THE PHARMACEUTICAL INSPECTORATE - COMPONENT PART OF THE PHARMACEUTICAL CONTROL SYSTEM

Tatiana ȘCHIOPU, Igor GARABAJIU, Vladimir SAFTA, Mihail BRUMĂREL, Stela ADAUJI
Department of social pharmacy „Vasile Procopișin”
State University of Medicine and Pharmacy „Nicolae Testemițanu”, Republic of Moldova
E-mail: tatiana.schiopu@usmf.md

INTRODUCTION

The activity of the Pharmaceutical Inspectorate is the key to ensuring the quality of pharmaceutical practice, whose mission is to contribute to the improvement of health and to help patients with health problems to rational use of medicines. Until 2016, Pharmaceutical Inspectorate was subordinated to the basic authority, responsible for the management of the pharmaceutical system – Agency of Medicines and Medical Devices (AMDM). Afterwards, according to the amendments in art. 4 paragraph (2^{l}) of Law no. 131 of 8.06.2012 – AMDM is not specified as a public authority/institution with the right to carry out the control function, but the single control body in the field of public health is the National Agency of public health. AMDM further provides data on GMP inspections of drug manufacturers and GDP inspections of wholesale distributors of drugs in the Republic of Moldova. The fact that AMDM no longer carries out GPP inspections is a constant topic in specialist debates, and in this sense supervision and control require a permanent legislative update and for the proper functioning of the pharmaceutical system.

GOAL

Assessing the attitudes of experts from pharmaceutical field with reference to the current functioning of the pharmaceutical control system in order to highlight some problems related to it.

RESULTS OF RESEARCH

54 experts in the field were questioned regarding the identified problems and it was established:

- ✓ the majority of respondents support that the Pharmaceutical Inspectorate should be subordinated to the Agency of Medicines and Medical Devices, but not to National Agency of Public Health (fig. 1);
- ✓ the number of current pharmaceutical inspectors within the Pharmaceutical Inspectorate (PhI) does not correspond to the number of pharmaceutical enterprises up to date and that the legal regulations provided for in the normative acts in force must be applied, because there is no decision-making transparency of the PhI and amendments to the legislation in force with regarding the regulation of the PhI activity (fig. 2 and 3);
- ✓ the considerations regarding the organization of an expert Commission to evaluate the activity of the PhI were partially divided (fig 4);
- ✓ the experts indicated that they had no tangents and do not know whether the fundamental principles of control are respected in the pharmaceutical inspection process and whether the control process carried out by the Pharmaceutical Inspectorate has a commercial imprint (fig. 5 and 6);
- ✓ the experts believe that it is necessary to fulfill the rights/obligations of the pharmaceutical inspector and to change the periodicity of the controls carried out by the Pharmaceutical Inspectorate fig. (7 and 8).

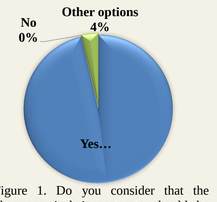

Figure 1. Do you consider that the pharmaceutical inspectorate should be subordinated to AMDM, but not to ANSP

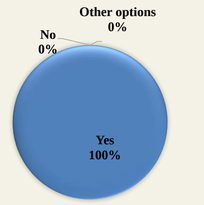

Figure 2. Do you consider that the number of current pharmaceutical inspectors within the Pharmaceutical Inspectorate is in correspondence with the number of pharmaceutical enterprises up to date

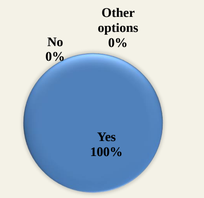

Figure 3. Do you support the need for decision-making transparency of the Pharmaceutical Inspectorate

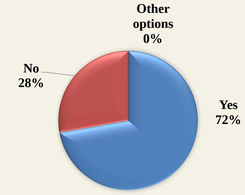

Figure 4. Do you consider necessary to organize a Commission of experts to evaluate in turn the activity of the Pharmaceutical Inspectorate

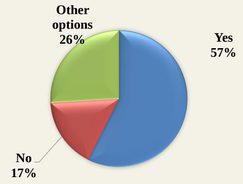

Figure 5. Do you consider that the fundamental principles of control in the pharmaceutical inspection process are respected

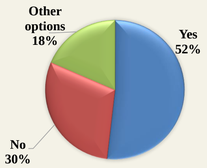

Figure 6. Do you consider that the control process carried out by the Pharmaceutical Inspectorate has a commercial imprint

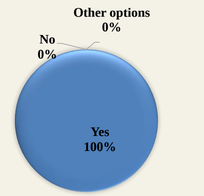

Figure 7. Do you consider that it is necessary to change the periodicity of the controls carried out by the Pharmaceutical Inspectorate

Figure 8. Do you consider that it is necessary to fulfill the duties of the pharmaceutical inspector.

MATERIAL AND METHODS

- ➢ The materials subject to research include: public reports of the Ministry of Health, the Agency of Medicines and Medical Devices, the National Agency of Public Health and legislative-normative acts that regulate the pharmaceutical activity.
- ➢ In order to highlight the opinions of pharmacists-practitioners, sociological research was carried out with the application of the questionnaire tool (14 questions).
- ➢ 54 experts from the pharmaceutical field were selected, all respondents being pharmacists with higher education who work in the pharmaceutical field and who are members of Pharmacists Association from Republic of Moldova, with experience in different types of pharmaceutical activity, such as: Teaching staff within the Faculty of Pharmacy – 16; AMDM representatives – 3; Representatives of domestic producers – 5; Representatives of distributors – 3; Representatives of community pharmacies – 27.

CONCLUSIONS

The current pharmaceutical control system is considered to be ineffective. In order to ensure a good functionality of the pharmaceutical control system, the Pharmaceutical Inspectorate should have an optimal number of pharmacist-inspectors. Changes and adjustments to the quality standards of pharmaceutical inspection with their subsequent implementation in practice are relevant.