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The Need of Education, Awareness and Continuous Training in Pharmacovigilance

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Abstract

Pharmacovigilance is a critical factor in today's healthcare practice. Education, awareness and training, ensure its proper implementation and achievement of its goals. The need for this mainly focuses on four relevant stakeholders: healthcare sciences students, healthcare professional, pharmaceutical industry employees and patients. Although a lot of progress has taken place, there is still the need of a more structured approach, improvement and optimization; this has to focus on patients, which are the end users of healthcare services and the most important stakeholder in the life cycle of medicinal products.

Introduction

According to the World Health Organization definition, Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. An important milestone for the establishment of the science of PV was the thalidomide disaster in the early 60s [1]. Since then, many things have changed and evolved. Currently PV activities include the collection, recording and evaluation of adverse drug reactions, adverse events, and promotion of the safe use of medicines, as well as appropriate communication to healthcare professionals and the public. PV main scope is improvement of patient care, safety and effectiveness of medicines, protects public health, assess benefit/risk ration of medicines and minimize risks [2]. In this context, education, continuous awareness and appropriate and recurrent training of all the parties involved is crucial for the appropriate implementation and achievement of PV goals in the benefit of the patient who is the end user of the medicinal products and healthcare services. The stakeholders involved in PV activities and are in the center of the need of PV training and educations vary and include many aspects of the healthcare services provision and activities as well as medicines' lifecycle [3]. In this article we will focus on the four main pillars that should be in the scope PV training as they are the most critical factors for the implementation of safety and effectiveness in the use of medicines: healthcare sciences' students, healthcare professionals, pharmaceutical industry and – last but not least – patients.

Health Care Science Students

Healthcare sciences are a matter of culture. Pharmacovigilance is a matter of culture. The humanitarian nature of healthcare sciences, as they focus on patients' lives and well-being, are beyond business plans and short-term strategic or political goals. They have by nature and definition a more holistic and beneficiary approach. The same happens with PV; PV is and/or should be an integral part of healthcare sciences higher education academic programs [4]. Pre-graduate academic courses of physicians, pharmacists, dentists, nurses, and vets should include a mandatory theoretical course on PV [5-6].The course should have an appropriate structure. It should incorporate the main principles, the aims and the history of PV. In addition, it should include the legal and regulatory background, actions, activities, requirements and obligations in every day's clinical practice, the benefits of PV for the patient, as well as the legal consequences that an entity (healthcare professional, hospital, pharmaceutical industry or other) may face in case of non-compliance. Apart from theoretical education, under-graduate student practice has also to include PV. From identifying and reporting an adverse event or adverse reaction to participating in risk minimization activities for the safe use of medicines [7]. Thus, PV can be an integral cultural and mentality part of a healthcare professional after graduation so that PV implementation should come spontaneously; not as something "like to have" or "cosmetic".

Healthcare Professionals

Healthcare professionals are the most critical factor for PV. Even if someone does not accept this allegation, they are certainly the main "interface" between medicines disposal and patients. This includes safe and effective use of medicines, incorporating manifestations of undesired effects such as adverse events, adverse reactions, lack of efficacy, exposure during pregnancy and others. Having said that academic PV education is most important for a graduate healthcare scientist, continuous training and awareness in PV is also important during clinical practice and professional life. That serves as the basis for alertness for evolution and changes in PV scientific definition and infrastructure, regulatory requirements and implementation. However, this is not enough. Healthcare professionals must receive continuous education in PV. Governments, State Health Institutions, Ministries of Health and Health Authorities should also pay special attention to PV by establishing and organizing appropriate recurrent PV education programs, lectures or seminars. The inclusion of PV awareness in continuous medical (and healthcare professional in general) education is something that should be rendered mandatory. Medical, pharmacists or nurses' associations can play an important role in this by constantly infusing to their members the importance of PV in their daily practice. Osmosis and interaction with Pharmaceutical Industry and Pharmaceutical Industry Associations is something that can also contribute highly in healthcare professionals' PV alertness. It worth to be mentioned that a great leap for PV training of Healthcare professionals has been made via the establishment of the PV Curriculum jointly by the World Health Organization (WHO) and International Society of Pharmacovigilance (ISoP) [8].

Pharmaceutical Industry

Pharmaceutical industry is the main stakeholder that drives pharmaceutical, pre-clinical and clinical research, marketing and post-marketing surveillance and monitoring of medicines. By default, the relevant legislation imposes strict provisions and high requirements concerning Pharmacovigilance [9-10]. In both the European Union and the United States, (but also worldwide) the demands for pharmaceutical companies include the establishment of a pharmacovigilance system, a qualified person for PV, Risk Managements Systems and Risk Minimization Measures for medicinal products as well as expedited and periodic safety reporting for marketed or investigational medicinal products [11]. In this strict environment, training of PV professionals is of great significance. Qualified persons for PV and PV professionals are responsible towards the law and regulations for PV compliance of the company. This requires a high level of training, continuous devotion to PV and drug safety. Various PV trainings and educational courses are available by several of institutions, societies and commercial entrepreneurs. Adverting flyers or the internet are the main sources where someone can find a pertinent training addressing his/her needs [3]. In addition, pharmaceutical companies themselves offer in-house high level training to their PV employees. As this ensures an important aspect of legal compliance of a pharmaceutical company, these trainings are usually demanding, very specific and recurrent in order to respond to the continuous evolution of the science of PV. Apart from PV professionals, PV training concerns all pharmaceutical industry employees. This includes not only specialized personnel that assigned to evaluate, assess and handle further drug safety data such as regulatory and medical affairs professionals, clinical research scientists and medical information personnel, but also employees that it is more possible to get in touch with the source of data for medicines such as sales representatives. Concisely, modern PV requirements demand a high level of PV awareness for all Pharma industry employees at all levels. It is clear, that the more knowledge is available, the more the safe and effective use of medicines will ensure the benefit of the patient, which is ultimate goal via which pharmaceutical industry, will achieve its business purposes.

Patients and Consumers

Patients and consumers are without doubt the more under-recognized stakeholder for PV in terms of awareness and education. Spontaneous adverse event reporting and recording is strongly encouraged to healthcare professionals and pharmaceutical industry but reporting by the patients usually happens only when presenting or seeking medical information. Even when a patient takes legal actions for an undesired drug effect, PV reporting is not among his/her priorities and usually takes place when the defended party acknowledges the action. Health Authorities such the British MHRA or the Cypriot Pharmaceutical Services have established on-line adverse event report forms (yellow cards) in their websites also accessible to patients. Still campaigns, patient awareness programs or publications alerting patients for the importance of PV is something yet to happen. There is still a lot of room for improvement in this field. At the end of the day, all happens about the patient. So patient engagement needs to enhance concerning PV.

Conclusion

PV is an integral part of current clinical and healthcare practice. Important milestones have achieved regarding to training and education mainly among healthcare professional and pharmaceutical industry employees. Big steps have also taken place in academic education of healthcare sciences students. Concerning patients' awareness there are still a lot to do in order to sensitize the public in PV. However, the biggest room in the world is the room for improvement. Since PV is a critical factor for the safety and effectiveness of medicines, there is a need of constant and continuous improving in education, training and awareness of all the involved stakeholders; this will optimize the effective implementation of PV in the benefit of the patient.

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