Direct Patient Reporting in the EU: A Snapshot of Reporting Systems in Seven Member States

I. Introduction

Adverse drug reactions (ADRs) are a serious public health concern. It is estimated that 5% of all hospital admissions in the European Union (EU) are due to an ADR, and that ADRs are the fifth leading cause of hospital death. This represents approximately 197,000 deaths a year.Although the most common adverse reactions to medicines may be identified in clinical trials, rarer ones might only be recognised when numerous patients have used the medicine in normal clinical practice, over the long term, or even after the end of treatment—and only if reported.

By collecting reports on suspected adverse drug reactions after medicines are made available to patients and evaluating these data, regulatory authorities can identify whether harms outweigh benefits and take necessary action to protect patient safety. In spite of the fact that spontaneous reporting is crucial for signal detection, under-reporting is common. It is estimated that only 1% to 10% of serious adverse reactions are reported.

Healthcare professionals are a key source of information about medicines safety, but they do not report as much as they should. Doctors often cite lack of time as a barrier to reporting and sometimes only report adverse reactions when completely confident that they are related to the use of a drug. Additionally, whilst patients consider certain ADRs to be very significant in terms of impacting their quality of life, healthcare professionals do not to the same extent.

The combination of reports from healthcare professionals with first-hand information from patients is of great added value because it increases chances to identify new safety issues. Reports initiated by patients often provide more detailed information about experienced ADRs and their impact on patients' everyday lives. This also has important implications for patients, empowering them to participate more actively in their treatment instead of being passive recipients of medical interventions.

The advantages posed by complementing reports from healthcare professionals with reports from patients have been facilitated by a number of changes to established systems of pharmacovigilance in Europe. In 2003, Denmark and the Netherlands became the first countries to allow patients and consumers to report suspected ADRs directly to their regulatory agency. These countries were followed by Italy (2004), the United Kingdom (2005) and Sweden (2008).

With the implementation of new EU pharmacovigilance legislation in 2012, patient reporting has been expanded throughout the EU. The EU now mandates Member States to encourage

patients to report suspected ADRs directly to the regulatory agency and to enable reporting through web-based formats and alternative means. The new legislation also states that marketing authorisation holders (MAHs) shall not refuse to consider ADR reports received from patients through appropriate means.

Direct patient reporting to regulatory authorities is of particular relevance in that it avoids the conflict of interest situation that arises when patients report suspected adverse reactions directly to MAHs. Without independent verification, there is a higher risk that spontaneous ADR reports received by a pharmaceutical company are stripped of clinical significance when encoded and subsequently transferred to the regulatory authorities.

By introducing a legal right for patients to report suspected ADRs directly to regulatory authorities, the EU acknowledges patients and consumers as key sources of information on medicines safety and paves the way for a faster—and more comprehensive—collection of data on adverse drug reactions.

But to maximise the benefits of direct patient reporting, appropriate reporting systems must be in place. The general public must also be made aware of the possibility to initiate ADR reports and guided throughout the process. To contribute knowledge on patient reporting, particularly on direct reporting to regulatory authorities, we aim to describe the reporting systems of selected EU Member States to identify best practices and issue recommendations for improvement.

This publication follows Health Action International's 2010 report, *Direct Reporting of Adverse Drug Reactions: A Twelve-country Survey and Literature Review*, which advocated for the implementation of direct patient reporting in EU pharmacovigilance legislation.

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