



**Response to:
“European Commission Public Consultation: An assessment of the
Community System of Pharmacovigilance”**

**submitted by the
International Society for Pharmacoepidemiology (ISPE)
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Introduction

The International Society for Pharmacoepidemiology (ISPE) is an international professional organization dedicated to advancing the health of the public by providing a forum for the open exchange of scientific information and for the development of policy; education; and advocacy for the fields of pharmacoepidemiology and therapeutic risk management. ISPE's more than 1000 members come from over 45 countries and work in academic institutions, the pharmaceutical industry, government agencies, and non-profit and for-profit private organizations.

ISPE applauds the European Commission for its efforts to improve systems to assure the safety of medicines in Europe, and is grateful for the opportunity to participate in the Commission's Public Consultation.

Scope of the Fraunhofer Report

The Fraunhofer Report defines pharmacovigilance as "the processes and science of monitoring the safety of medicines and taking action to reduce risk and increase benefit." This unusually broad definition of this term implicitly includes the identification of potential drug safety signals, the evaluation of those potential signals through the conduct of pharmacoepidemiologic studies, and the optimization of the risk-benefit balance of medicines through the performance of therapeutic risk management activities. However, in contrast to this broad definition, the body of the report appears to focus primarily on the narrower topic of the use of spontaneous reports to identify potential drug safety signals.

ISPE strongly encourages the European Commission to broaden the scope of its evaluation to also include pharmacoepidemiology and therapeutic risk management more broadly.

ISPE's Recommendations

In pursuit of its mission to advance the health of the public, ISPE makes the following recommendations with regard to European systems to assure the safety of medicines.

1. *The health of the public would be served by increasing the emphasis and resources currently devoted to pharmacoepidemiology in Europe.* Pharmacoepidemiology is the study of the use and effects of medications in populations. Just as epidemiology is the key scientific discipline underlying public health practice, pharmacoepidemiology is the key scientific discipline underlying public health practice related to medication safety. Pharmacoepidemiology is crucial to identifying and confirming (or refuting) potential drug safety signals, to better characterizing drug safety issues, and to developing, implementing, and evaluating the impact of risk management programs designed to improve the risk-benefit balance of medication use. The resources devoted to pharmacoepidemiology in Europe are tiny compared to those devoted to pre-marketing trials, and wholly inadequate to produce the necessary science to assure the health of the public with regard to medication safety. The need for additional resources is urgent.

2. *The health of the public would be served by enhancing European infrastructure for conducting pharmacoepidemiologic research, including the development of epidemiologic data resources and additional training capacity in pharmacoepidemiology.* Additional

research-quality epidemiologic data resources are needed to allow the timely conduct of crucial pharmacoepidemiologic studies, whether pre-planned or in response to urgent public health needs. Data privacy considerations need to be addressed, but should not preclude the development of such resources. The scarcity of individuals with training in pharmaco-epidemiology is an important but remediable impediment to needed improvements to systems to assure medication safety. Additional European capacity for training in pharmacoepidemiology is badly needed. Particularly given the existing shortage of pharmacoepidemiology infrastructure, regulatory agencies should evaluate pharmacoepidemiologic research findings based on scientific merit regardless of its country of origin.

3. *The health of the public would be served by granting regulatory agencies the resources needed to commission pharmacoepidemiologic research.* European regulatory agencies generally lack the resources to commission independent pharmacoepidemiologic research. A notable exception is the recent invitation from the UK Medicines and Healthcare products Regulatory Agency (MHRA) for applications for funding of commissioned and collaborative research in pharmacoepidemiology. While this invitation represents a promising development, the impact of the program will be limited by its modest budget. Another potential model (albeit a woefully under-funded one) for pharmacoepidemiology research funded by a regulatory agency is the US Food and Drug Administration's contracts with external organizations that have both access to important pharmacoepidemiologic data resources and the expertise needed to conduct rigorous pharmacoepidemiologic studies using those resources. Additional resources are badly needed to ensure that promising partnerships between regulatory agencies and outside experts realize their huge potential impact on public health.
4. *The health of the public would be served by granting regulatory agencies the appropriate powers to compel pharmaceutical manufacturers to conduct drug safety studies, either as a condition of licensure or in response to important potential drug safety signals that arise post-licensure.* European regulatory agencies generally lack sufficient regulatory power to compel pharmaceutical companies to conduct post-licensure safety studies, whether promised as a condition of approval or in response to potential drug safety signals arising after licensure. The public health imperative for such authority is clear.

This response has been approved by ISPE's Board of Directors, and thus represents the official position of ISPE. ISPE hopes that the Commission finds this response helpful.