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Patient Health Protection

Explanatory note: EudraVigilance access policy for medicines for human use

1. Introduction

The core responsibility of the European Medicines Agency and the European Medicines Regulatory Network is the protection and promotion of public health through the evaluation and supervision of medicines. Central to this responsibility is the evaluation and coordination of the safety of medicines, including the collection, management and dissemination of information on suspected adverse reactions to medicines (pharmacovigilance). The key European Union (EU) resource to support this activity is EudraVigilance, a centralised European database of suspected adverse reactions related to medicinal products authorised in the European Economic Area (EEA) and those that are subject to clinical trials.

The Agency has developed this EudraVigilance Access Policy to provide stakeholders such as Medicines Regulatory Authorities in the EEA, healthcare professionals, patients and consumers, as well as the pharmaceutical industry and research organisations with access to adverse reaction reports, also referred to as Individual Case Safety Reports (ICSRs). The Agency considers the proactive and reactive disclosure of ICSRs as complementary by putting the principle of transparency into effect in the sense that maximum data are released proactively, that the needs of the public are met and that the requirements of personal data protection pursuant to the provisions of Regulation EC (No) 45/2001 are adhered to.

2. Current legal framework

The EudraVigilance Access Policy has been developed in the context of the current legal framework (i.e. Regulation (EC) No 726/2004, Directive 2001/83/EC as amended and Directive 2001/20/EC) taking into account that the interest in and the use of the data may vary between stakeholders.

Anticipated changes as part of the new pharmacovigilance legislation have been considered in the drafting of this Access Policy, where possible. However, further adaptations may be necessary considering stakeholder feedback following initial implementation and technical progress at international level e.g., as part of the implementation of the future ISO Individual Case Safety Report (ICSR) and Identification of Medicinal Product (IDMP) standards.

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3. Implementation of the EudraVigilance Access Policy

The Access Policy will be implemented in a stepwise approach based on a revised implementation plan agreed with the EMA Management Board at their meeting on 17 March 2011. The planning is based on the need to be as cost-efficient as possible until enhanced EudraVigilance functionalities, which have to be implemented in the context of the new pharmacovigilance legislation, are made available.

The plan foresees a phased approach as follows:

- **Stakeholder Group I: Medicines Regulatory Authorities**
  - Access to EEA Medicines Regulatory Authorities was granted in July 2007
- **Stakeholder Group II: Healthcare professionals and the general public**
  - Pre-produced monthly reports for centrally authorised medicinal products by the end of 2011
  - Searchable, data protected safety reports for all medicinal products, independent of the authorisation procedure, by end of 2012
  - The Agency aims to make further improvements to the search and data-output functions by 2015, subject to available budget
- **Stakeholder Group III: pharmaceutical industry, sponsors and research organisation**
  - The Agency aims to provide access to EVDAS in line with the data set and functionalities described in the Access Policy including product specific access for marketing authorisation holders by 2015, subject to available budget

To successfully implement the EudraVigilance Access Policy, a number of pre-requisites need to be fulfilled to ensure high quality and reliable data outputs. Those pre-requisites are being addressed in the context of the EudraVigilance Data Quality Management project of the Agency, which started in September 2010 and is expected to run for a period of four years.