

**UNIVERSITATEA DE MEDICINĂ ȘI FARMACIE
“IULIU HAȚIEGANU” CLUJ-NAPOCA
FACULTATEA DE FARMACIE**

**STUDII PRIVIND ASIGURAREA CALITĂȚII
ACTIVITĂȚII DE DISTRIBUȚIE ANGRO DE
MEDICAMENTE**

**REZUMAT
TEZĂ DE DOCTORAT**

**Conducător științific
Prof. Dr. Constantin Polinicencu**

**Doctorand
Farm. Dorina Gabriela Pop (Dascăl)**

**Cluj-Napoca
2010**

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Cuvinte cheie: distribuție medicamente, depozit de medicamente, Reguli de bună practică de distribuție

Introducere

Distribuția de medicamente este un domeniu complex, care după 1990 s-a dezvoltat foarte mult datorită creșterii pieței farmaceutice. Distribuitorii de medicamente asigură legătura între producătorii de medicamente (naționali și internaționali) și cumpărători – farmacii comunitare și farmacii de spitale – care, la rândul lor, deserveșc clienții finali, pacienții.

Scopul acestei lucrări a fost evidențierea importanței activității de distribuție în lanțul farmaceutic și necesitatea desfășurării ei la un nivel calitativ înalt.

Pentru realizarea acestor deziderate, s-au întreprins următoarele cercetări: s-au analizat regulile de bună practică de distribuție, elaborate de Ministerul Sănătății Publice din România, s-a trecut apoi la elaborarea unor criterii de evaluare pentru cuantificarea activității unui depozit de medicamente. În final, s-au analizat relațiile de colaborare între farmaciile comunitare și depozitele de medicamente și piața farmaceutică, din România, în 2009. S-a încercat, de asemenea, o prezentare critică a evoluției legislației farmaceutice privind distribuția de medicamente în România, pe o perioadă de aproape douăzeci de ani: 1990-2009.

PARTEA II: CONTRIBUȚII PERSONALE

2. O PRIVIRE PERSONALĂ ASUPRA LEGISLAȚIEI FARMACEUTICE DIN ROMÂNIA, DIN PERIOADA 1990-2009

Legislația farmaceutică a avut și are o evoluție care este strâns legată de evoluția socială, de cea a practicii farmaceutice, de evoluția structurilor legislative, administrative, profesionale, civice [30]. Se pot evidenția trei perioade ale acestei evoluții: *perioada de tranziție* a legislației de la un sistem legislativ anacronic la unul modern, *perioada de pregătire* pentru aderarea la Uniunea Europeană și *perioada post-aderare*. Din păcate, nu se poate vorbi strict de o legislație aplicabilă doar distribuției de medicamente angro, decât în perioada post-aderare.

Perioada 1990 – 2000

În perioada imediat următoare anului 1989, a funcționat legislația anterioară, adică Legea sanitară nr 3/1978 privind asigurarea sănătății populației, din care s-au anulat aspectele politice legate de conducerea sistemului sanitar de către Partidul Comunist Român.[31] Această lege a rămas în vigoare, așa incompletă cum era, timp de peste 10 ani.

Legea nr 31/1990 privind societățile comerciale [32] și Hotărârea Guvernului nr 15/1991 privind înființarea societăților comerciale farmaceutice pe acțiuni [33], au creat cadrul legal pentru demararea procesului de privatizare în domeniul producției și distribuției de medicamente.

În anul 1995, a apărut primul act normativ, cu caracter de lege, referitor la activitatea farmaceutică și anume Ordonanța Guvernului nr. 31 privind reglementarea regimului de producere, circulație și comercializare a produselor farmaceutice [43]. Nu era trasată însă o delimitare netă a activităților dintr-un depozit de medicamente.

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- Simpozionul „Tratamentul hipertensiunii arteriale. Diuretice de actualitate.”, Oradea, aprilie 2004
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- Al XII-lea Congres Național de Farmacie, Bucureşti octombrie 2002

CURSURI POSTUNIVERSITARE:

- „Negocieri constructive” organizat de Ascendis, Braşov, noiembrie 2008
- „Think on your feet” organizat de Interact development, Poiana Braşov, mai 2006
- „Communication skills” organizat de TMI consulting, Poiana Braşov, octombrie 2005
- „Managementul Distribuţiei” organizat de AFP-MKT consulting&management, Poiana Braşov, octombrie 2005
- „Managementul achiziţiilor şi stocurilor” organizat de AFP-MKT consulting&management, Poiana Braşov, iulie 2005
- „Logistică şi Supply-Chain Management”, organizat de AFP-MKT consulting&management, Poiana Braşov, aprilie 2005
- „Tehnici de recrutare şi selecţie” organizat de AIMS Human Capital Romania, Poiana Braşov, aprilie 2005
- „Comunicare asertivă” organizat de Amadeus Rom Consulting, Bucureşti, octombrie 2004

ACTIVITĂŢI EXTRACURICULARE:

- schimb de experienţă interuniversitar Nancy-Cluj, participând la cursuri în cadrul Facultăţii de Farmacie Nancy – Franţa, septembrie 2002
- stagiu de pregătire practică la Facultatea de Farmacie din cadrul Universităţii de Ştiinţe Medicale Debrecen, Ungaria, iulie-august 2002

ACTIVITĂŢI ŞTIINŢIFICE:

Articole publicate ca prim autor

- **Dorina Pop**, Claudiu Morgovan, Constantin Polinicencu – Metodă de evaluare a activităţii unui depozit de medicamente, Clujul Medical 2010; 83(1): 91-98
- **Dorina Pop**, Constantin Polinicencu – Managementul relaţiei farmacie comunitară – depozit de medicamente, Clujul Medical, 2010, în curs de publicare
- **Dorina Pop** - Aspecte de logistică în lumea farmaceutică, www.arilog.ro, august 2007,

LIMBI STRĂINE: Maghiară (conversaţie), Engleză (conversaţie)

CUNOŞTINŢE: în utilizarea calculatorului (MS Office), posed carnet de conducere cat.B din anul 1997

**UNIVERSITY OF MEDICINE AND PHARMACY
“IULIU HAȚIEGANU” CLUJ-NAPOCA
FACULTY OF PHARMACY**

**STUDIES ON ENSURING THE QUALITY OF
WHOLESALE MEDICINE DISTRIBUTION ACTIVITY**

**SUMMARY
PHD THESIS**

**Scientific coordinator
Prof. Dr. Constantin Polinicencu**

**Ph. D. candidate
Pharm. Dorina Gabriela Pop (Dascăl)**

**Cluj-Napoca
2010**

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Key words: medicine distribution, medicine warehouse, Rules of good practice in distribution.

Introduction

Medicine distribution is a complex field which development very much after 1990 due to the increasing pharmaceutical market. Medicine dealers ensure the link between both national and international medicine producers and the buyers – community and hospital pharmacies – which in their turn serve end customers, namely the patients.

The aim of this thesis is to underline the importance of distribution within the pharmaceutical chain and the necessity of its development on a high quality level.

To achieve these goals, the following researches have been carried out: rules of good practice in distribution issued by the Ministry of Romanian Public Health have been analyzed, then evaluation criteria for measuring the activity of medicine warehouse have been elaborated. Finally, the collaboration between community pharmacies and medicine warehouses in Romania during 2009 has been analyzed. I have tried to write a critical presentation regarding the pharmaceutical legislation on medicine distribution in Romania within a period of almost twenty years, between 1990 and 2009.

PART II: PERSONAL CONTRIBUTIONS

7. A PERSONAL VIEW ON PHARMACEUTICAL LEGISLATION IN ROMANIA DURING 1990-2009

Pharmaceutical legislation has and has had an evolution strongly related to social evolution, to pharmaceutical practice, to the evolution of the legislative, administrative, professional, civic structures.[30] There can be underlined three periods of the above mentioned evolution: *the period of transition* of the legislation, from an anachronic towards a modern legislative system, *the period of preparation* for EU accession and *the period of post-accession*. Unfortunately, one cannot speak about a particular legislation applicable only to wholesale medicine distribution until the post-accession period.

Between 1990 – 2000

Immediately after 1989, the former legislation, namely Health Law No. 3/1978 regarding the health insurance, was in force, of which were cancelled political aspects regarding the managing of the health system by the Romanian Communist Party. [31] That law stayed in force, incomplete as it was, for over 10 years.

Law no. 31/1990 regarding commercial companies [32] and Government Decision no. 15/1991 regarding the establishment of pharmaceutical joint stock companies [33] have created the legal background for the privatization process in the field of medicine production and distribution.

In 1995, the first normative act was issued, bearing legal character and referring to pharmaceutical activity, i. e. Government Ordinance no. 31 on the regulation of production, circulation and marketing of pharmaceutical products [43]. But there was no clear cut distinction among the activities carried on in a medicine warehouse.

Between 2000 – 2004

The period between 2000 – 2004 was marked by the implementation of measures to bring the Romanian pharmaceutical legislation to concord with that of EU. One of the main issues regarded the medicine circulation.

In 2001, the Rules of good practice in wholesale medicine distribution was approved by the Ordinance of Ministry of public health no. 863. [50] That was the first document that underlines the importance of the quality insurance within the medicine warehouses and divides in different chapters the activity of a medicine warehouse.

Between 2004 – 2007 or bringing the legislation to concord

Bringing the Romanian legislation to concord with that of EU has started with Emergency Ordinance no. 152/1999 [45], in the field of medicine circulation, approved by Law no. 336/2002 [52]. In order to be applied, the ordinance needed several normative acts, among which some referring to wholesale medicine distribution.

In 2006, Law no. 95/2006 regarding health reform was adopted; it represents the first systematized legal set up in the field of health. [13]

When writing about medicine distribution, it is worth mentioning the Norms on the authorization of wholesale medicine distribution approved by the Ordinance of Ministry of public health no. 893/2006 [53] and the Rules of good practice in wholesale medicine distribution approved by the Ordinance of Ministry of public health no. 892/2006. [54]

Between 2007 – 2009

The year 2008 is worth mentioning on the one hand for the issuance of Law no. 266/2008 [15] and of Law no. 236/2009 on modifying and completing the Law of Pharmacy [16], and on the other hand for the modification occurred in the control of wholesale medicine distribution.

The very same year, the two Ordinances no. 1963/2008 and no. 1964/2008 are issued. The former refers to the approval of the Guide on good practice in wholesale medicine distribution [11], and the latter refers to the approval of the Norms on the establishment, organization and functioning of the wholesale units of human medicine [17], both ordinances being important in outlining the direction the Romanian medicine distribution needs to follow.

Current legislation

At present time, the pharmaceutical legislation in Romania has reached an acceptable level regarding wholesale medicine distribution. The application of the latest rules and norms issued in 2008 will have to lead to the quality assurance in the field of wholesale medicine distribution.

8. ANALYSIS OF GOOD PRACTICE IN DISTRIBUTION

Introduction

The Guide on good practice in wholesale medicine distribution [11] represents an adaptation of European norms to the situation in Romania. The rules stipulated in the Guide refer to all the important stages medicine goes through, from the moment it enters the warehouse to the moment it is delivered to the client, and they focus on counterfeited medicine, withdrawn or returned, but they also tackle aspects of management such as organization and management, warehouse personnel, quality management, complaints solution, self inspection, etc.

Analysis and discussion

I have analyzed the rules of good practice in distribution in order to seize certain inaccuracies, shortcomings or incorrect formulations, which, corrected, would form a Guide of good practice in distribution better adapted to the conditions in Romania.

Each chapter has been tackled separately and recommendations of improvement have been made on the content of the text, in accordance with reality.

Unfortunately, the Guide shows some deficiencies. Thus, when drawing it up, several expressions with general meaning and insufficiently precise have been used, such as: “all parties involved in medicine distribution”, “insufficient capacity”, “periodic derating”, “periodic calibration”, “adequate protection”, “necessary resources”, “to allow a normal circulation of the personnel”, etc., which all leave place to different interpretations.

Another aspect worthy of being noted is that each distributor must elaborate their own policy regarding quality, eventually resulting in a “Manual of Quality Management”. It would have been more fair if the National Agency of Medicine had elaborated a national policy regarding quality in wholesale distribution, a policy all distributors would have adopted.

It needs to be criticized the fact that the Guide has no supplement to contain all the procedures regarding the activities in a medicine warehouse which contribute to the insurance of the quality of the distribution activities; there should at least be a list of all procedures existent in each medicine warehouse.

9. RESEARCHES ON ELABORATING QUALITY CRITERIA FOR EVALUATING MEDICINE WAREHOUSES

Introduction

One of the issues the distributors are facing is the lack of an evaluation grid for the warehouses, containing the quantification of the infrastructure, of the equipment and of the activities carried out in a warehouse, which would allow a transparent and objective evaluation of each warehouse, finalized in a certain score. Thus, the aim of my thesis is to present an original method which, based on the infrastructure, the equipment and the activities in the warehouse, would allow both a general and a partial objective appreciation of the activities carried out in a warehouse, identifying the less performing aspects of the activities and thus offering the possibility to be corrected.

Results and discussion

The quantitative evaluation, according to the proposed grid, has been performed at two warehouses: warehouse A [12] and warehouse B in Cluj-Napoca [69]. Warehouse A obtained a general total of 3795.8 points, whereas warehouse B obtained 3490 points.

Table no. 1 – Evaluation grid of a medicine warehouse

Indicator	Feature	Granted score	Warehouse A	Warehouse B
SECTION A – INFRASTRUCTURE OF THE WAREHOUSE				
<u>a. Locations</u>				
1. Position of the warehouse	Outside or at the margins of the locality or in industrial area	10	10	10

I have drawn up a questionnaire for the community pharmacies and especially for the pharmacy chief. The questionnaire is made up of 10 questions. The questions referred to the following aspects: the pharmacy – medicine distributors relationship, the number of distributors, the place each warehouse occupies in supplying pharmacies according to the value of the acquisition, but also according to preferences (questions 1-3), the commercial conditions the medicine warehouse offer to pharmacies, namely: payment terms, discounts, delivery period (questions 4-6), the positive and negative aspects of the services offered by the medicine warehouses, from the pharmacies point of view (questions 7-8), the criteria they consider important in the pharmacy – medicine warehouse collaboration, and their classification (question 9), and a look on future evolution of the medicine warehouses, from the community pharmacist's point of view who collaborates with the warehouse (question 10).

Results and discussion

I shall further analyze but the most important questions. For the question regarding the number of warehouses that collaborate with a pharmacy, the answers have shown that the majority of pharmacies (50%) work with 5 to 10 medicine warehouses, whereas 30% of the pharmacies are supplied by maximum 5 warehouses.

The classification of the warehouses given by the pharmacies, according to the value of the acquisitions is given in Table 3.

Table no. 3: The first four medicine warehouses preferred by the pharmacies according to collaboration

No.	Warehouse	No. of occurrence	Percentage %
1	Relad	19	63%
2	Farmexim	17	56%
3	Mediplus	15	50%
4	Europfarm	14	46%

The classification of distributors according to the degree of satisfaction of the collaboration is drawn in Table no. 4.

Table no. 4: The first four medicine warehouses according to the satisfaction expressed by the pharmacies.

No.	Warehouse	No. of occurrence
1	Relad	18
2	Mediplus	14
	Europfarm	14
	Farmexim	14
3	Farmexpert	8
4	Montero	7

For the question regarding terms of payment requested by the distributors and the offered discounts, the majority of pharmacies have answered that the terms of payment most frequently requested was of 90 – 120 days, and the practised discounts were between 1 – 10%, according to the product, the terms of payment and to the quantity of acquisition.

Regarding the period of ordered products delivery, the answers have been very different, depending on the distance between the medicine warehouse and the pharmacy. However, the delivery timing of the orders fit in the interval: several hours up to 24 hours. Except for certain cases, the delivery timing exceeded 24 hours.

The pharmacists' complains related to the supplying of the pharmacies by the medicine warehouse have been the following: the faulty supplying of the medicine warehouses, errors and delay in delivering ordered products, lack of communication within the warehouse between Sells and Expedition departments, insufficient personnel, too short terms of payment, sometimes difficult contacts with the warehouses, small discounts.

For the question referring the services offered by the medicine warehouses and assessed by the pharmacists, the majority showed the promptness of the deliveries, and for the question regarding the services offered by the medicine warehouses which need improvement, the majority of the pharmacists have pointed to the supplying of the warehouses and to the lack of continuity in supplying warehouses with different products.

For the question regarding the criteria considered important in a collaboration with medicine warehouses, the majority of pharmacists have explained that both the economical criteria and the interhuman relationships, the social – human and the professional quality of the personnel are important.

11. ANALYSIS ON THE EVOLUTION OF THE PHARMACEUTICAL MARKET IN ROMANIA IN 2009

Introduction

The aim of this chapter is to grant a large view on pharmaceutical market in Romania within the economical context of the year 2009.

The aim of this subject has been the analysis of the evolution of the pharmaceutical market in Romania during the year 2009, a challenging year for the medicine distributors, but also very difficult mostly due to unfavorable regulations.

Results and discussion

Table no. 5 present total medicine sale in 2009, but also separately recorded on community and hospital pharmacies.

Table no. 5 – Medicine consumption in community and hospital pharmacies (million euros) in Romania, in 2009. [74]

Values (m.EUR)	Q1 2009	Q2 2009	Q3 2009	Q4 2009	Total
Total	1,971.5	1,928.0	1,903.0	1,912.0	7,714.6
Community pharmacies	1,706.2	1,672.7	1,660.8	1,680.7	6,720.4
Hospital pharmacies	265.3	255.3	242.3	231.3	994.2

Regarding medicine consumption, from the point of view of the analysis of the value of consumed medicine, the figures are represented in Table no. 6.

Table no. 6 – Medicine consumption with medical prescription and without prescription, in Romania, in 2009, counted in millions of euros. [74]

	Values (m.EUR)				
Report	Q1 2009	Q2 2009	Q3 2009	Q4 2009	Total
Total	1.971,5	1.928,0	1.903,0	1.912,0	7.714,6
Prescribed medicine	1.640,1	1.609,2	1.597,2	1.609,7	6.456,1
Medicine without prescription (OTC)	331,4		305,9	302,3	1.258,5

Analyzing the data in Table no. 5 and no. 6, one can notice a decrease of medicine consumption in the first quarters of the year 2009 by approximately 3% (in euro), with a modest reoccurrence towards the end of the year. The problems existing in the Romanian health system are being mirrored in the decrease of medicine consumption in hospitals and in the increase of medicine consumption in community pharmacies.

To the distributors, the year 2009 was the year when they had to reconsider their strategies and to adapt as they go to the modifications induced by the under financing of the Romanian govern. Due to difficult economical situation, it is possible for some distributors to confront serious problems and to be forced to adopt measures such as reducing personnel, warehouse closure, etc., the gravity of their situation depending on the pharmaceutical market and the world economy.

GENERAL CONCLUSION

The Guide of good practice in wholesale medicine distribution aims at creating a unitary functional system for the medicine distributors in Romania and at ensuring quality in medicine distribution.

I have analyzed the Guide of good practice in wholesale medicine distribution and showed that there are some aspects insufficiently precise or perfectible, a sign that that the Guide may be improved through the collaboration of all those involved in this field.

The implementation of an evaluation grid as a supplement to the Guide, would allow transparent and objective evaluation, resulted in a certain score which would lead to a hierarchy of the medicine distributors at a national level, and would also allow the beneficiaries (pharmacies) to select their distributors.

In order to fill in this gap, I propose a quantitative evaluation method of the activity in a warehouse, based on the provisions of the Rules of good practice in wholesale medicine distribution and on performance indicators. The method presents an evaluation grid where score is granted for the infrastructure of the deposit, the aspects reflecting the well functioning of the warehouse and the economical performances of the warehouse.

I have conducted a research based on questionnaires on the services offered by 22 medicine warehouses, community pharmacies, in three counties: Bihor, Maramureş and Sălaj in view of improving the management of the relationship between community pharmacy and medicine warehouse.

The main complaints of the pharmacies in the study regarding the services offered by the warehouses were the following: faulty supplying, lack of concordance between the written and the actual, sometimes the delay of the deliveries.

Among the services offered by the warehouses, the pharmacies appreciated the most the following: delivery promptness, good communication with the pharmacy, sometimes favourable offers.

The year 2009 was characterized by a decrease of medicine consumption by approximately 3%, in the first three quarters, with a modest reoccurrence in the final quarter.

The reduced consumption of medicine in hospitals is explained by the gathered debts of the hospitals during the years and by the impossibility to pay off the liabilities, because of the lack of money in the government budget.

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DORINA – GABRIELA (POP) DASCĂL

54 Sovata Street, Bl. C5, Ap 56

ORADEA ROMÂNIA

Phone - home 0359-411827

- mobile 0740-307888

Email: dorina.g.pop@gmail.com

Date of birth: 18th July 1979

Place of birth: Marghita, jud. Bihor

Marital status: Married.

EXPERIENCE:

November 2007: Key Account Manager - Hospitals, Europharm Holding SA Brasov ;

April 2005 - November 2007: Warehouse Chief Pharmacist, Europharm Holding SA Brasov
- Oradea Branch;

June 2004 - March 2005: Pharmacist, Europharm Holding Branch Brasov Oradea

November 2003 - May 2004: Pharmacist, s.c. Sanifarm S.A. Oradea - Pharmacy no. 68;

SCIENTIFIC ACTIVITY:

Since 2005: PhD in the field of Pharmacy within “Iuliu Hațieganu” University of Medicine and Pharmacy, Cluj-Napoca; the title of the PhD Paper is "Studies on ensuring the quality of wholesale drug distribution”, scientific leader Prof. Dr. Constantin Polinicenu.

PROFESSIONAL ACTIVITY:

September 2003 - June 2004: Master within the department of "Analysis and drug control" of the Faculty of Pharmacy, University of Medicine and Pharmacy Cluj-Napoca;

1998-2003: Student at the Faculty of Pharmacy, University of Medicine and Pharmacy, Iuliu Hațieganu Cluj-Napoca;

1994-1998: student of “Mihai Eminescu " National College, Oradea.

MEMBER OF PROFESSIONAL SOCIETIES:

Member of the College of Pharmacists, Romania, Bihor County.

PARTICIPATION IN SCIENTIFIC DEMONSTRATIONS, CONGRESSES, SYMPOSIUMS AND CONFERENCES:

- “Standard ISO 9001 – 2008” Symposium, Poiana Brașov, February 2010;

- Continuous professional training course entitled "News on anti-aging therapy", Bucharest, January 2009;
- "Gastroesophageal reflux disease and complications; News in managing flu and cold in children; Vitamins between myth and reality" Symposium, Oradea, June 2008
- "Pharmacist role in child health care" Symposium, Cluj-Napoca, May 2008;
- Continuous professional training course entitled "Pharmacotherapy in GERD and peptic ulcer", Bucharest, January 2008;
- "The Role of the pharmaceutical industry in supporting health programs" Symposium, Oradea, May 2007;
- Continuous professional training course entitled "Interaction and pharmaceutical incompatibilities", Baia Mare, February 2007;
- The National Congress of the Students in Pharmacy, Cluj-Napoca, April 2006;
- The 13th National Pharmacy Congress, "A Powerful pharmacy in an European Romania", Cluj-Napoca, September 2006;
- "The Role of the pharmacist in assisting diabetic patient" Symposium, Cluj-Napoca, May 2005;
- Course entitled "News in homeopathy", Oradea, March 2005;
- Continuous professional training course entitled "Need of quality standards in generic medication", Oradea, February 2005
- "Benefits of oral contraceptives, efficacy, reversibility, prospects" Symposium, Cluj-Napoca, October 2004;
- "Treatment of hypertension. Current diuretics" symposium, Oradea, April 2004;
- "Pharmacogenomics and gene therapy" course and "News in phytotherapy and pharmaceutical legislation" symposium, Oradea, March 2004;
- "Pharmacist - healthcare provider" symposium, Cluj-Napoca, May 2003, with the paper entitled "Preparing Students for work in Community Pharmacy";
- The 12th National Pharmacy Congress, Bucharest, October 2002.

POST GRADUATE COURSES:

- „Constructive Negotiation”, organized by Ascendis, Braşov, November, 2008;
- „Think on your feet”, organized by Interact development, Poiana Braşov, May 2006;
- „Communication skills”, organized by TMI consulting, Poiana Braşov, October 2005;
- „Distribution Management”, organized by AFP-MKT consulting&management, Poiana Braşov, Octobre 2005;

- „Acquisition and stock management”, organized by AFP-MKT consulting&management, Poiana Braşov, July 2005;
- „Logistics and Supply-Chain Management”, organized by AFP-MKT consulting&management, Poiana Braşov, April 2005;
- „Recruiting and selection techniques”, organized by AIMS Human Capital Romania, Poiana Braşov, April 2005;
- “Assertive communication”, organized by Amadeus Rom Consulting, Bucureşti, Octobre 2004.

EXTRACURRICULAR ACTIVITIES:

- Interuniversity experience exchange Nancy – Cluj-Napoca, attending the courses the Pharmacy Faculty Nancy, France, September 2002;
- Practical training at the Faculty of Pharmacy within the University of Medical Sciences Debrecen, Hungary, July – August 2002.

SCIENTIFIC ACTIVITIES:

Articles published as prime author:

- **Dorina Pop**, Claudiu Morgovan, Constantin Polinicencu – Metodă de evaluare a activităţii unui depozit de medicamente, Clujul Medical 2010; 83(1): 91-98
- **Dorina Pop**, Constantin Polinicencu – Managementul relaţiei farmacie comunitară – depozit de medicamente, Clujul Medical, 2010, în curs de publicare
- **Dorina Pop** - Aspecte de logistică în lumea farmaceutică, www.arilog.ro, august 2007,

FOREIGN LANGUAGE:

Hungarian (conversation), English (conversation)

SKILLS AND ABILITIES:

Computer skills (MS Office)

Driving licence B category since 1997