients first and, with this perspective, should aim to reduce differences in access to information and should ensure the availability of good-quality, objective, reliable and non-promotional information on medicinal products. The following main policy objectives will be pursued by this legal proposal:

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establishing a framework which provides citizens of EU Member States with understandable, objective, high-quality and non-promotional information about the benefits and the risks of their medicines, and which maintains the confidence of citizens, regulators and healthcare professionals;
- maintaining the ban on direct-to-consumer advertising of prescription medicines, making sure that there is a clear distinction between advertising and non-promotional information;
- avoiding unnecessary bureaucracy, in line with the principles of Better Regulation.

In accordance with Better Regulation practices, the proposal will be substantiated by an impact assessment of the different policy options.

Medicinal products for human use: Community code. Codification

1999/0134(COD) - 15/12/2000 - Legislative proposal

In view of the legslative modifications following the initial proposal and in light of the work carred out within the Council, the Commission has decided to present a codified amended proposal.

Medicinal products for human use: Community code. Codification

1999/0134(COD) - 25/06/2003 - Implementing legislative act

COMMUNITY MEASURE : Commission directive 2003/63/EC amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use. CONTENT : the detailed scientific and technical requirements of Annex I to Directive 2001/83/EC need to be adapted to take account of scientific and technical progress and in particular of a large set of new requirements resulting from recent legislation. The presentation and content of the marketing authorisation application dossier have to be improved in order to facilitate the assessment and the better use of certain parts of the dossier which are common to several medicinal products. It is appropriate to establish a new system aimed at simplifying procedures for both the approval of and subsequent changes to human plasma-derived medicinal products. The standardised marketing authorisation dossier requirements (harmonised format) should be applicable to any type of medicinal product for human use, regardless of the procedure for the granting of the marketing authorisation. Some medicinal products present, however, such specific features that all the requirements cannot be fulfilled. To take account of these particular situations, a simplified dossier presentation should be provided for. To this end the concept of a plasma master file (PMF) should be introduced, in particular in order to allow the pooling of national expertise and through the coordination by the EMEA of a single evaluation. A PMF should serve as a stand-alone document, which is separate from the marketing authorisation dossier and through which a harmonised control of the relevant information regarding starting material used for the manufacture of plasma-derived medicinal products could be achieved. The PMF system should consist of a two-step assessment: first, an assessment of the PMF carried out at Community level, the result of which, i.e. a certificate of compliance with the Community legislation for each PMF, must be taken into account by any national competent authority, preventing them of any subsequent reassessment; second, an assessment of the finished plasma-derived medicinal product containing the modified part of the PMF (the two essential parts of the content, plasma origin and plasma quality-safety). This should remain the task of the competent authority that granted the marketing authorisation for the plasma-derived medicinal product. In the case of vaccines for human use, the same antigen may be common to several medicinal products (vaccines) and any change to that particular antigen, ipso facto, may impact, therefore, on several vaccines authorised by different procedures. In order to simplify the existing procedures for the assessment of such vaccines, both for the granting of a first marketing authorisation and for subsequent changes to it due to modifications to the manufacturing process and testing of individual antigens involved in combined vaccines, a new system based on the concept of a vaccine antigen master file (VAMF) should be introduced. This VAMF will allow the pooling of national expertise, and through the coordination by the EMEA, a single evaluation of the concerned vaccine antigen. The VAMF should serve as a stand-alone part of the marketing authorisation dossier and provide allrelevant information of a biological and chemical nature related to one specific antigen, which constitutes one of the active substances of one or several combined vaccines. The VAMF system should consist of a two-step assessment: first, an assessment of the VAMF carried out at Community level, the result of which, i.e. a certificate of compliance with the Community legislation for each VAMF, must be taken into account by any national competent authority, preventing them from any subsequent reassessment; second, an assessment of the finished medicinal product (combined vaccine) containing the modified antigen which is the task of the competent authority that granted the combined vaccine marketing authorisation. Herbal medicinal products differ substantially from conventional medicinal products in so far as they are intrinsically associated with the very particular notion of herbal substances and herbal preparations. It is therefore appropriate to determine specific requirements for herbal medicinal products with regard to the standardised marketing authorisation requirements. Lastly, the treatment of various acquired and inherited pathological dysfunctions in humans calls upon novel concept-based approaches based on the development of biotechnology techniques. The latter involve the use of advanced therapy medicinal products based on processes focused on various gene-transfer-produced bio-molecules (gene therapy medicinal products) and manipulated or processed cells (cell therapy medicinal products) as active substances. The general principles already applicable to these products should be specified from a scientific and technical point of view and the specific requirements with regard to the standardised marketing authorisation requirements should be determined.

Medicinal products for human use: Community code. Codification

1999/0134(COD) - 06/11/2001 - Final act

PURPOSE : to codify and expand Community provisions on medicinal products for human use.

COMMUNITY MEASURE : Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use.

CONTENT : This directive codifies and assembles in a single text the following directives, which have been frequently and substantially amended:

Council Directive 65/65/EEC, Council Directive 75/318/EEC, Council Directive 75/319/EEC, Council Directive 89/342/EEC, Council Directive 89/343 /EEC, Council Directive 89/381/EEC, Council Directive 92/25/EEC, Council Directive 92/26/EEC, Council Directive 92/27/EEC, Council Directive 92/28 /EEC and Council Directive 92/73/EEC.

There are also the following main provisions:

- A Committee for Proprietary Medicinal Products is set up, attached to the European Agency for the Evaluation of Medicinal products, established in Regulation 2309/93/EEC. This body will deal with cases where there is disagreement between Member states about the quality, the safety or the efficacy of a medicinal product. A scientific evaluation of the matter is undertaken according to a Community standard, leading to a single decision on the area of disagreement which is binding on the Member States concerned.
- To avoid any unnecessary duplication of effort regarding the obtaining of marketing authorization, Member States must systematically prepare assessment reports in respect of each medicinal product which is authorized by them, and exchange the reports upon request. A Member State must suspend consideration of an application for marketing authorization if it is currently under active consideration in another Member State, with a view to recognising the decision made by the latter Member State.
- Minimum requirements are laid down for manufacture and imports coming from third countries and for the grant of authorization relating to them. - There are specific provisions for immunological medicinal products, homeopathic medicinal products, radiopharmaceuticals, and medicinal products based on human blood or plasma.

ENTRY INTO FORCE : 18 December 2001.

Medicinal products for human use: Community code. Codification

1999/0134(COD) - 30/03/2015

The Commission presented a report on the exercise of the delegation of powers conferred on the Commission pursuant to:

- **Directive 2001/83/EC** of the European Parliament and of the Council on the Community code relating to medicinal products for human use;
- Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

Delegation of power: pursuant to the aforementioned texts, the power to adopt delegated acts is conferred on the Commission for five years from January 2011. The Commission is required to report on its exercise of those powers at the latest six months before the end of this period.

The Medicinal Product Directive, as amended by Directive 2010/84/EU and Directive 2011/62/EU, empowers the Commission to adopt delegated acts on:

- post-authorisation efficacy studies (Article 22b),
- the principles of good manufacturing practice for active substances (Article 47),
- criteria to assess the potential falsified character of medicinal products transiting through the EU (Article 52b) and
- safety features for medicinal products (Article 54a).

Exercise delegated powers: to date the Commission has exercised the delegated powers provided for by Regulation (EC) No 726/2004 and in two of the four instances provided for by Directive 2001/83/EC.

Post-authorisation efficacy study: under Article 22b of the Medicinal Product Directive, the Commission is empowered to specify the situations in which post-authorisation efficacy studies may be required.

The Commission adopted the Delegated Regulation (EU) No 357/2014 and notified the European Parliament and the Council of it. Neither institution objected to the delegated act. The Commission Delegated Regulation was published in the Official Journal and entered into force on 30 April 2014.

Good manufacturing practice for active substances: as a result of the amendment to the Directive on medicinal use of products for human use introduced by Directive 2011/62/EU, since 2 January 2013, the manufacturing of active substances has been subject to good manufacturing practice for active substances regardless of whether the substances are manufactured in the Union or imported.

In this context, it is necessary to set EU-wide standards for the manufacturing of active substances and to harmonise the implementation and enforcement of these standards throughout the EU. To this end, the Commission is empowered to adopt, by means of delegated acts, measures supplementing the provisions of that Directive on good manufacturing practice for active substances.

The Commission adopted the Delegated Regulation (EU) No 1252/2014 and notified the European Parliament and the Council of it on 17 July 2014. The European Parliament decided to extend the deadline for objections until 17 November 2014, but neither it nor the Council issued any objections. The Delegated Regulation was published in the Official Journal and entered into force on 15 December 2014.

Other delegations:

Safety measures for medicinal products (Article 54a): the Commission intends, **before the end of 2015**, to adopt a delegated regulation supplementing the Directive with regard to the detailed rules for the safety features appearing on the packaging of medicinal products for human use.

To prepare this delegated regulation, the Commission carried out extensive consultations with interested parties. An Expert Group on the delegated act on safety features for medicinal products for human use was set up.

Evaluation criteria of the potential falsified character of medicinal products introduced into the EU (Article 52b): the public consultation carried out by the Commission showed that Member States' and stakeholders' interest in the proposed measures was limited. Consequently, **the Commission does not intend to initiate work** on a delegated act at this stage

In conclusion, **the Commission is of the view that the delegated powers** conferred by Articles 22b, 47, 52b and 54a of Directive 2001/83/EC, as amended by Directive 2010/84/EU and Directive 2011/62/EU, **should remain in force**.

Medicinal products for human use: Community code. Codification

1999/0134(COD) - 22/03/2017 - Follow-up document

In accordance with Directive 2001/83/EC on the Community code relating to medicinal products for human use, the Commission presented an assessment report on current shortcomings in the summary of product characteristics and the package leaflet and how they could be improved in order to better meet the needs of patients and healthcare professionals.

The Directive requires that a summary of product characteristics and a package leaflet be included in the application for authorisation to place medicinal products on the market in the Union.

Based on two studies by external experts and a European-wide stakeholder survey, the report concluded that the current EU legislation on medicinal products for human use allows for **enhancement of the statutory medicines information** to support the safe and effective use of medicinal products.

The following recommendations were made:

- more focus on **improving the package leaflet** rather than the summary of product characteristics. The clarity of the notice and its readability could be improved. The language used is often too complex and the presentation is not always practical. The elderly and those who have low literate skills are particularly disadvantaged;
- revise the **existing guidelines**, in particular, the readability guideline, the packaging information guideline and, where appropriate, the summary of product characteristics guideline. These revisions should also include the introduction of guidance on **translations** that go beyond the principle of faithful translation to ensure that the lay language introduced through user testing in the original language version is not lost during translation;
- **the input from patients during the process and the related methodology** should be further improved, for example, by considering the requirement to make the user testing process more iterative and to ensure that a sufficiently mature version of the package leaflet is user-tested. This iterative user-testing would be coordinated by regulatory authorities in parallel to the assessment in a way that does not disrupt the whole marketing authorisation process. It should focus on the content of the package leaflet rather than on format and layout;
- **best practice examples** of aspects of the package leaflet and the summary of product characteristics design could be made available for pharmaceutical companies on a platform that would be suitable for that purpose and that could be regularly updated;
- explore how **electronic formats** can be used to provide the information to individual EU-citizens in accordance with the existing legislation (e. g. in terms of presentation, format or use of multiple languages). For example, developing mechanisms through electronic tools to inform patients and healthcare professionals on changes in the SmPC and PL should be considered. The exploratory work in this area should be based on and further develop the existing work done by the European Medicines Agency in this area and should follow a multi-stakeholder approach involving also the pharmaceutical industry, patients, consumers, healthcare professionals, the Member States and the Commission. The aim will be to develop the key principles for the use of electronic summary of product characteristics and package leaflet formats;
- the **potential introduction of the "key information" section** in the summary of product characteristics and package leaflet with the objective to allow patients and healthcare professionals to rapidly identify key safety messages, balanced with information on the benefits of medicines, has been also subject to the assessment. It is suggested to continue further exploratory work on the use of such key information in the package leaflet.

Lastly, the Commission and the European Medicines Agency will work towards implementation of the above-mentioned recommendations in close collaboration with the Member States. It will be ensured that the key stakeholders will be duly consulted and involved as appropriate with regards to the respective proposed possible actions.

Medicinal products for human use: Community code. Codification

1999/0134(COD) - 08/08/2016

The Commission presented a report on pharmacovigilance related activities of Member States and the European Medicines Agency (EMA) concerning medicinal products for human use (2012 – 2014).

The EU legal framework of pharmacovigilance for medicinal products for human use is established by Regulation (EC) No 726/2004 and **Directive 2001/83/EC**. The legislation was amended in 2010 and 2012.

Pharmacovigilance, as defined by the World Health Organisation (WHO), is 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem'.

This report and the accompanying Staff Working Document describe the **activities of the EU's networked and collaborative system for monitoring and controlling the safety of human medicines** and is focused on activities since the start of operation of new legislation in 2012 until the end of 2014, but also includes information on some tasks and processes initiated up to July 2015.

The main conclusions of the report are as follows:

Strong collaboration between the European regulatory authorities: the medicines regulatory authorities in 31 European Economic Area (EEA) countries, the EMA and the European Commission closely **collaborate and work in partnership as a network** to discuss and deal swiftly with any emerging problem in the interest of patients' access to safe and efficacious medicines. The ability to take quick and robust regulatory action was **enhanced through the legislation by**:

- the creation of the Pharmacovigilance Risk Assessment Committee;
- strengthening of the Co-ordination group for Mutual recognition and Decentralised procedures – human;
- the introduction of new procedures to fast-track decision-making when public health is at risk.

Continuing and future development of the network: over the period of the report and beyond, the pharmacovigilance network is focusing on training to develop understanding of pharmacovigilance and regulatory science to enable sharing of best practice, improving the efficiency and effectiveness of the processes, and building capacity.

The European pharmacovigilance network represents an example of successful co-operation at the European level, to the benefit of EU citizens. The networked system allows participants to share in the best available expertise and evidence and co-ordinate the regulatory actions, producing more efficient and consistent outcomes for everybody.

The regulatory tools made available under the revised legislation represent an increasingly proactive approach to medicines safety. These tools comprise the following:

- **risk management planning**: Pharmacovigilance Risk Assessment Committee (PRAC) reviewed 48 risk management plans (RMPs) in July–December 2012, 637 in 2013 and 597 in 2014. The Member States, collectively, received around 3 500 (2012), 7 500 (2013), and 9 000 (2014) RMPs for nationally authorised medicines;
- **post-authorisation studies**: between July 2012 and December 2014, PRAC reviewed protocols for 38 imposed non-interventional post authorisation safety studies (PASSs);
- **signal detection and management at EU level**: analysing reports of suspected side effects to identify signals. Some 193 unique signals were evaluated by PRAC between September 2012 and December 2014;
- **periodic safety update reports**: routine benefit-risk monitoring of medicines via periodic safety update reports (PSURs) and maintaining the list (EURD list) of schedules for submitting PSURs;
- **inspections**: carrying out inspections to ensure company pharmacovigilance systems comply with good pharmacovigilance practice.

The regulatory tools are complemented by improvements in regulatory action and communication when safety concerns are identified.

Increased transparency: mechanisms have been put in place to ensure that accurate safety information reaches the EU public in a timely manner. Engagement of key stakeholders such as patients and healthcare professionals is embedded in the system including through patient reporting of suspected side effects.

For the future, **deepening involvement** is foreseen, including the holding of public hearings for critical safety issues.

Improving service systems: work is proceeding on the infrastructure needed to support further development of the system, and to **simplify and streamline existing processes** where possible so that the regulatory burden is minimised for all stakeholders.