COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 2001/82/EC and Directive 2001/83/EC as regards variations to the terms of marketing authorisations for medicinal products

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

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Within the EU, medicines are regulated throughout their entire lifetime. Their placing on the market cannot be made without a marketing authorisation. The requirements for granting a marketing authorisation are fully harmonised at Community level, through EU legislation. The authorisation can be given through three main ways: the 'centralised' procedure (a single authorisation process, a single authorisation valid in the whole EU); the 'mutual recognition' procedure (one Member State acting as a reference competent authority and carrying the evaluation for the other concerned Member States); and the 'purely national' procedure (one evaluation and authorisation per Member State).

Changes to medicines that are subsequent to their placing on the market, such as change in the production process, change in the packaging or change in the address of the manufacturer, are called **'variations'**. They are handled according to a Community legislative framework: the 'Variations Regulations'. However, this framework is currently established in such a way that it does not apply to the vast majority of marketing authorisations, which are granted at 'purely national' level. Therefore, today's paradoxical situation is that the requirements for granting a marketing authorisation are fully harmonised, while the requirements for post-authorisation changes -variations- are not.

In the absence of a harmonised Community framework, variations affecting purely national authorisations are therefore handled according to purely national rules. These rules vary from one Member State to the other, leading to disharmonised requirements.

This situation has negative consequences in terms of public and animal health, administrative burden and overall functioning of the internal market. From a health perspective, there is no justification why the scientific criteria for evaluating changes to medicines should differ from one Member State to the other. Different requirements in Member states can lead to inequalities in patients' access to treatments. The current situation also increases the administrative burden for companies and Member States.

Genuine harmonisation, by including variations to all types of marketing authorisations within a single Community framework, has been advocated by a large majority of stakeholders. The main objectives are therefore to achieve simplification and an equal level of patient safety through such harmonisation, thereby ensuring that all authorised medicinal products, irrespective of their legal status, are subject to the same criteria for the evaluation, approval and administrative handling of variations.

Several options including non-legislative ones have been envisaged to achieve these objectives. Extensive consultation with all interested parties was also conducted. Regulatory action at Community level in order to cover all types of marketing authorisations after a limited period of transition was selected as the most appropriate approach to achieve genuine harmonisation. It is also the option preferred by the majority of stakeholders who contributed to the consultation process.

The proposal to which this Impact Assessment is attached is of purely legal nature: it consists solely of an amendment to the legal basis of the Variations Regulations. Therefore, this

proposal alone does not achieve the abovementioned objectives of simplification and harmonisation: it only empowers the European Commission with the legal competence to do so, by subsequently modifying the scope and content of the Variations Regulations by 'comitology' procedure to make the rules concerning variations clearer, simpler, more flexible and truly harmonised.