

Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Directive	1999/0134(COD) 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)	
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		06/03/2001
		ELDR BEYSEN Ward	
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health, Consumer Policy		
Council of the European Union	Council configuration	Meeting	Date
	Competitiveness (Internal Market, Industry, Research and Space)	2371	27/09/2001
European Commission	Commission DG Legal Service	Commissioner	

Key events			
23/07/1999	Committee referral announced in Parliament, 1st reading		
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
	<p>Amended by 2000/0323(COD)</p> <p>Amended by 2001/0253(COD)</p> <p>Amended by 2002/0008(COD)</p> <p>Amended by 2004/0217(COD)</p> <p>Amended by 2005/0227(COD)</p> <p>Amended by 2006/0295(COD)</p> <p>Amended by 2008/0045(COD)</p> <p>Amended by 2008/0260(COD)</p> <p>Amended by 2008/0261(COD)</p> <p>Amended by 2012/0025(COD)</p> <p>Amended by 2012/0266(COD)</p> <p>Amended by 2014/0256(COD)</p>
Legal basis	Rules of Procedure EP 52-p1; EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed

Documentation gateway

Initial legislative proposal	COM(1999)0315	28/06/1999	EC	Summary
Economic and Social Committee: opinion, report	CES0933/1999 OJ C 368 20.12.1999, p. 0003	21/10/1999	ESC	
Legislative proposal	COM(2000)0830	15/12/2000	EC	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	EP	Summary
Implementing legislative act	32003L0063 OJ L 159 27.06.2003, p. 0046-0094	25/06/2003	EU	Summary
Follow-up document	COM(2007)0862	20/12/2007	EC	Summary
Follow-up document	SEC(2007)1740	20/12/2007	EC	
Follow-up document	COM(2008)0584	29/09/2008	EC	Summary
Follow-up document	COM(2015)0138	30/03/2015	EC	Summary
Follow-up document	COM(2016)0498	08/08/2016	EC	Summary
Follow-up document	SWD(2016)0284	08/08/2016	EC	
Follow-up document	COM(2017)0135	22/03/2017	EC	Summary
Follow-up document	COM(2021)0497	31/08/2021	EC	

Additional information

European Commission	EUR-Lex
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Final act

[Directive 2001/83](#)
[OJ L 311 28.11.2001, p. 0067](#) Summary

Final legislative act with provisions for delegated acts

Delegated acts

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

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 contents 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

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

Medicinal products for human use: Community code. Codification

The European Parliament adopted the proposal without debate. ?

Medicinal products for human use: Community code. Codification

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

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 all relevant 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

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:

- 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

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

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.