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THE ROLE OF THE AUTHORIZED PERSON RESPONSIBLE FOR PHARMACOVIGILANCE IN THE ORGANIZATION OF THE PHARMACOVIGILANCE SYSTEM OF THE LICENSE HOLDER

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The pharmacovigilance system, organized by the holder of the license to control the safety of manufactured medicines, is a necessary function of the healthcare system and is aimed at identifying potential safety hazards associated with the use of medicines. The regulatory authorities of the Russian Federation in the field of healthcare pay special attention to monitoring the safety and effectiveness of the use of medicines not only at the stages of their obtaining of marketing authorization and production, but also at all stages of civil circulation. A key role in the organization of the pharmacovigilance system in a pharmaceutical company holding a license is played by a Qualified Person Responsible for Pharmacovigilance.

Keywords: pharmaceutical company, Qualified Person Responsible for Pharmacovigilance, medicine safety, Pharmacovigilance

The extent of the problem of the safety of the use of the medicines brought to the pharmaceutical market in the Russian Federation defines the development and updating of legislation in the field of pharmacovigilance regulating the involvement of all subject of circulation of medicinal products into the work of the pharmacovigilance system [1,3]. In accordance with international standards, the responsibility for the safety of manufactured medicines is borne by the license holder (LH) [4,7]. The importance of studying the issue of medicine safety of medicines defines the need to study the causes and mechanisms of adverse reactions at all stages of circulation of medicinal products.

According to the rules of good practice of pharmacovigilance (GPvP), the license holder has a special role as the main participant in the monitoring of adverse reactions of medicines, which must control the safety by monitoring the information, assessing the benefit-risk ratio of manufactured medicines, training the pharmaceutical company employees, ensuring effective communication with medical organizations, pharmacy organizations, consumers, regulatory authorities [4]. Safety should be ensured at all stages of the life cycle of the medicine [3]. Also the license holder must organize pre-licensure safety monitoring activities at all stages of clinical trials of medicines [1,3].

The purpose of our study was to specify the key tasks, ways of organizing and maintaining the system of pharmacovigilance of the license holder within the framework of the performance of the duties of the Qualified Person Responsible

for Pharmacovigilance in the process of pharmacovigilance in a pharmaceutical company. In order to ensure timely monitoring of pharmacovigilance activities, according to GPvP, the license holder must appoint and have at its disposition a Qualified Person Responsible for Pharmacovigilance (QPRPV).

RESULTS AND DISCUSSION

The criteria for the appointment of the Qualified Person Responsible for Pharmacovigilance in a pharmaceutical company holding the license include:

- pharmacovigilance systems management skills;
- expertise skills / access to expertise in areas such as medicine, pharmaceutical sciences, epidemiology and biostatistics [4,7].

Responsibility for training and retraining of the Qualified Person Responsible for Pharmacovigilance in the field of its pharmacovigilance system is laid on the senior management of the license holder [4]. Training of the Qualified Person Responsible for Pharmacovigilance and its results are documented properly. The Qualified Person Responsible for Pharmacovigilance has the authority to manage and make changes to the pharmacovigilance system, risk management plans, preparation of regulatory actions in response to emergencies to change the safety profile of medicines [7]. The areas of work of the Qualified Person Responsible for Pharmacovigilance are extensive and are specified by the job description [4].

Based on the requirements of regulatory acts [4,6,7] and the experience of the Qualified Person Responsible for Pharmacovigilance of the license holder, we have specified the following key tasks of the Qualified Person Responsible for Pharmacovigilance (see Figure):

1) review of medicine safety profiles and emergency situations connected with changing the medicine safety profiles;

2) organization of work with information on safety and efficacy in relation to medicines covered by the system of pharmacovigilance of the license holder, accounting, reporting on adverse events;

3) identification of new safety and efficacy data concerning the use of medicines at the pre-licensure and post-licensure stages;

4) development and updating of standard operating procedures of the pharmacovigilance system of license holders;

5) working with the master file of the pharmacovigilance system, its development and updating;

6) collection and systematization of comprehensive information on risk minimization measures;

7) advanced training and continuous professional development on the issues of improving the system of pharmacovigilance of license holders and ensuring the safety of medicine;

8) training of license holder's employees on medicines safety, collecting spontaneous reports and transmitting them to the Qualified Person Responsible for Pharmacovigilance; documenting the results of training;

9) functioning as a contact person for authorized bodies with 24-hour access.

In order to solve the identified key tasks, the Qualified Person Responsible for Pharmacovigilance must permanently interact:

1) with employees of a pharmaceutical company involved in receiving spontaneous reports on the safety and efficacy of medicines;

2) with regulatory authorities on medicine safety issues, ensuring timely preparation and provision of reports, risk management plans, provision of complete and timely responses to requests.

High-quality and timely fulfillment of the assigned tasks allows the Qualified Person Responsible for Pharmacovigilance to avoid errors in the operation of the pharmacovigilance system of the license holder. The Qualified

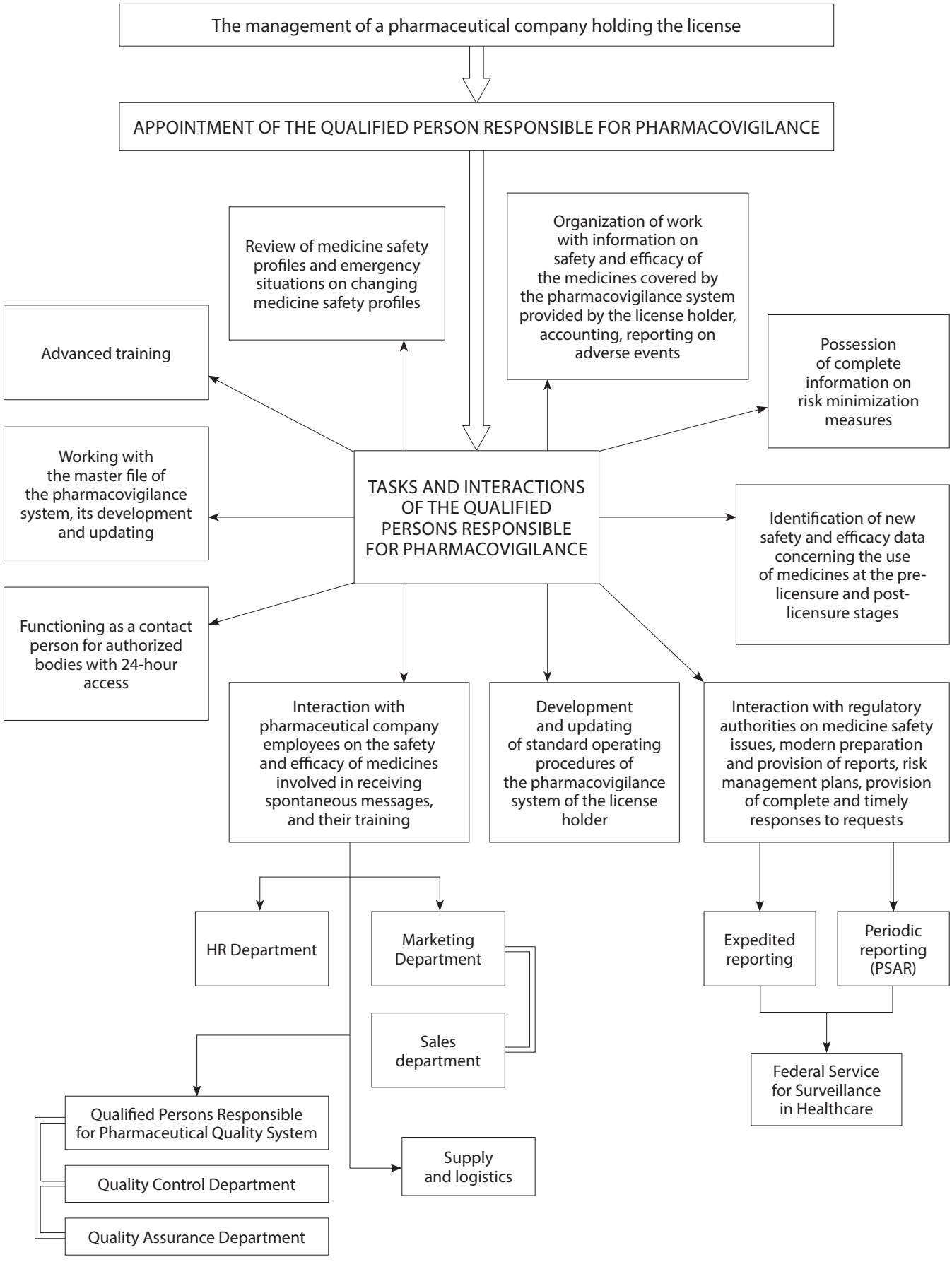

FIG. *The main tasks and ways of interaction of the Qualified Persons Responsible for Pharmacovigilance in the pharmaceutical company holding the license*

Person Responsible for Pharmacovigilance should have information about the validation status of the database of adverse reactions to medicine, including all shortcomings identified during validation and corrective actions taken [4].

In addition, the Qualified Person Responsible for Pharmacovigilance interacts on a daily basis with various divisions (departments) of the pharmaceutical company such as departments of sales, marketing, HR, quality control and assurance, supply and logistics to coordinate monitoring and evaluation of spontaneous reports on adverse reactions

Employees of departments that closely interact with the pharmacovigilance system and participate in monitoring spontaneous reports undergo introductory training at the workplace, and then at least once a year update their knowledge of the basics of good practice according to the developed internal plan and training program. At the workplaces of employees of a pharmaceutical company, there is always a protocol for transmitting data on safety, efficacy or quality according to an internal form. The manager or specialist who received the spontaneous report fills in the internal form of the data transmission protocol on safety, efficacy or quality and sends it to the Qualified Person Responsible for Pharmacovigilance by e-mail or in paper format within one calendar day. Then, the employees of the Pharmacovigilance and Medical Information Department carry out an assessment, analysis and registration of reports on suspected adverse reactions according to internal procedures. The license holder pharmacovigilance system is designed in such a way as to ensure a proper assessment of the quality of the collected reports on adverse reactions in terms of authenticity, legibility, accuracy, consistency and the possibility of verifying the maximum completeness of the data for their clinical judgement [4].

The Qualified Person Responsible for Pharmacovigilance can delegate to trained persons with appropriate qualifications the performance of specific tasks under their supervision, for example, the performance of activities as specific medicine safety experts, provided that the Qualified Person Responsible for Pharmacovigilance will monitor the functioning of the entire system and the safety profiles of medicines [4,7].

CONCLUSIONS

The tasks of the Qualified Person Responsible for Pharmacovigilance are associated with high responsibility, therefore, for their successful implementation, the Qualified Person Responsible for Pharmacovigilance shall have extensive knowledge in the field of medicine and pharmacy, analytical abilities, the ability to maintain documentation and process a large amount of data.

For all medicines, there is a certain balance between the benefits they bring and the potential risk they can cause. The effectiveness of the pharmacovigilance system directly depends on the level of responsibility and competence of the Qualified Person Responsible for Pharmacovigilance. The potential risks of the use of medicines can be minimized due to the Qualified Person Responsible for Pharmacovigilance, which in the pharmaceutical company holding the license performs the functions, on the one hand, of a safety expert, and on the other hand – coordinator of the correct operation of the pharmacovigilance system at the pre-licensure and post-licensure stages of medicine safety monitoring. The priority of the work of the Qualified Person Responsible for Pharmacovigilance is the timely and accurate fulfillment of the tasks set, the preservation of the safety of medicines when received by consumers, as well as the improvement of the quality of products

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