

Portuguese Pharmaceutical Society

Pharmaceutical Industry

FROM:	Nuno Moreira DATE: 2013.04.18					
то:	EIPG					
cc:	Colégios de Especialidades					

The Portuguese Pharmaceutical Society

The Portuguese Pharmaceutical Society (PPS) is the public association that encompasses and represents graduates in Pharmacy or Pharmaceutical Sciences practicing the profession or pharmaceutical practice acts in the Portugal.

The main duties of the PPS are the following:

- a) Collaborate in the development and implementation of health policy in cooperation with the Government:
- b) Defending the dignity of the pharmacy profession;
- c) To promote and defend the interests of the pharmaceutical profession.

In order to pursue these tasks, the PPS exerts its action in the social, scientific, cultural, ethical, professional and economic development fields of pharmaceutical activity.

College of Specialty in Pharmaceutical Industry

The College of Specialty in Pharmaceutical Industry represents the Portuguese Order of Pharmacists in the EIPG.

The specialty colleges are the professional bodies of Order of Pharmacists that congregate qualified pharmacists in a particular pharmaceutical area.

The competences of the College of Specialty in Pharmaceutical Industry, with the agreement of the national board, are:

- a) To promote and closer the professional and scientific relations either nationally or internationally;
- b) To ensure the enhancement and promotion of their technical members;
- c) To ensure the compliance with the basic rules needed to assure the qualification of their members as well as for their maintenance;
- d) To propose the jury of exams of candidatures for registration in the specialty;
- e) To advise the National Board.

Presently, there are 12 929 active members, of whom 779 works in Pharmaceutical Industry (6, 0% of the total).

Nowadays there are 341 specialists in Pharmaceutical Industry.

According to the Portuguese law the figure of Qualified Person as described in the European Parliament Directive 2001/83/E is only fulfilled by a Pharmacist with the title of Specialist in Pharmaceutical Industry by the Pharmaceutical Portuguese Society.



Portuguese Pharmaceutical Society

Pharmaceutical Industry

In 2012 the main activities of the College of Specialty in Pharmaceutical Industry were:

- > To perform the exams for acceptance of a member of the Order of Pharmacists as Specialist in Pharmaceutical Industry
- ➤ Handover ceremony of Diplomas of Specialty in Pharmaceutical Industry (Headquarters of the Order of Pharmacists, Lisbon, June 27, 2012);
- Participation on the Editorial Board of the Center for Medicine Information (Body of the Order of Pharmacists responsible to assure the Medicine Information)
- Participation on the Board of Qualification and Admission of Order of Pharmacists (responsible to assure that all pharmacists have the proper qualification to be pharmacists and maintain it along the career)
- Collaboration with the National Direction and Regional Chambers in the analysis of documents and issuing opinion
- ➤ Proactive collaboration in the Magazine of the Order of Pharmacists, spreading the actions of the College and themes of importance to the pharmaceutical industry by ensuring the relevant new information and current affairs
- Realization of the Annual Meeting of the College's Specialty Pharmaceutical entitled: "GMP's: Back to Basics" (Cultural Centre of Caldas da Rainha, 16, 17 and 18 March 2012) with the participation of 120 Industrial Pharmacists
- Realization of the EIPG General Assembly in Lisbon, 4 to May 6, 2012
- > Realization of 17 regular meetings of the Board of the College's Specialty Pharmaceutical Industry

Principal Remarks:

In general terms Portugal is under an economic intervention and suffers a strong recession. Following the agreement to reduce the expenses in the health sector until now the main measures happens in the medicines market. In 2012 among others two major measures impact strongly the market:

Law decree nº 112/2011

New pricing methodology: with a new set of reference countries (Spain, Slovenia and Italy), new marketing margins for wholesalers and pharmacies, and new generic prices (50% below the RRP of the reference product, or 25% if the wholesale price is less than $10 \in$) - (Jan.)

Downward prices review for branded drugs 1/April by the application of the new reference countries (Spain, Italy and Slovenia) - DL. 112/2011

For the first time in Portugal we assist to the bankruptcy of pharmacies. We start 2013 with the information that 600 pharmacies are not financially viable and bankruptcy is eminent. The reduction in consumption of medicines strongly affected the pharmaceutical companies

Ref.: NI/DN/2011/ASG/001 - 2 / 6 - T-NI-01



Portuguese Pharmaceutical Society

Pharmaceutical Industry

ANNEX:	

In this annex are described other activities of the Order of Pharmacists in which the College of Specialty in Pharmaceutical Industry usually participates

ANNEX:			

PORTUGUESE PHARMACEUTICAL SOCIETY REPORT 2012-2013

1. EDUCATION AND TRAINING

Board of Pharmaceutical Industry Specialists Annual Meeting (RACI)

"GMP 's: Back to Basics"

Organizing committee: Board of Pharmaceutical Industry of the Portuguese Pharmaceutical Society Caldas da Rainha, 16^{th} to 18^{th} March 2012

Symposium "Novas Alterações na Farmacovigilância e Boas Práticas de Distribuição"

"New changes in Pharmacovigilance and Good Distribution Practices"

Organizing committee: Board of Regulatory Affairs Specialists of the Portuguese Pharmaceutical Society Lisbon, 24th May 2012

Symposium "Os Farmacêuticos e a Ética"

"Pharmacists and Ethics"

Conference "A Justiça e os Justos"

"Justice and the Just"

Organizing committee: Portuguese Pharmaceutical Society

Coimbra, 26th September 2012

These events were part of the celebration of the National Pharmacist's Day, organized annually by the Portuguese Pharmaceutical Society.

Inaugural ceremony of "Pharmaceutical Documentation Center"

> This space was created by the Portuguese Pharmaceutical Society in order to ensure the preservation of the relevant documents that collect the memory of the Portuguese pharmacists, and to contribute for the consolidation of the pharmaceutical profession's culture and identity.

1st Luso-Brazilian Symposium of Pharmacy "Resposta dos Farmacêuticos à Necessidade de Ganhos em Saúde"

"Pharmacists answering the need for health gains"

Organizing committee: Portuguese Pharmaceutical Society and Brazilian Pharmacists Federal Council Lisbon, 1st November 2012

This symposium aimed to promote a joint reflection about specific topics of Pharmacy, Medicines and Biological Analysis, as well as promote the sharing of experiences between Portuguese and Brazilian pharmacists.

Pharmacists National Congress'2012 "Mais Intervenção na Sociedade, MELHOR SAÚDE" "More intervention in Society, BETTER HEALTH"

Organizing committee: Portuguese Pharmaceutical Society

Lisbon, 2nd to 4th November 2012

Ref.: NI/DN/2011/ASG/001 - **3 / 6** - T-NI-01



Portuguese Pharmaceutical Society

Pharmaceutical Industry

This congress intended to promote a deep consideration on the Portuguese health system and on the relevance of the pharmacists' professional intervention.
It included plenary sessions related to the sociological approach to the role of pharmacists in

society, pharmacy practice, pharmacist education, ethics and deontology, as well as a debate on healthcare policy. The parallel sessions referred to the entrepreneurship and competitiveness of pharmacists, and the solidarity between generations. Other parallel sessions were on specific professional areas, such pharmaceutical industry, regulatory affairs and pharmaceutical distribution.

Educational Plan on Quality matters

Organizing committee: National Quality Council of the Portuguese Pharmaceutical Society

The training plan includes the following sessions: Checklists: How and What Do?; Quality Management and Risk Assessment in Health; Quality Audits; Good Pharmacy Practices; Good Manufacturing Practices (GMPs); Good Regulatory Practices; Good Distribution Practices; Quality as a tool for Competitiveness and Efficiency; Root Cause Analysis; Business Intelligence and Security; Standards for Medical Devices.

Seminars "A Patente e o Medicamento"

"Patents and Medicines"

Organizing committee: Portuguese Pharmaceutical Society

Porto Regional Chamber, September | Coimbra Regional Chamber, January

2. TECHNICAL DOCUMENTS/GUIDES

"Material de Penso com Acção Terapêutica"

"Wound Dressing Material with Therapeutic Activity"

Coordinated by: Board of Hospital Pharmacy Specialists of the Portuguese Pharmaceutical Society

"Gases Medicinais"

"Medical Gases"

Coordinated by: Board of Hospital Pharmacy Specialists of the Portuguese Pharmaceutical Society

• "Boas Práticas na Preparação de Citotóxicos"

"Good Practices on the Preparation of Cytotoxics"

Coordinated by: College of Hospitalar Pharmacy of the Portuguese Pharmaceutical Society

• "Normas de Orientação Terapêutica"

"Therapeutic Orientation Norms"

Coordinated by: Portuguese Pharmaceutical Society

3. PROTOCOLS

Pharmaceutical Industry Internship Program

▶ Under a cooperation agreement signed by the Portuguese Pharmaceutical Society, the Portuguese Pharmaceutical Industry Association (APIFARMA), the Portuguese Young Pharmacists' Association (APJF) and the Portuguese Pharmaceutical Students' Association (APEF), there were 36 vacancies available for internship in the pharmaceutical industry.

Collaboration Protocol between Portuguese Pharmaceutical Society and the Mozambique Pharmacists Association

Ref.: NI/DN/2011/ASG/001 - **4 / 6** - T-NI-01



Portuguese Pharmaceutical Society

Pharmaceutical Industry

The agreement covers pre and post-graduate training of the Mozambican pharmacists, and aims to promote the expertise in different professional areas, scientific research, technological development and the innovation in health sector, as well as the production of technical, scientific and professional information directed to Mozambican pharmacists. In addition, the protocol covers the assistance to elaborate and draft documents on healthcare and medicines policy. It is also foreseen that this charter of collaboration will aid the process of turning AFARMO into a professional society with powers delegated by the state. Under this protocol, these two organizations also undertake the organization of a biennial joint event named "Luso-Mozambican Conference of Pharmacy".

4. INTERNATIONAL AFFAIRS

INTERNATIONAL PHARMACEUTICAL FEDERATION (FIP)

- 72th Annual Congress "Improving Health Through Responsible Medicines Use" Amsterdam, 3rd to 8th October 2012
- Council Meeting
 Amsterdam, 3rd October 2012
- Signature of the FIP Centennial Declaration "Improving Global Health by Closing Gaps in the Development, Distribution, and Responsible Use of Medicines" Amsterdam, 4th October 2012

PHARMACEUTICAL GROUP OF THE EUROPEAN UNION (PGEU)

- **General Assembly -** Brussels, 15th March
 - Approval of the Memorandum of Understanding with key stakeholders in the supply chain of the product, which establishes the principles of a European medicines verification system.
 - Acceptance of the "Sustainable European Community Pharmacies Part of the Solution" declaration.
- Annual Meeting and General Assembly Paris, 19th June 2012
 - Symposium "Community Pharmacy: Minimizing Risks, Maximizing Benefits to Patients".
- **General Assembly -** Brussels, 15th November 2012
 - Acceptance of the strategic document "European Community Pharmacy Blueprint", proposed by the Professional Issues Working Group (PIWG) members.

EUROPHARM FORUM

- General Assembly Amsterdam, 7th October 2012
 - Elections to the executive committee
 - Approval of the declaration "The role of Pharmacists in Individual Patient Care".

FARMACIA LATINA

Lisbon, 19th January 2012

In this informal meeting there were presentations about political, economic and professional current affairs in the different countries represented (France, Italy, Portugal and Spain), with speeches by representatives of the General Council of Spanish Pharmacists, Federation of Pharmaceutical Unions of France, Italian Pharmacy Owners Federation, Federation of the Order of Italian Pharmacists, and of the Centre for Health Evaluation and Research of the National Association of Pharmacies (Portugal).



Portuguese Pharmaceutical Society

Pharmaceutical Industry

EUROPEAN HEALTH PROFESSIONS COMPETENT AUTHORITIES (EURHECA)

Brussels, 31st May 2012

Formal constitution of the EurHeCA, association that brings together the authorities responsible to regulate the activity of nurses, pharmacists, doctors, dentists and midwives, and which of them the Portuguese Pharmaceutical Society is constitutive member.

ANNFX:			
7.11.11.27.11			

Ref.: NI/DN/2011/ASG/001 - **6 / 6** - T-NI-01