

# CONSIDERATIONS ON THE ROMANIAN COLLEGE OF PHARMACIST'S ACTIVITY



**INTERVIEW with Prof.Farm.  
DUMITRU LUPULEASA,  
President of the Romanian  
College of Pharmacist**

**Professional Experience  
Education**

25.03.2015 – ongoing	Director of the Council of PhD Studies of the University of Medicine and Pharmacy "Carol Davila"
11.03.2008 – 25.03.2015 1996 – 2004	Dean of Faculty of Pharmacy, University of Medicine and Pharmacy "Carol Davila" București
2007 – 2010	Supervisor. The program for recognition of bachelor degree in pharmacy Ministry of Education
2000 - ongoing 1994 – 1996	President of the Romanian College of Pharmacists
2000 – 2010	Consultant, National Medicine Program Romanian Government
2000 – 2006	External Expert National Agency of Medicine – Quality Assessment Department
1998 – ongoing	Professor, Department of Pharmaceutical Technology and Biopharmacy Faculty of Pharmacy, University of Medicine and Pharmacy "Carol Davila" București
1998 – 2001	Technical-scientific Expert and Monitor Management Agency for Scientific research, Innovation and Technological Transfer IPB (RELANSIN)
1997 – ongoing	Member of the Romanian Academy of Medical Sciences
1994 – 1998	Associate Professor, Pharmaceutical Technique II Faculty of Pharmacy, University of Medicine and Pharmacy "Carol Davila" București
1997	UN Expert, chosen vicepresident, PNUD Program for narcotics The 40th Conference on narcotics, Vienna, Austria.
1993 – 1997	Vicepresident, The Commission for Medicine Ministry of Health
1991 – 1994	Lecturer, Discipline II Technical Pharmaceutical Faculty of Pharmacy, University of Medicine and Pharmacy "Carol Davila" București
1984 – 1991	Assistent, Discipline II Technical Pharmaceutical Faculty of Pharmacy, University of Medicine and Pharmacy "Carol Davila" București
1979 – 1982	Pharmacist intern National Institute for Drug Control and Pharmaceutical Research "Petre Ionescu Stoian"

1994	Pharm. PhD., Pharmacology – Pharmaceutical Technology Farmacognostic study of algae Spirulina Plaensis Geitleri to make products used in metabolic disorders, University of Medicine and Pharmacy "Carol Davila" București
1993	Pharmacist (senior)
1993	Training, "Le medicament de la douleur" Ecole Nationale de la Sante Publique, Strasbourg
1992	Training, "Stage Statutaire des Pharmaciens – Inspecteurs de la Sante" Ecole Nationale de la Sante Publique, Strasbourg
1992	Training in Deposit Management MoH, Center for Professional Development
1992	Initiation and training in homeopathy MoH, Center for Professional Development MoH, Center for Professional Development
1992	Training in Immunology – Cancer Immunology Universite Rene Decartes - Paris V, Faculte des sciences pharmaceutique et biologiques de Paris, Laboratoire d'Immunologie URA 1484 CNRS
1992	Training in Pharmaceutical Technology University of Medicine and Pharmacy "Carol Davila" București
1992	Training in TIC applications in pharmaceutical sector Faculty of Pharmacy, University of Medicine and Pharmacy "Carol Davila" București
1991	Initiation in Medical Informatics MoH, Center for Professional Development
1991	Principal Pharmacist University of Medicine and Pharmacy "Carol Davila" București
1990	Training in Homeopaty Universite d'ete en Homeopatie, Homeopates sans Frontiers, Montpellier, Franța
1989	Cours in Informatics and Statistics MoH, Center for Professional Development
1987 – 1998	Cours in Spectrofotometry Faculty of Pharmacy, University of Medicine and Pharmacy "Carol Davila" București
1987	Cours in General theory of sistems: applications in medical and pharmaceutical sector Faculty of Pharmacy, University of Medicine and Pharmacy "Carol Davila" București
1985	Cours in Education and perspective of a new quality Faculty of Pharmacy, University of Medicine and Pharmacy "Carol Davila" București
1985	Postuniversity cours in Molecular biology (genetic inginery) Medical Science Academy, Institute of Virusology "Ștefan S. Nicolau",
1979	Pharmacist Faculty of Pharmacy, University of Medicine and Pharmacy "Carol Davila" București

Monographies/other books in international printhouses – coauthor (2)

Treaties in national printhouses - coordinator (3)

Monographies/ other books in national printhouses (15)

In extenso articles published in ISI Thomson Reuters magazines (35)

-as main author (11)

-coauthor (24)

In extenso articles published in indexed magazines in other BDI (30)

In extenso articles published in abstract in journals with impact factor (10)

In extenso articles published in abstract in journals of scientific events with ISBN/ISSN (26)

#### Member in scientific or professional organizations, at national and international level

1. College of Pharmacists in Romania (President).
2. Society of Pharmaceutical Sciences of Romania (member).
3. Romanian Society of Pharmacy (member).
4. Catalan Society of Pharmacy (Sociedad de Amigos from Historia y Ciencia of Pharmaceutical Catalana - Barcelona (member).
5. International Society for the History of Pharmacy (member).
6. Teachers Association of the Faculty of Pharmacy (founding member).
7. New York Academy of Sciences (member).
8. CNADTCU Commission, Ministry of Education, Research and Sports (member).
9. CNDRA Commission, Ministry of Education, Research and Sports (member).

#### Member of international scientific organizing committees (4)

1. SoAS 2014: School of Advanced Studies Biowaivers, development of in vitro - in vivo correlations and quality generic drugs, 9-11 iulie 2014, București, România.
2. Hands on Dissolution Workshop, 11-12 iunie 2012, Poiana Brașov, România.
3. Hands on Dissolution Workshop, 6-7 Octombrie 2005, București, România.
4. International Regulatory Workshop on Bioequivalence and Dissolution, 4-5 Decembrie 2003, București, România.

#### Awards / national distinctions (3)

*Reporter: Professor, you are the President of the College of Pharmacists in Romania, an important organization in terms of defending the interests and prestige of the professionals that you are representing. Profession of pharmacist is regulated by law and pharmacists must meet certain conditions in order to practice in Romania.*

- Please be kind enough to inform us in short, which are the main tasks of the College of Pharmacists in Romania.

*DUMITRU LUPULEASA:* The main tasks of the College of Pharmacists in Romania are set out by Law 95/2006 Healthcare Reform, Title XIV, Article 579 and 580. According to Art. 579, College of Pharmacists of Romania shall:

- a. cooperate in the field of competence with the Ministry of Health by providing enforcement of regulations and rules that organize and regulate the profession of pharmacist any form of exercise and pharmaceutical unit where the activity is held;
- b. protects the dignity and promotes the rights and interests of its members in all spheres of activity; defend the honor, freedom and professional independence of pharmacists and their right of decision in the exercise of professional act; ensures compliance by pharmacists of their obligations to patient and public health;
- c. attests repute and professional conduct of its members;
- d. draw up and keep updated Unique Register of Pharmacists in Romania, manages web pages, and forward quarterly a report to Ministry of Public Health on the number of its members, and the events recorded in the authorization, control and supervision of the pharmacist profession;
- e. develops and adopts rules of organization and functioning of the College of Pharmacists of Romania and Code of Ethics of the pharmacist;
- f. in the field of competence of Ministry of Public Health collaborats in formation, specialized training and perfecting of the pharmacists;
- g. approves, according to the regulations of the organization and functioning of pharmaceutical units, the tasks of the job sheet for pharmacist in each pharmacy;
- h. collaborates with the Ministry of Public Health to establish and increase standards of professional practice, to ensure the pharmaceutical quality of the pharmaceutical units;
- i. cooperates with the Ministry of Public Health and participates, through their representatives, in the work of the Pharmaceutical Inspection organized by it, including common themes based on inspection and control
- j. cooperates with the Ministry of Public Health in developing the methodology for granting professional degree and theme of competition;

- k. initiates, promotes, organizes and accredits in its field of competence forms of pharmaceutical continues education in order to raise the level of professional competence of its members, except complementary study programs for which are obtaining certificates
- l. controls how are respected by employers professional independence and the right of professional decision of the pharmacist;
- m. represents and defends the interests of its members, at their request, against employers;
- n. promotes and establishes relations abroad with institutions and similar organizations;
- o. cooperates in the field of competence with the Ministry of Health in drafting regulations for pharmacist profession;
- p. organizes prosecuting the cases of violations of professional ethics rules or those governing the exercise of profession or professional act;
- q. organizes language training centers which are necessary for practicing the professional activity of pharmacists, citizens of Member States of the European Union, Members of the European Economic Area or of the Swiss Confederation;
- r. works in the field of competence with the Ministry of Public Health, employers' organizations and trade unions, and other associations or non-governmental organizations in all matters concerning public health insurance

## ART. 580

In exercising the powers provided in this title, the College of Pharmacists of Romania, through national and regional structures has the right to make legal action on their own behalf or on behalf of its members.

- What are the main achievements of the College of Pharmacists in the last two years?

**DL:** The main achievements of the College of Pharmacists in the past two years were related to its involvement in several large projects with Medicine and Pharmacy University "Carol Davila", Bucharest which was aimed at achieving national programs of Continuing Pharmaceutical Education, including IT technology.

Another important achievement binds implementation of good pharmaceutical practice translating the provisions of Order 75/2010. To better collaboration between patient organizations, pharmacists, distributors and manufacturers of drugs and the Ministry of Health in 2016 was founded the Group for Dialogue Farma, which has proposed to identify and find ways of solving the main problems of accessibility and ensure continuity of treatment.

- But the main difficulties / obstacles you faced in your work?

**DL:** The main difficulties that we encountered were caused by too frequent changes of the Ministry of Health, having discontinuity in terms of finding and implementing solutions to the problems of lack of necessary medicines to treat chronic diseases. Drug pricing policy was marked by contrary desires, which led to the disappearance of a number of drugs on the Romanian market over the past two years.

*R: As President of the College of Pharmacists in Romania, you are in close contact with almost everything that is undertaken in health policy in Romania, especially with drug policy. In this context:*

- What is the role of the College of Pharmacists of Romania in developing drug policy.

**DL:** College of Pharmacists of Romania cooperates with the Ministry of Health to achieve a coherent drug policy so that patients accessibility to treatments of any kind to be ensured throughout Romania. College advocated a balanced price policy so that imported drugs to be available to the patient in Romania and not take the road to export. While they advocate for the lowest price in Europe, romanian patient is in danger of being deprived not only of modern treatments, but even common drugs.

*R: The pharmaceutical market was always one of the landmarks for strategies and policies undertaken or foreseen in Romanian healthcare. Although were developed and implemented measures considered effective and efficient the implementation of some of these measures demonstrate the opposite.*

- Please refer to some examples that have caused dissatisfaction to the players on the pharmaceutical market.

- What is your opinion about these contrasting aspects ((claw-back and claw-back differentiated, innovative new molecules, etc.)?)

**DL:** I think the most important decision that has displeased manufacturers of drugs is related to the establishment of claw-back tax that was originally a welcome step, but became burdensome a few years later from its implementation. There have been numerous disputes pros and cons of establishing a claw-back Differentiated for innovative molecules on the one hand and generic medicines on the other. There were many promises, but until now did not take any clear-cut decision on this issue.

*R: Research and development is one of the key sectors of the pharmaceutical industry, considering the pace of progress in medical and pharmaceutical area*

- Do you think that the healthcare system in Romania is prepared enough to cope with the accelerated pace of progress in pharmaceutical field?

- What assumptions and what conditions should meet pharmaceutical market players in order to succeed in this context?

**DL:** The health system in Romania might be prepared to cope with the accelerated pace of progress in the pharmaceutical, if the allocation of resources should take account of the progress acceleration that are made in pharmacy field. A number of measures in recent years have shown that it is possible to implement the latest generation of drugs that proved

their effectiveness and benefits. To cope with the fast-paced the health decision makers should push for an increase in the percentage of GDP for health, desideratum of 6% haven't been achieved in the last 10 years since Romania joined the EU. If we will rely only on the contribution of claw-back, it might be possible an increase of the gap that separates us from other health systems in Europe.

*R: As President of the Society of Pharmaceutical Sciences you have recently collaborated with numerous scientific societies for producing a material on biological medicinal products, what is the way this initiative materialised?*

**DL:** Concerning the use of safe biological treatments for patients it was very present in recent years in discussions between pharmaceutical and medical professionals. Presence of the biological drugs in Romania is growing and their use in medical practice prompted adds value to patients. Therefore, the scientific community has extensively debated issues specificity of these product classes and realized later a Position Paper On Biological Medicinal Products. This document was signed along with eight other scientific societies (Rheumatology, Pulmonology, Hematology, Radiotherapy, Oncology, Dermatology, Crohn's disease and ulcerative colitis) and is available on the website of the Society of Pharmaceutical Sciences of Romania.

*R: What is the difference in these drugs and what is their added value for patients?*

**DL:** The medicinal biologic products contain one or more biologically active substances produced or obtained from a biological source. The active substances of biological medicines are greater and more complex than those of non-biological drugs, and only living organisms can reproduce this complexity. Therefore, due to the variability of their structure, biological products may not be identically replicated, have no generic equivalent, and the patient's response to treatment with the same active substance may be different. Thus, class of biological medicinal products differs from that of synthetic drugs through a series of specific characteristics that the national legislation takes them into account, thus establishing the central role of the doctor as a decider of treatment together with each patient.

*R: What aspects would you like to highlight in your Position Paper of Scientific Societies?*

**DL:** The document sets out a number of principles of good practice and expose the societies recommendations on how prescribing of the drugs other than synthetic, extrapolation of indications, interchangeability treatment, the patient's informed consent, issues on immunogenicity or pharmacovigilance. All these elements are clearly established in Romanian legislation and their knowledge is important for professionals in the pharmaceutical and healthcare area.

*R: Among the issues mentioned, what would be very important and you would like to explain in more detail?*

**DL:** For example, I remember about interchangeability between different medicinal products, because we have here a clear

difference between synthetic drugs and biological. Regarding the medicinal with a relatively simple chemical structure, after the patent that protects drug expire the producer can develop and bring to market generic drugs. They are considered to have an active substance identical to the original drug and, therefore, they are often interchangeable with that. In biological products, on the other hand, a very complex and relatively variable structure makes their exact replication impossible. Here there is no generics for an original product, but biosimilar - the term being designed by international authorities to designate a biologically similar to another. These biosimilars can be used for the same indications as the original products, thus have very much in common, but are not interchangeable. The physician should decide early on if a patient will receive either the original or a biosimilar and then regimen should be maintained as such without a change of product at the pharmacy. When and if necessary, the doctor decide the product change when the former falls efficacy or adverse reactions dangerous to patients. Every time the patient's informed consent is part of the steps for such a change.

Interview translated by Carmen Sasu