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Health Action International Europe's Response to the Consultation on the Review of the Variations Regulations Better Regulation of pharmaceuticals: toward a simpler, clearer and more flexible framework on variations

HAI Europe welcomes the initiative to clarify the legislative framework for marketing authorization variations within the European Union. Yet, further harmonization of procedures and increased transparency are needed as to ensure public health needs.

The quality and safety of medicinal products are safeguarded by essential administrative constraints to be imposed on manufacturers. Any attempt to trim down these measures within the EU would jeopardize citizens' health. The use of the mutual recognition or decentralised procedure, currently predominant, is prejudicial to the global efficiency of the EU medicines market and undermines the safety of European citizens. A harmonized system, which creates a level playing field for competing companies and offers EU citizens concrete guarantees of safety, is the only option for a world-class system.

The **heterogeneity** of the current marketing authorization procedures preclude European citizens, namely health professionals and patient and consumer organisations, from understanding the process through which medicines' authorizations are appraised, granted and reviewed. If citizens are expected to make informed decisions in what concerns their health and their treatments, simplified and transparent procedures are key.

At present, medicines are authorized through the centralised, national or mutual recognition procedures. The scenario's complexity increases as exceptions are progressively accumulated. These include accelerated procedures, conditional, simplified and paediatric marketing authorisation, and orphan drug status, among others.

In some Member States, national provisions such as authorization for temporary use and approval for "temporary therapeutic protocols" are advantageous to pharmaceutical manufacturers seeking rapid market access for their products.

Even though harmonised rules exist, the heterogeneous nature of national marketing authorizations conditions, particularly in what regards variations, generates conflicts that

require arbitration procedures. When an agreement is reached, decisions are slowly enacted. It becomes difficult to identify the different indications in which a drug is authorised.

The market authorisation process is still characterized by **secrecy** at all levels. Decisions taken by drug regulatory agencies are not systematically upheld by readily accessible assessment reports. The European Medicines Evaluation Agency does post European Public Assessment Reports online, yet EPARs for extensions of indications are sometimes release months after being the fact. National agencies do not publish all their assessment reports and when they do, these are very hardly ever available in English.

A transparent and centralised procedure for all medicines

A first step would be to harmonise administrative requirements and criteria for extensions of national marketing authorisations. This would avoid complications for applicants, healthcare professionals and patients, and would also eventually reduce the need for arbitration. Nevertheless, further reform is essential to create a fair and comprehensible system to all stakeholders, one that promotes the rational use of medicines and strengthens the credibility of the European regulatory system.

In order to promote transparency of the marketing authorization procedures, the EMEA should introduce "open committee hearings", similar to those established by the US Food and Drug Administration. These open meetings create a public forum for discussion and stimulate information sharing among stakeholders, enabling the input of consumer, academic, expert and independent groups. In addition, it is fundamental to collect post-market follow-up data in each Member State, particularly pharmacovigilance data, so that it can serve as basis for valid decisions, to be applicable throughout the European Union.

The plea in favour of the centralised procedure was heard by the European Parliament: as of 20 May 2008, the centralised procedure will be obligatory for 7 categories of drugs, namely those indicated in AIDS, cancer, neurodegenerative disorders, diabetes, rare diseases, autoimmune diseases, and viral infections. However, the mutual recognition procedure is judged more "flexible" by drug companies and more directly lucrative for those regulatory agencies that are most often chosen as the "reference Member State". As a result, the mutual recognition procedure and the decentralised procedure are still widely used.

Whatever legislative and regulatory measures are taken in order to harmonize variations of national marketing authorisations, HAI Europe calls for real efforts to ensure full harmonization of the European system for approving new drugs and indications, and for existing transparency requirements be respected in practice.