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EDITORIAL

Closing session. Which role for regional PharmacoVigilance centers (RPVC) in the new European PharmacoVigilance regulation

Conferencia de Clausura. Papel de los centros regionales de farmacovigilancia en el nuevo escenario de la farmacovigilancia europea

Amaierako hitzaldia. Farmakozaintzako eskualdeetako zentroen zeredina europako farmakozaintzaren eszena berrian

PharmacoVigilance activities remain today the sole mean to prevent disasters of public health caused by drugs. The purpose of PharmacoVigilance is to detect safety signals in order to protect patients from drug risks. Thus, the new European PharmacoVigilance legislation offers in theory unique chances for patients and society to improve drug safety and finally to allow use of drugs with a better benefit risk profile.

The new European PharmacoVigilance legislation gives a modified definition of PharmacoVigilance. PharmacoVigilance includes now not only prevention, detection, evaluation, comprehension of the risk of Adverse Drug Reactions (ADRs) but also misuse, abuse, drug errors and professional exposure. The role of RPVC in these new aspects of PharmacoVigilance needs more precisions. Moreover, definition of ADRs is extended since notification to the PharmacoVigilance system is justified as soon as there is at least one suspicion of involvement of drug in the occurrence of ADR. Thus, a new paradigm is defined: ''a suspected ADR''.

Other major points concern PRAC (Pharmacovigilance Risk Assessment Committee which will be in charge of the global evaluation of drug risk), list of drugs under surveillance and the development of Risk Management plans, modifications of SPC (Summary of Products Characteristics) and finally, the methods for evaluation of ADRs and drug signals.

There are several points to discuss. First, the proposition to rely on sophisticated methodologies to detect signal in databases (data mining, automatic generated statistics) shows a deep misunderstanding on how PharmacoVigilance works in practice. In fact, signal on drug safety is given, first, by spontaneous notification to trained PharmacoVigilance structures which have the formation and competence to validate ADRs notifications, including the PharmacoVigilance data into clinical perspectives in order to detect a signal. Recent studies have clearly shown that spontaneous notifications remain the cornerstone in drug safety and PharmacoVigilance. Very few (if not none) significant clinical signals of ADRs were given by automatic generated methods. PharmacoVigilance is a clinical discipline and cannot be resumed to automatic detection or administrative decisions. As medical and clinical pharmacologists, we have to maintain every day this link between clinical practice and PharmacoVigilance. This is one of the missions of the RPVC which cannot be assumed by national authorities.

Another major point in this new European PharmacoVigilance legislation is the fact that several activities of PharmacoVigilance will be, in practice, left to pharmaceutical companies: it is impossible to market one product and to be in charge of its surveillance because of evident conflicts of interest. This argument is one reason more to reinforce national structures of PharmacoVigilance, and especially their RPVC. RPVC are independent groups, far from the marketing influences of drug companies. Moreover, generalization of risk management plans is not the mean to prevent ADR epidemics. It could be used, in contrast, to market drugs earlier or even to maintain on the market drugs without any clinical benefit...

Finally, this new European PharmacoVigilance legislation offers too much opportunities to the pharmaceutical industry and not enough to the national and regional structures of PharmacoVigilance, especially the RPVC, which, in contact to patients and health professionals in their geographical area, are responsible of ADR signal detection, investigation and research about ADRs as well as teaching and information

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about ADRs. We would hope more transparency in order to avoid other Mediator scandals, like in recent year in France.

As stated by Menard, ''*we are likely to propose more regulations, more controls and more procedures. I propose more science, more pharmacological knowledge than promotion of trade names and more attachment to professional and ethical values when developing, targeting, selling, prescribing or dispensing drugs. This would constitute a precautionary principle, even more important at the time of the indispensable generic drugs arrival, and the insufficiency of public funding for continued medical education, now included among public health safety actions. This major educational function of the State, in charge of health safety, has yet to be fulfilled and that has contributed, in my opinion, to this severe dysfunction of the private and public health system*'' (Diab Metab 2011, 37, 169—175).

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