

**To the President  
International Society of Pharmacovigilance  
Dr. Nicholas Moore**

Dear Dr. Moore:

I am pleased of sending you a report of the “Argentinian Pharmacovigilance Course”, which has the International society of Pharmacovigilance auspice, and was given in 2006. It is foreseen to be repeated in 2007.

Yours sincerely,

Dr. Luis Alesso

Córdoba, Argentina, December 2006

## Pharmacovigilance course for Argentinian Physicians Auspiced for International Society of Pharmacovigilance (ISoP)

### Authors:

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### The country:

Argentina, is a quite big country: the territory has 3,8 millions km<sup>2</sup>, from Capricorn's tropic to 55° of South latitude (3.694 km. length , 1.423 km. widest diameter) . Argentina has nearly 38 millions of inhabitants; the great majority of Argentines live in the cities: 12 millions live in Buenos Aires city and neighborhoods (the “great” Buenos Aires), Córdoba is the biggest second city of the country (1,3 millions).

Argentina is a federal country divided in 23 provinces ruled by National laws; however, pharmacovigilance's activities vary widely in different regions of the country, just as provincial policies concerning drug safety and medicine's purchase.

### Aim:

The aim of this course is to **disseminate** the concept and methodology of Pharmacovigilance among Argentinian physicians, in order to provide a **basic knowledge** of this science, and to **promote** an **active attitude of physicians** and their participation in reporting systems of ADRs. Local reality and drug's problem are emphasized, just like regulatory measures taken for solve these problems.

## **Distance course:**

The course is available as a distance course (e-mail every month, a chapter attached each time), in order to reach the highest possible number of physicians around the country.

**The course is sent to 764 physicians in all the country**

**Cost: free**

## **2006 Pharmacovigilance Course: geographic distribution**

Buenos Aires province	309
Capital Federal	121
Catamarca	12
Chaco	58
Chubut	1
Córdoba	13
Corrientes	40
Entre Ríos	8
Formosa	10
La Pampa	1
La Rioja	13
Mendoza	9
Río Negro	4
Salta	24
San Luis	2
Santa Cruz	1
Santa Fe	74
Santiago del estero	47
Tucumán	17
<b>TOTAL</b>	<b>764</b>

## **ESPECIALIDADES:**

Hospital Administration	2
Alergia	1
Bioquímica	3
Cardiología	132
Cirugía	2
Clínica medica	340
Dermatología	5
Endocrinología	6

Farmacología	8
Gastroenterología	2
General	9
Geriatría	13
Ginecología	4
Hematología	1
Hemodinamia	1
Infectología	1
Medicina familiar	5
Medicina interna	7
Medicina laboral	1
Nefrología	3
Neurología	23
No disponible	1
Nutrición	2
Obstetricia	1
Pediatría	8
Psiquiatría	171
Terapia intensiva	12
<b>TOTAL</b>	<b>764</b>

### **Face to face postgraduate course**

A face to face postgraduate course for physicians attending the Residence Training Program of the Hospital Nacional de Clínicas was given in 2005 and 2006. Dr. Luis Alesso and Dr. Raquel Herrera are teachers.. This course includes classes and practical activities. 22 physicians attended the course in 2006, and the Hospital Pharmacists. Cost: in 2005 and 2006 the course was free. It will be repeated in 2007 (the course is foreseen to be paid, with an affordable cost)

**Contents:**

Contents are chosen in order to show both the complexity and magnitude of ADRs problem and how WHO, Uppsala Monitoring Center and National Systems of Spontaneous Reporting work. The course emphasizes the importance of physicians and pharmacist's contribution in building a better knowledge of drug's adverse effects.

**Language:**

This course is written in Spanish, the National Argentina's language. References like National web sites, provincial and national Pharmacovigilance's centers, and where and how to report are included.

**PROGRAMME**

1

Concept of "drug". Drug Development. Ethical principles  
Pre-clinical development. Clinical Phases of drug development

2

Pharmacovigilance: concept. The importance of Pharmacovigilance in Drug Safety. History of Pharmacovigilance. Who must participate in Pharmacovigilance.

3

Adverse Drug Reaction: definition, classification, clinical manifestation. Adverse Effect. Side Effect. Secondary Effect: differences and similitude  
Assessing causality of ADR. Methods in Pharmacovigilance.

4

The Nacional Administration of Food, Drug and Medical Devices. The National System of Pharmacovigilance. Internacional organization of Pharmacovigilance: WHO, Uppsala Monitoring Center

5

The Spontaneous Reporting System. The Yellow Card: how and what report. Systems of coding ADR: WHO-ART, MedDRA terminologies  
Reporting therapeutic ineffectiveness. Vaccine's Pharmacovigilance.

6

Generics drugs. Bioavailability/bioequivalence trials. "Parallel" products

7

The role of Pharmaceutical Industry in Pharmacovigilance  
Technovigilance. Quality control of medicines and biomedical products. How to send medicine's samples for analysis.

8

Alerts in Pharmacovigilance. Withdrawal of products from the market.

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