Authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

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PURPOSE : to reform Community pharmaceutical legislation. LEGISLATIVE ACT : Regulation 726 /2004/EC 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. 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 providingearly scientific advice to companies before they embark on the trials and tests necessary to obtain an authorisation for their products. 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, isintroduced. For the Over The Counter (OTC) sector, one year of data exclusivity will be granted on the studies that allowed the switch 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. This Regulation sets out the responsibilities and the administrative structure of the European Medicines Agency. ENTRY INTO FORCE : 20/05/2004. Titles I (Definitions and scope), II (Authorisation and supervision of medicinal products for human use), III (Authorisation and supervision of veterinary products) and V (General and final provisions) shall apply from 20 November 2005.