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Commission européenne,  
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Via e-mail: [peter.arlett@ec.europa.eu](mailto:peter.arlett@ec.europa.eu)

Dear Dr. Arlett:

In response to the request for public consultation, please accept the following information regarding the European Commission legislative proposals for the European Union system of pharmacovigilance and the document, *Strategy to Better Protect Public Health by Strengthening and Rationalising EU Pharmacovigilance*.

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Committed to preventing medication errors and to contributing to safer care, the International Network of Safe Medication Practice Centres aims to achieve the essential objectives stated in the “*Salamanca Declaration to promote safe medication practices globally* (1),” and to encourage and further the development of safe medication practice centres in all countries and to facilitate cooperation amongst them.

Although pharmacovigilance systems are in place to identify and manage harm from adverse drug reactions, confidential, non-punitive and independent medication error reporting and learning systems need to be introduced and significantly strengthened at all levels of the healthcare system. Moreover, collaboration must occur between countries and at all levels of the healthcare system, to share learning from local, national and international medication error reporting and learning systems, identify unsafe conditions and support implementation of strategies that prevent patient harm. Developed nations should recognize and establish an independent focal point (centre) for safe medication practice in a collaborative, complementary, yet distinct way from pharmacovigilance systems (1).

On the basis of these principles and its medication safety work, the INSMPC makes the following comments on the European Commission legislative proposals on the European Union system of pharmacovigilance, in an attempt to help to improve European citizens’ medication safety (2). This commentary is centred on the following new provisions on medication errors, which incorporate the European Commission pharmacovigilance proposals (2):



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The INSMPC considers that it is of primordial importance for European authorities and member states to be fully informed regarding preventable adverse drug events which are the consequences of medication errors and that it is necessary to act upon this information, taking steps to avoid the reoccurrence of such errors, thus improving safety for European citizens.

The INSMPC welcomes the framework provided by the EU pharmacovigilance legislative proposals for managing medication errors in Europe at the various national levels. However, these legislative proposals do not guarantee effective management of medication error information, because, as drafted by the European Commission, the reporting of medication errors and approach to communicating about medication errors will confuse the public, and co-operation between pharmacovigilance and patient safety or medication error reporting systems (MERS) is not clearly described, particularly concerning the conditions and the nature of exchanges between these structures.

The proposed legislation fails to capitalize on the undeniable public health benefits to be derived when patient safety organizations and medication safety experts outside of pharmacovigilance centres are each involved. Medication error causality is multifactorial, involving both product and practice-related issues. Therefore, information about reported errors must be shared with patient safety organizations so that appropriate root cause analysis takes into account all contributing factors, including both product and practice-related issues. Further, the public health is best served when the health care community in general is kept informed of important incidents, root causes, and prevention strategies. Unfortunately, the proposed legislation directs that error reports reach pharmacovigilance centres but no provision is made to share this vital information with expert organizations and individuals outside the pharmacovigilance body who are well positioned to share this information with the public. In fact, the proposed legislation offers no channel to assure that patient safety organizations are informed about medication errors at all (see below). Instead, the proposed legislation must invite the involvement of patient safety organizations. Excellent models for such cooperative efforts exist among our member organizations and pharmacovigilance centres.

The INSMPC considers this consultation as a unique opportunity for establishing a working framework that will clarify, organize, and support MERS actions in a collaborative and complementary way with regard to pharmacovigilance systems in Europe, a framework that could even serve as a model at the international level.

Several important clarifications are needed with regard to medication errors reporting in the European Union in order to achieve cooperation between the pharmacovigilance and patient safety systems, especially as concerns MERS.

### **Key aspects that need clarification:**

**Conditions of voluntariness, anonymity and confidentiality which assure that healthcare professionals will be protected when they report medication errors, given the lack of a legal framework in force for all the European countries.**



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The Council of Europe called on European health authorities and member states to establish, in a collaborative and complementary way to pharmacovigilance systems, MERS involving primary care as well as hospital settings, nursing homes and comprising local, regional, national and European elements (3,4).

According to the WHO recommendations, successful reporting systems should be voluntary, non-punitive, confidential, independent, based on expert analysis, timely, system-oriented, and responsive (5). These principles were endorsed by the Recommendation Rec(2006)7 of the Council of Europe (4), which stipulates that a patient safety incident reporting system, encompassing a MERS, should:

- Be non-punitive and fair in purpose
- Be independent of other regulatory or accrediting processes,
- Offer enabling conditions for the healthcare providers and healthcare personnel to report safety incidents (such as voluntariness, anonymity, confidentiality, where applicable).

In most European countries, there is no legal framework established (such as exists in Denmark) to protect healthcare professionals who report incidents. For this reason, medication error reporting must be voluntary, and must guarantee anonymity and confidentiality at the option of the reporter.

It must be remembered that, unlike with information concerning an adverse medication reaction which is attributed to the properties of the medication itself (not to the actions of the professionals who work with the medication), in the case of medication errors, the mindset of our cultures tends to lay blame, in many cases, on the healthcare professionals who were working with the medication. This is true even with errors provoked by unclear labelling on a medicinal product. For all of these reasons, again we state that medication error reporting within the current legal framework needs to be voluntary and must meet all requirements that guarantee anonymity and confidentiality. If these guarantees are not met, the likelihood of important errors not being reported to any system is only going to increase. In addition, our pharmacovigilance systems may find themselves drowning in extremely serious legal problems.

In European it is considered mandatory to report all adverse drug reactions (ADRs), yet anonymity is not assured. For this reason, the implantation of the new regulations as proposed by the EU, in the absence of a set of legal codes to protect those submitting reports, may well create an insecure situation for healthcare professionals who choose to not report medication errors to the MERS or to the existing patient safety systems.

### **The types of medication incidents that healthcare professionals ought to report to the pharmacovigilance systems and to the patient safety organizations, especially MERS.**

Clearly, in the last few years, patient safety has become a matter of priority for healthcare authorities, as well as for international organisms and organizations. Much work has been done in this area and many recommendations have been made with the aim of improving patient safety. These recommendations have pointed to the necessity of urging the creation of reporting systems for incidents on local, regional, and national levels. In fact, work in this



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area is one of the main priorities for the *World Alliance for Patient Safety* of the World Health Organization (WHO) (6).

As a result of all these initiatives, patient safety reporting systems and/or medication error reporting systems (MERS), have been created in many nations. These systems have been now in place for some time and their achievements cannot be ignored. According to the Recommendation Rec(2006)7, and others, these MERS are not only designed to analyse medication errors that do not cause harm including “potential adverse drug events,” “close calls” or “near misses” but also circumstances or events that may lead to errors. They also receive reports of medication errors that have caused health damages (preventable adverse drug events) (3).

The new legislative norms broadened the definition of adverse drug reactions, to include harm caused by medication errors, which, from now on, must be reported to the pharmacovigilance systems, instead of MERS. Now it is unclear whether medication errors should be reported exclusively to pharmacovigilance centres, although European and national medicine agencies have authority only concerning naming, packaging and labelling of medicines for preventing medication errors. This could reduce to a large extent the chances of direct and immediate communication to the public about medication error causality including both product and practice issues.

These new proposals are based to a great extent, on the idea that healthcare professionals who submit reports should not have any doubt as to where they should report patient harm related to medication, whether the harm be due to an ADR or a medication error. However, with the proposed changes, the uncertainties experienced by professionals concerning patient harm simply rise to another level, since professionals now can believe that they must report all types of errors (with and without harm) to the pharmacovigilance system.

The INSMPC believes that there is a need to establish a complementary design between the different patient safety incident reporting systems and with the pharmacovigilance systems to avoid any confusion regarding what should be reported to MERS. If not, professionals who now are unclear as to what they need to report will continue to be in doubt. Therefore, EU legislative proposals should be completed and clarified by provisions regarding medication error reporting systems.

### **Building complementary and co-operation between pharmacovigilance and medication error reporting systems.**

According to the new EU proposals, and facing the same error situation, one resulting in patient harm and another that did not, what should a healthcare professional do? For example, when a particular medication has been administered by a wrong route, if the errors have resulted in patient harm, will they be communicated to pharmacovigilance systems, and if they have not resulted in patient harm, will they then be communicated to the MERS?

Since the analysis of medication errors is very specific, how will this information be evaluated and are they going to identify the causes based on the information recorded on a yellow card?



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The INSMPC believes that medication error reporting programmes should be authorized to share, anonymously, the reports involving preventable adverse drug reactions with the pharmacovigilance system, in order to guarantee the confidentiality to healthcare personnel. In this way, all suspected adverse drug reactions due to medication errors reported would be handled by the pharmacovigilance system in the same way as other adverse drug reaction reports. Conversely, the MERS expertise for error analysis should lead European and national authorities to recognise medication error reporting systems and to use the expertise of medication error analysts for improved prevention of medications errors. An excellent model exists for such a relationship. In the United States, all medication error reports received by the Institute for Safe Medication Practices (a nongovernmental public charity) are shared automatically with the US Food and Drug Administration and vice versa (any information regarding identity of reporters, their organizations, patient and practitioner names, etc. is redacted before sharing).

### **The terminology used in medication safety.**

An important problem when considering medication safety all over the world is that confusion and misunderstandings occur frequently because the different terms used for medication safety are not clearly defined and not used in the same way. An accurate distinction between medication error and adverse drug reaction should be established in order to manage each of them properly in the patients' interest. A clear and consistent terminology should be provided to healthcare professionals and public health officers involved in pharmacovigilance as well as to those involved in patient safety in a more general sense. This terminology should be very clear and should be established at an international level. It should refrain from incorporating new definitions that would only result in misunderstandings.

In conclusion, the time has come to build efficient working relationships between pharmacovigilance centres and MERS. Therefore, the INSMPC members would consider it beneficial for the European Commission to consider these issues carefully and democratically in order to maximize the public health benefits of spontaneous reporting of medication errors. We all need to reach a decision together on a conceptual and operative framework for reporting systems for medication incidents. With such cooperation, information on medication safety will be better organized and managed in such a way as to be more efficiently utilized as a resource for learning how to develop medication use systems that are continually safer for patients. Our group, which is composed of some of the world's leading medication safety expert physicians and pharmacists, stands ready to communicate directly with the world's pharmacovigilance leaders to further the cause of medication safety.

Most sincerely,

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