Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2001/0254(COD)
Veterinary medicinal products: Community code Amending Directive 2001/82/EC 1999/0180(COD) Subject 3.10.08 Animal health requirements, veterinary legislation and pharmacy	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health, Consumer Policy	PPE-DE GROSSETÊTE Françoise	13/09/2001
Former committee responsible		
ENVI Environment, Public Health, Consumer Policy	PPE-DE GROSSETÊTE Françoise	13/09/2001
Former committee for opinion		
BUDG Budgets	PSE KUCKELKORN Wilfried	22/01/2002
CONT Budgetary Control	ELDR MULDER Jan	21/02/2002
JURI Legal Affairs and Internal Market	The committee decided not to give an opinion.	
ITRE Industry, External Trade, Research, Energy	PSE READ Imelda Mary	23/01/2002
AGRI Agriculture and Rural Development	PPE-DE STURDY Robert	08/01/2002

Council of the European Union

Council configuration	Meeting	Date
Competitiveness (Internal Market, Industry, Research and Space)	2570	11/03/2004
Agriculture and Fisheries	2528	29/09/2003
Health	2440	26/06/2002

European Commission

Commission DG	Commissioner
Internal Market, Industry, Entrepreneurship and SMEs	

Key events

26/11/2001	Legislative proposal published	COM(2001)0404	Summary
13/12/2001	Committee referral announced in Parliament, 1st reading		
26/06/2002	Debate in Council	2440	Summary
02/10/2002	Vote in committee, 1st reading		Summary
02/10/2002	Committee report tabled for plenary, 1st reading	A5-0334/2002	
22/10/2002	Debate in Parliament		
23/10/2002	Decision by Parliament, 1st reading	T5-0506/2002	Summary
03/04/2003	Modified legislative proposal published	COM(2003)0163	Summary
29/09/2003	Council position published	10951/3/2003	Summary
09/10/2003	Committee referral announced in Parliament, 2nd reading		
27/11/2003	Vote in committee, 2nd reading		Summary
27/11/2003	Committee recommendation tabled for plenary, 2nd reading	A5-0444/2003	
16/12/2003	Debate in Parliament		
17/12/2003	Decision by Parliament, 2nd reading	T5-0578/2003	Summary
11/03/2004	Act approved by Council, 2nd reading		
31/03/2004	Final act signed		
31/03/2004	End of procedure in Parliament		
30/04/2004	Final act published in Official Journal		

Technical information

Procedure reference	2001/0254(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
	Amending Directive 2001/82/EC 1999/0180(COD)
Legal basis	EC Treaty (after Amsterdam) EC 152; EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/16948

Documentation gateway

Legislative proposal		COM(2001)0404	26/11/2001	EC	Summary
Economic and Social Committee: opinion, report		CES1007/2002	18/09/2002	ESC	
Committee report tabled for plenary, 1st		A5-0334/2002	02/10/2002	EP	

reading/single reading					
Text adopted by Parliament, 1st reading/single reading		T5-0506/2002 OJ C 300 11.12.2003, p. 0167-0389 E	23/10/2002	EP	Summary
Modified legislative proposal		COM(2003)0163	03/04/2003	EC	Summary
Council statement on its position		12155/1/2003	24/09/2003	CSL	
Council position		10951/3/2003 OJ C 297 09.12.2003, p. 0072-0100 E	29/09/2003	CSL	Summary
Commission communication on Council's position		SEC(2003)1082	07/10/2003	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0444/2003	27/11/2003	EP	
Text adopted by Parliament, 2nd reading		T5-0578/2003 OJ C 091 15.04.2004, p. 0133-0335 E	17/12/2003	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(2004)0124	17/02/2004	EC	Summary

Additional information

European Commission	EUR-Lex

Final act

Directive 2004/28
OJ L 136 30.04.2004, p. 0058-0084 Summary

Veterinary medicinal products: Community code

PURPOSE : to amend Directive 2001/82/EC on the Community code relating to veterinary medicinal products. CONTENT : The Commission maintains a parallel approach as far as possible with the Community code relating to medicinal products for human use (see COD010253), taking into account the specific features of veterinary products. The costs of research and development to meet increased requirements as regards the quality, safety and efficacy of veterinary medicinal products are leading to a gradual reduction in the range of products authorised for food producing animals. The main amendments concern the following: -there are derogations from the authorization requirement either for certain new categories of pets, such as dwarf rabbits or ferrets, or for the use of a medicinal product on animals subject to compulsory specific health provisions with a view to export to non-member countries or import into the Community. -If no authorised medicinal product is available for a given species or disorder, it is proposed that the use of other products be made more straightforward. -economic incentives are introduced to encourage the pharmaceutical industry to place veterinary medicinal products on the market without delay. The main amendment is a proposal to increase the period of administrative data protection in some cases and hence provide for a more attractive return on investment for an economic operator. -the provisions on the analytical methods to be used to determine the amounts of residues have been amended. -the proposal amends the general provision on total exclusion from human consumption of foodstuffs from animals used for testing medicinal products if maximum residues have not been established. This provision is a major obstacle to the development of new medicinal products for food producing animals. The obligation for the prior establishment of maximum residue limits is abolished, and this measure is accompanied by a withdrawal period. -the provisions on homeopathic veterinary medicinal products are revised, especially with regard to the use of the simplified registration system. -the revision of the mutual recognition procedure in order to increase the scope for cooperation between Member States. A coordination group is established and its role in settling disagreements is defined. -the arrangements on immunological veterinary products are reviewed, partly by restricting the scope for official release of batches to certain types of products, i.e. live vaccines or immunological medicinal products for diseases covered by Community measures, which would mean particular responsibility for the competent authorities. It is also proposed to define the obligations on pharmaceutical companies and the competent authorities under these circumstances, particularly as regards the tests that need to be done by official control laboratories. -the pharmocovigilance procedures have been amended.?

Veterinary medicinal products: Community code

The Council held a policy debate on the basis of a Presidency questionnaire on three proposals - a Regulation (see COD/2001/0252) and two Directives (COD/2001/0253) and (this text) - the main aims of which are to achieve completion of the single market in the medicinal products sector, to improve the competitiveness of the pharmaceutical industry (particularly small and medium-sized enterprises) and to simplify Community legislation. The Opinion of the European Parliament at first reading should be available in October 2002. Two topics were

discussed at this stage following the proceedings of the Working Party: - the scope of the proposal for a Regulation: the text provides for extension of the compulsory centralised Community procedure to medicinal products for human or veterinary use containing new active substances; a majority of delegations wanted to be able to continue to choose between a centralised system and a system of national authorisations with the principle of mutual recognition. Some delegations, however, made distinctions depending on whether the medicinal product was for human or veterinary use. Some delegations said they could support an extension of the scope for medicinal products for human use only. Delegations which recommended an optional system put forward the following main arguments: several delegations wanted the Commission to provide a better definition of medicinal products containing new active substances; several delegations expressed concern regarding the situation of small and medium-sized enterprises and argued that some flexibility was the best solution for them; some delegations expressed fears that extension of a centralised procedure would not take sufficient account of the views of national authorities. As regards medicinal products for veterinary use, some delegations pointed out that, since in some cases their use and authorisation involved only a few regional animal species (e.g. northern Finland), a national authorisation system would be preferable. Some delegations stressed in particular the need to improve the technical resources of the European Agency for the Evaluation of Medicinal Products (EMEA) - computerised files, national databases - and to extend its evaluation methods, along the lines of the methods available to the United States Food and Drug Administration. - the new composition of the Management Board of the European Agency for the Evaluation of Medicinal Products (EMEA): under the proposal this Board would consist of four representatives of the Member States, four representatives of the European Parliament, four representatives of the Commission and four representatives of patients and the industry; a very large majority of delegations wanted to maintain representation by Member States only. Two delegations stressed in particular the need for the Management Board to have a composition different from that of the European Food Safety Authority (EFSA) - a consultative body - taking account of the executive role of the EMEA in issuing authorisations for placing medicinal products on the market. The Council agreed to take account of these positions expressed by the Member States when continuing its discussions in the second half of 2002.?

Veterinary medicinal products: Community code

The committee adopted the report by Françoise GROSSETÊTE (EPP-ED, F) amending the proposal under the codecision procedure (1st reading). The main amendments were as follows: - a clearer differentiation between provisions relating to non food-producing animals and those relating to food-producing animals; - extension of the scope for using medicinal products which have been authorised in another Member State for non-food-producing animals; - stepping up of pharmacovigilance requirements; - to ensure that the competent authorities are fully independent, public funding of activities relating to pharmacovigilance, the operation of communications networks and market suveillance; - speeding up the time within which generic medicines can be brought onto the market: the committee stipulated that applicants should not be required to provide the results of pre-clinical tests or pre-clinical trials if they can demonstrate that the medicinal product is a generic of a reference medicinal product authorised for 8 years in a Member State or in the Community, rather than 10 years as proposed by the Commission. The committee added, however, that such a generic medicinal product cannot be manufactured or placed on the market until ten years have elapsed since the first authorisation of the reference product; - the introduction of definitions of 'homeopathic medicinal product', 'risk related to use of the product' and 'risk/benefit balance'; - for homeopathic products, compliance with the provisions of the "Homeopathic Preparations" monograph of the European Pharmacopoeia; - extending the period following which an authorisation ceases to be valid (because the product was not actually marketed) from two years, as specified in the proposal, to three years; - speeding up assessment procedures, through shorter decision-making deadlines; - unused medicinal products to be returned to the point of purchase and not to be disposed of with other waste; - a ban on advertising to the general public of prescription-only veterinary medicines.?

Veterinary medicinal products: Community code

The European Parliament adopted the report by Mrs Fran?oise GROSSETETE (EPP-ED, F). Please refer to the summary dated 02/10/2002 for an outline of the amendments subsequently adopted. It should be noted that the Parliament suggest that the Commission should investigate whether it is possible to develop a standardised environmental classification system for veterinary medicinal products and, if it finds a suitable model, it should submit a proposal to that effect to the European Parliament before the end of 2003. In addition, Parliament states that a generic medicinal product authorised pursuant to this provision cannot be manufactured or placed on the market until ten years have elapsed from the first authorisation of the reference medicinal product. The ten-year period is extended to 15 years in the case of veterinary medicinal products for smaller species and laying hens, provided that the applicant places the veterinary medicinal product on the market in the course of the first two years following authorisation.?

Veterinary medicinal products: Community code

The Commission accepted 16 of the Parliament's amendments. These include the following: - the requirement that the applicant submit documents as proof that he will be able to meet certain pharmacovigilance obligations; - defining the strength related to the effect of homeopathic medicinal products; - making public the rules of procedure for the co-ordination group in charge of decentralised procedures for marketing authorisation; - providing a timetable for the work to harmonise the summary of product characteristics for veterinary medicinal products authorised for not less than ten years; - it is obligatory for the committee to appoint a rapporteur for the assessment of a referral; - the Commission must prepare a draft decision in 15 not 30 days; -inspections can be carried out without prior notification; - the rules of procedure of the Standing committee must be published; 20 amendments were accepted in part or principle, including the following: - a more precise definition of homeopathic veterinary medicinal product and its identification; - a precision of the definition of risks with the use of veterinary medicinal products and the benefit/risk ration; - strengthening the exceptional nature of the use of veterinary medicinal products outside the authorised use for non-food producing species in a Member State, while allowing for the possibility of access to such products authorised in other Member States; - the requirement to supply information on the pharmacovigilance system intended for a product and specific tests relating to the potential environmental risks posed by the product, where appropriate; - an extension from three to five years for the development of products for use in additional non-food producing species; - information on marketing authorisations to be made available to the public; - obligatory referral of cases of risk to human or animal health or the environment where a Community interest is involved to allow for a scientific assessment of the question at Community level; this is extended to other referral procedures; - the transfer of the future report on the functioning of the decentralised system for authorisation of veterinary medicinal products to the European Parliament and the Council; - the prohibition of direct advertising of veterinary medicinal products containing psychotropic or narcotic substances; - the use of homeopathic

veterinary medicinal products in exceptional circumstances where there is no authorised veterinary medicinal product for the treatment of a particular condition, under certain circumstances for food-producing animals; - requirement to renew the authorisation five years after the first marketing authorisation. After the first renewal, the authorisation will be considered as valid for an unlimited period; - the definition of veterinary medicinal product includes a reference to pharmacological, immunological and metabolic action; - derogation from establishing maximum residue limits for active substances for the Equidae species; - an abridged application for a generic product in a Member State even if the reference product has not been authorised in that State but only in another Member State. The Commission proposes certain modifications to bring this Directive into line with Directive 2001/83/EC. The Commission rejected 26 amendments.?

Veterinary medicinal products: Community code

The Council common position, adopted by unanimity, introduced a number of changes in the Commission's amended proposal. The Council incorporates, in totality, 14 amendments adopted by the European Parliament and accepts 16 in part or in principle. The common position incorporates a number of technical and editorial changes, which the Commission accepts. In addition, the Council has introduced a number of changes of substance, which depart from the Commission's proposal. Some of the changes have been introduced to align the text of the veterinary directive to that of the political agreement concerning the Regulation and the Directive relating to medicinal products for human use. The common position is consistent with the objectives and main principles contained in the proposal. The common position does not purport to amend the legal basis of Directive 2001/82/EC, since the Council considers that this is neither necessary nor appropriate. To increase the availability of veterinary medicinal products, the Council has widened the scope of the "cascade" procedure for food-producing animals (Article 11, paragraph 1). The scope of the procedure would in fact be the same in principle for all animals, but additional safeguards, particular as regards withdrawal periods, would remain in place for food-producing animals. In Article 67, which specifies those veterinary medicinal products that are to be available only on prescription, point (d) no longer contains a reference to the magistral formula. This was superfluous, since the magistral formula by definition requires a veterinary prescription. To be consistent with the rule for authorised veterinary medicinal products, veterinary prescription would be necessary for veterinary medicinal products prepared in accordance with the officinal formula only when destined for food-producing animals. As regards food from test animals, the common position provides two options for withdrawal periods. In addition to reinstating the existing provision of Article 95, which deals only with cases where maximum residue limits have been established, it provides for the use of the withdrawal periods set out in Article 11, paragraph 2 as an alternative. More specifically, as regards the European Parliament amendments accepted in full, the Council has accepted the amendment concerning allowing manufacturers of generic veterinary medicinal products to submit an application 8 years after the granting of the marketing authorisation for the reference products. It would permit the placing on the market of authorised generics 10 years after the granting of the marketing authorisation for the reference product. The Council has accepted amendments concerning transparency, and included them in its common position with some drafting changes. The common position also incorporates amendments relating to : - the mutual recognition procedure; - prescriptions; - the inspection of premises; - advertising. The common position is consistent with the principle of a number of amendments that have the aim of increasing the availability of veterinary medicinal products, namely those concerning: ??the cascade procedure : since the same cascade procedure wouldapply to all non food-producing animals and would permit the exceptional use of veterinary medicinal products authorised for use with another animal species or for another condition in the same species, including those authorised in another Member State; - providing for additional commercial incentives by widening the circumstances in which extended data-protection periods would be available (Article 13); - establish simplified procedures for the administration of homeopathic veterinary medicinal products provide a derogation from the requirement to establish maximum residue limits for animals of the equidae family that are not intended for slaughter for human consumption. As concerns the renewal of marketing authorisations, the Council has accepted the principle of the amendment on this issue. It agrees that there should be one renewal after a 5-year period and that, after that, the validity of the marketing authorisation ought generally to be unlimited. However, the Council believes that it would be administratively simpler for the 5-year period to start running on the date of the marketing authorisation. In addition, the Directive should, like the Regulation and the human Directive, enable the competent authority to require one extra 5-year renewal to take place on justified pharmacovigilance grounds. The Council believes that this addition would provide the competent authority with an extra tool to ensure the effective surveillance of authorised products. The common position is also consistent with the principle of the amendments concerning: - the definition of a "homeopathic veterinary medicinal product" and the labelling of such products; - clarifying the definitions of risks and of the risk-benefit balance; - pharmacovigilance information : it would require all applications for marketing authorisations to include information on pharmacovigilance and potential risks to the environment; - the "sunset clauses" for authorised veterinary medicinal products that are never placed on the market or cease to be placed on the market; - withdrawal periods : in that it provides for the modification of the minimum withdrawal periods specified for the cascade procedure if there are valid reasons for such modification. On the other hand, the Council cannot accept three amendments relating to the prescription of veterinary medicinal products: - since it would place undue restrictions on the definition of a "veterinary prescription". Instead, the Council agrees with the Commission that Directive 2001/82/EC should contain a definition of "veterinary prescription" corresponding to the definition of "medical prescription" in Directive 2001/83/EC. To clarify the definition, the common position states explicitly that national law will specify which are the professional persons qualified to issue such prescriptions. While this person will very often be a veterinarian, it would not be appropriate to exclude the possibility of other professional qualified persons delivering prescriptions in certain circumstances. Although the Council agrees that Article 67 ought to establish the general principle that veterinary medicinal products for food-producing animals fall into the category of veterinary medicinal products available only on prescription but provide for exceptions, it cannot accept the amendment. Since there is freemovement of live animals and food within the Community, the Council believes that it is desirable to have harmonised rules for exemptions from the general principle. The common position therefore provides for the adoption of harmonised criteria through comitology by 31 December 2006. While it cannot accept detail of the amendment concerning new active substances, the Council has in fact reduced the period during which all veterinary medicinal products containing new active substances must be available only on prescription from 7 to 5 years. The Council could not accept a number of amendments relating to homeopathic veterinary medicinal products: - it believes that there is no need to reinstate the current requirement for Member States to take due account of products that other Member States register or authorise, since this would not create any legal requirement for Member States to recognise each other's actions. - it considers that "potentisation" is not the correct terminology in this context as potentisation and dilution are different operations.?

Veterinary medicinal products: Community code

The Commission agrees with the text of common position, adopted by unanimity, for a Directive amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.?

Veterinary medicinal products: Community code

The committee adopted the report by Françoise GROSSETÊTE (EPP-ED, F) amending the Council's common position under the 2nd reading of the codecision procedure. It retabled a number of key amendments adopted by Parliament at 1st reading which had not been accepted by Council: - the procedure for granting a marketing authorisation for medicinal products should be completed within 150 days (rather than 210 days as proposed by the Council) after a valid application has been submitted, including 80 days for scientific data analysis and preparation of the assessment report; - a definition of "food-producing animals" should be inserted in the directive as follows: "(a) animals bred, raised, kept or slaughtered specifically for the purposes of producing food for human consumption, or (b) those animals bred, raised and kept for sport and leisure purposes, from the time when they become destined for the food chain"; - the 10-year data protection period for veterinary medicinal products should be extended by one year for each extension of the marketing authorisation not only to another food-producing species, as specified in the proposal, but also to one or more "significant new therapeutic indications", meaning those which, during the scientific evaluation prior to their authorisation, are held to bring a "signficant clinical benefit" in comparison with existing therapies; - Member States should ensure that unused medicinal products or waste and packaging from used products are delivered to the collection systems which exist. In Member States which do not have appropriate collection systems, unused veterinary medicinal products should be returned to the point of purchase; - in order to guarantee the total independence of the competent authorities, activities connected with pharmacovigilance, the operation of communication networks and market surveillance should receive public funding.?

Veterinary medicinal products: Community code

The European Parliament adopted a resolution drafted by Fran?oise GROSSETETE EPP-ED, France) making some amendments to the Council's common position. The amendments adopted by Parliament were agreed in advance with the Council for both veterinary products : - biological medicinal products similar to a reference medicinal product do not usually meet all the conditions to be considered as a generic medicinal product mainly due to manufacturing process characteristics, raw materials used, molecular characteristics and therapeutic modes of action. When a biological medicinal product does not meet all the conditions to be considered as a generic medicinal product, the results of appropriate tests should be provided in order to fulfil the requirements related to safety (pre-clinical tests) or to efficacy (clinical tests) or to both; - environmental impact must be assessed and, on a case-by-case basis, specific arrangements to limit it must be envisaged. In any event this impact should not constitute a criterion for refusal of a marketing authorisation; - Member States should also take all appropriate measures to ensure that the procedure for granting a marketing authorisation for medicinal products is completed within a maximum of 210 days of the submission of a valid application; - Member States should ensure that unused medicinal products or waste and packaging from used products are delivered to the collection systems which exist. In Member States which do not have appropriate collection systems, unused veterinary medicinal products should be returned to the point of purchase; - in order to guarantee the total independence of the competent authorities, activities connected with pharmacovigilance, the operation of communication networks and market surveillance should receive public funding.?

Veterinary medicinal products: Community code

The Commission can accept in full the 32 amendments to the Council's common position adopted by Parliament on the proposal for a regulation, the 30 amendments to the Council's common position adopted by Parliament on the proposal for a directive on medicinal products for human use and the 22 amendments to the Council's common position adopted by Parliament on the proposal for a directive on veterinary medicinal products. The Commission notes the convergence of views between the three institutions on the general approach and on the most important issues regarding the compulsory field of application of the centralised procedure, the administrative structure of the agency, the period of data protection, definitions, information for patients and the assessment of the environmental impact. The amendments adopted by Parliament mainly concern the issues of the compulsory field of application of the centralised procedure, the period of data protection and the administrative structure of the agency as far as the regulation is concerned, and the definitions, period of data protection, information for patients and assessment of the environmental impact as regards the two directives on medicinal products for human use and veterinary use.?

Veterinary medicinal products: Community code

PURPOSE : to reform Community pharmaceutical legislation. LEGISLATIVE ACT : Directive 2004/28/EC of the European Parliament and of the Council amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products. CONTENT : the Council adopted a package of Community legislation on pharmaceuticals, updating the existing rules with the aim of responding to technical and scientific innovations whilst maintaining a high level of health protection and continuing to ensure the proper functioning of the EU's internal market in the pharmaceuticals sector. The four main objectives of this package are particularly relevant: - to guarantee a high level of public health protection, particularly by providing patients, as swiftly as possible, with innovative and reliable products and by increasing market surveillance by reinforcing monitoring and pharmacovigilance procedures; - to complete the internal market in pharmaceutical products while taking account of the implications of globalisation, and to establish a regulatory and legislative framework that favours the competitiveness of the European pharmaceuticals sector; - to meet the challenges of the future enlargement of the European Union; - to rationalise and simplify the system, thus improving its overall consistency and visibility, and the transparency of procedures. The new Regulation is aimed at improving the operation of centralised and decentralised authorisation procedures for the placing of medicinal products on the Community market and at amending administrative aspects of the European Medicines Agency. More specifically, the new rules will improve and speed up access to new and innovative pharmaceutical products, building on the proven success of the European Medicines Evaluation Agency (EMEA) set up in 1995. Changes include a new fast-track authorisation procedure, the possibility of conditional authorisation for products and a harmonised period during which test and other data is protected in order to reward innovation. The generic pharmaceutical industry also benefits through clearer rules and procedures and the possibility for them to start testing their products in advance of patent expiry. Finally, the new rules should streamline procedures and reduce red-tape, while at the same time strengthening the supervision of pharmaceutical products. The changes include: the opening of the centralised procedure to more types of new medicines. Currently, the centralised procedure must be used for the authorisation of biotechnology products. Under the new rules the centralised procedure will become mandatory for medicines to treat

AIDS, cancer, diabetes, neurodegenerative disorders and orphan diseases and after 4 years this will be further extended to cover medicines for autoimmune diseases and viral diseases. A general review clause will enable further extension to other diseases. In addition, the role of scientific advice in the process is strengthened, as is the EMEA's in relation to scientific matters relating to medicinal products, international activities and its role in providing early scientific advice to companies before they embark on the trials and tests necessary to obtain an authorisation for theirproducts. With a view to increasing and accelerating availability of products, in terms of benefits for patients, the opportunity has been taken to respond to several challenges. The revised legislation aims to increase the availability and speed of access of new and innovative medicines to the European market, while at the same time ensuring that the basic criteria of safety, quality and efficacy are met: - a "fast-track" registration procedure for products of significant therapeutic interest has been introduced allowing these products to be assessed and authorised in an expedited way; - the possibility of a conditional marketing authorisation has been introduced, which allows for a one-year authorisation to be granted provided that there is an important expected health benefit for the patients concerned and that the company agrees to carry out additional monitoring and clinical studies, which will be reviewed at the end of this period; - subject to further additional provisions, a European wide system to make medicinal products available in advance of authorisation for a "compassionate use" will also be possible. This will help to ensure that patients are not discriminated against on the basis, in particular, of the location of the clinical trials performed by a particular company. In addition to the first two provisions, specific measures concerning the availability of veterinary medicinal products are also proposed as well as an incentive scheme to encourage companies to broaden the use of older products for example to cover other species. As regards better access to information for patients, the revised legislation provides for an overall increase in transparency and improves access to the results of the pharmaceutical decision making process, including assessment reports and the summaries of product characteristics. On the issue of promoting the competitiveness of the European pharmaceutical industry in a global context, the revised legislation introduces mechanisms to improve the competitiveness of innovative pharmaceutical, generic and OTC sectors. Concerning data submitted by companies for the approval of medicines, the legislation harmonises the rules governing data protection (data exclusivity). Following transposition of the legislation, whatever the authorisation procedure used, it will not be possible to market generics until ten years have elapsed. This can be extended by a further year if a further innovative indication for the medicine is authorised. This removes current ambiguities of application and allows the innovative pharmaceutical industry more time to recoup its investments before a generic product may be authorised. - for the generic pharmaceutical sector, the new rules introduce the possibility for companies to perform tests to support generic medicine authorisation in Europe and to obtain a marketing authorisation before the end of the data exclusivity period; - in addition, a new definition of generic medicines should provide greater legal security and better application of the regulatory procedures for generic medicines; - for "copies" of biological products, a proper definition of these products, so-called "bio-similar" medicinal product, is introduced. For the Over The Counter (OTC) sector, one year of data exclusivity will be granted on the studies that allowed theswitch of medicinal products from prescription only to OTC; - additionally, the revised legislation introduces the new possibility for an additional period of data protection in case of re-classification of a product as non-prescription ("switch") and in case of a new indication granted to a well-established product. In both cases, the protection will be of one year. The revised legislation includes important changes aiming to optimise, simplify and rationalise the current regulatory processes. The changes reduce the requirement to renew marketing authorisations while reinforcing pharmacovigilance and information sharing provisions. They also include measures to accelerate the Commission's decision making process so that the period between the scientific assessment and marketing a product is shortened. ENTRY INTO FORCE : 30/04/2004. IMPLEMENTATION : 30/10/2005.?