



**International Pharmaceutical Federation
Fédération internationale pharmaceutique**

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FIP STATEMENT OF POLICY THE ROLE OF THE PHARMACIST IN PHARMACOVIGILANCE

Introduction

The World Health Organization (WHO) defines pharmacovigilance as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems.”¹

Modern medicines have changed the way in which diseases are managed. Safety monitoring of medicines is an integral part of clinical practice. In providing high quality medical care, safety monitoring is essential to the ongoing effective use of medicines, Pharmacovigilance is recognised as a clinical discipline and it serves as an indicator of the standards of clinical care practised within a country.

Approval for a medicine is based on controlled and regulated clinical trials. Once an approved medicine is placed on the market, it leaves the controlled scientific environment of clinical trials. At this point, most medicines will only have been tested for short-term safety and efficacy on a limited number of carefully selected individuals. Therefore, it is important that the use of these medicines is monitored for their ongoing effectiveness and safety. Pharmacists have an important responsibility in monitoring the ongoing safety of medicines.

This is particularly true as pharmacists increasingly provide management of medication therapy through the use of pharmaceutical care² as a part of their professional practices. It is a significant advantage to the surveillance of medicines that the pharmacist practitioner is able to provide a patient’s complete medication history.

The central theme of pharmacovigilance should be the demonstration of safety rather than the identification of risks. Based on a prospective approach, insight must first be gained about the level of safety that has been demonstrated, before possible concerns are investigated. The benchmark should then be the medicine’s proven safety rather than its proven risks.

¹ WHO, “The Importance of Pharmacovigilance, 2002”

² FIP Statement of Professional Standards: Pharmaceutical Care, 1998

The Erice Declaration

The Erice Declaration³ asserted that

“Monitoring, evaluating and communicating drug safety is a public-health activity with profound implications that depend on the integrity and collective responsibility of all parties – consumers, health professionals, researchers, academia, media, pharmaceutical industry, drug regulators, governments and international organisations – working together.”

The Declaration still has relevance today because it emphasises that safety information on medicines must serve the health of the public. However, the pharmacist should also focus on the effectiveness of the medicine.

A healthcare system that includes pharmacovigilance in its structure will

- ensure safety by minimizing the occurrence of adverse drug reactions to medicines and reduce fatalities resulting from them;
- provide a warning network among the various healthcare providers, regulators, manufacturers and consumers so that remedial actions can be exercised in a timely and orderly manner.

Regulation of Medicines

“Clearly, on a global scale, major improvements can be made and the extent of Adverse Drug Reactions (ADR) and other drug-related problems underreporting can be considerably reduced by actively involving pharmacists in the surveillance of drug safety within the context of the pharmaceutical care they provide.”⁴

There are at least three levels of control of medicine use that occur within a society: governmental marketing approval process, third party payer and regulation of the pharmacist practitioner. And, as WHO has observed “pharmacovigilance programmes (of these organisations) need to be adequately supported to achieve their objectives”¹

The current role of the pharmacist in post-marketing monitoring is not confined to ADRs and other drug-related problems reporting, but also in the introduction of generic or therapeutically equivalent medicines, reviews of older medicines as well as traditional, complementary and alternative medicines, non-prescription medicines, blood products, biologicals, medical devices and vaccines.

³ Erice Declaration, International Conference on Developing Effective Communication in Pharmacovigilance, various sponsors including WHO, 1997

⁴ op cit

Role of the Pharmacist Practitioner in Pharmacovigilance

“Safety monitoring of medicines in common use should be an integral part of clinical practice. The degree, to which clinicians are informed about the principles of pharmacovigilance, and practice according to them, has a large impact on healthcare quality. Education and training of health professionals in drug safety, exchange of information between national centres, the co-ordination of such exchange, and linking clinical experience of drug safety with research and health policy, all serve to enhance effective patient care. National programmes for pharmacovigilance are perfectly placed for identifying research necessary for better understanding and treatment of drug-induced diseases.”¹

An important clinical responsibility of the pharmacist is in the early detection of ADRs and other drug-related problems as well as monitoring the effectiveness of medicines. The pharmacist, as a part of the healthcare team, is a source of both information and critical evaluation of drug information. The pharmacist’s expertise is vital to the application of the safety profile of a medicine to the needs of a particular patient.

An effective approach in pharmacovigilance requires the use of modern informatics. FIP recognises that pharmacists are a key part of the post-approval environment. Also, pharmacists can provide early detection of new ADRs and other drug related problems and identify certain patient subgroups with exceptional sensitivities.

Against this background, FIP asserts that pharmacists in all practice settings are the key health professional for effective pharmacovigilance programmes, and recommends that:

Pharmacist Educators

- should ensure that the curriculum include the pharmacist’s importance in pharmacovigilance. The contribution of the pharmacist and the pharmacy profession should also include the various pharmaceutical disciplines that enhance the understanding of the nature of safety of medicines.

Pharmacist practitioners

- should understand their pivotal role in the surveillance of the safe use of medicines. The pharmacy profession should acknowledge and promote this role of the pharmacist in the detection and reporting of suspected ADRs and other drug-related problems. Pharmacists need to be actively involved in the surveillance of drug safety issues within the context of their practices. Greater participation by pharmacist practitioner in all practice settings would be an important tool to increasing the reporting of ADRs and other drug-related problems. The pharmacist’s role in pharmacovigilance varies from country to country, but the professional responsibility is the same regardless of jurisdiction.

Pharmacists Associations

- should negotiate with governments to expand the pharmacist authority and primary responsibility for pharmacovigilance. This should include the following:
 - promotion to consumers and prescribers of the role of the pharmacist
 - acceptance of the pharmacovigilance activities for continuing education and continuing professional development requirements
 - provision of compensation and tools to support this expanded responsibility.

Governments and medicines control agencies authorised by governments

- should recognise the pivotal role of pharmacists in pharmacovigilance and ensure that the necessary resources and incentives are appropriately directed to achieve maximum benefit from their involvement;
- provide a method for reporting that is concise, electronic and compatible with pharmacy practice;
- promote a greater awareness about ADRs and other drug-related problems with emphasis on their significance, recognition, management and prevention as an important instruction to promote rational and safe prescription practices;
- assign the primary responsibility for the collection of pharmacovigilance to the pharmacist along with the necessary tools and compensation.