



## “Pharmacovigilance: partnering for patient safety”

On 20 November 2012, the IFPMA hosted a Geneva Pharma Forum titled “Pharmacovigilance: partnering for patient safety”. With a special focus on biotherapeutic medicines, the event highlighted the key role that pharmacovigilance systems play in assessing the safety profile of a medicine throughout its lifecycle and in protecting patients.



**Dr Otmar Kloiber**, Secretary General of the World Medical Association

Moderated by Dr Otmar Kloiber, Secretary General of the World Medical Association, the event featured presentations from

Dr Shanthi Pal (WHO Program Manager for Pharmacovigilance), Dr Fermin Ruiz de Erenchun (Roche; Chair of the IFPMA Biotherapeutics Group) and Mr Jeremiah Mwangi (Director of External Relations for the International Association of Patient Organizations).

The speakers discussed the work carried out by their respective organizations and highlighted the importance of developing and implementing pharmacovigilance standards and of raising public awareness. They also discussed the recent European Union pharmacovigilance legislative developments.

### Did you miss the Forum?

View the details and presentations at  
<http://www.ifpma.org/events/pharma-forums/view/article/-6a170e8745.html>

#### **Medicines Safety in WHO: promoting best practices in pharmacovigilance**

Dr Shanthi Pal, Medicines Safety Program Manager, World Health Organization

2

#### **Pharmacovigilance for biotherapeutics: partnering for patient safety**

Dr Fermin Ruiz de Erenchun (F. Hoffmann-La Roche), IFPMA Biotherapeutics Group Chair

3

#### **Pharmacovigilance: partnering for patient safety**

Mr Jeremiah Mwangi, Policy & External Affairs Director, International Alliance of Patients' Organizations (IAPO)

4

*“Because biotherapeutic medicines are more complex products with distinct characteristics compared to most chemically-synthesized small molecule medicines, the identification and traceability of individual biotherapeutic medicines are essential, and all stakeholders have a role in ensuring robust pharmacovigilance”*



# Medicines Safety in WHO: promoting best practices in pharmacovigilance



**Dr Shanthi Pal**

*Medicines Safety Program Manager, World Health Organization*

Following a resolution endorsed in 1963, WHO's pharmacovigilance program was established and Member States were invited to "systematically collect" data on adverse drug reactions during development and/or following wide-spread use, i.e. post-marketing approval, for the protection of patients worldwide. WHO would then, in turn, support the exchange of information between countries as well as develop educational materials, prepare guidelines and standards, and provide training and capacity building.

WHO estimates that up to 50% of adverse drug reactions are preventable and in 2010, 134 countries were participating in the WHO Pharmacovigilance program. Some of the major challenges these countries face include a lack of capacity, infrastructure and expertise. Barriers for reporting adverse drug reactions and the resulting lack of data are among the other challenges that have been identified.

The WHO currently hosts the Advisory Committee on Safety of Medicinal Products (ACSoMP), which was created in 2003 to provide advice on policies and issues relating to pharmacovigilance, and continues to develop the requisite policies and strategies for enhanced monitoring.

The Committee's current strategy focuses on the following elements:

- 1 understanding local needs
- 2 engaging public health programs
- 3 bringing in additional stakeholders
- 4 implementing "patient-centric" activities
- 5 expanding the scope of pharmacovigilance.

WHO is also working with the Global Fund to establish minimum pharmacovigilance requirements for national systems and has recently published a toolkit to support pharmacovigilance training and development.

## Did you miss the Forum?

View Dr Pal's presentation at [http://www.ifpma.org/fileadmin/content/Events/Pharma\\_Forum/20\\_Nov\\_2012/WHO\\_Dr\\_Shanthi\\_Pal.pdf](http://www.ifpma.org/fileadmin/content/Events/Pharma_Forum/20_Nov_2012/WHO_Dr_Shanthi_Pal.pdf)

*"WHO estimates that up to 50% of adverse drug reactions are preventable. In 2010, 134 countries were participating in the WHO Pharmacovigilance Program"*

## Resources:

**WHO Pharmacovigilance Toolkit**  
- [www.pvtoolkit.org](http://www.pvtoolkit.org)

## What is pharmacovigilance?

The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.

## The Importance of Pharmacovigilance, WHO 2002

## Pharmacovigilance consultants for Africa

The WHO Collaborating Center for advocacy and training in pharmacovigilance in Accra, Ghana, in collaboration with the Uppsala Monitoring Center, is training individual experts to consult with national public health programs in the area of pharmacovigilance within sub-Saharan Africa.

# Pharmacovigilance for bioterapeutics: partnering for patient safety



**Dr Fermin Ruiz de Erenchun**  
(F. Hoffmann-La Roche),  
IFPMA Biotherapeutics Group Chair

All medicines have the potential to cause adverse drug reactions. However, to understand the relevance and importance of pharmacovigilance for biotherapeutic medicines one must first understand the difference between chemically-synthesized small molecule medicines and biotherapeutic medicines. Dr Fermin Ruiz de Erenchun (F. Hoffmann-La Roche), IFPMA Biotherapeutics Group Chair, provided this comparison and highlighted the unique product characteristics of biotherapeutic medicines relating to their biological nature and complex structure.

Each biotherapeutic medicine, including similar biotherapeutic products (also known as “biosimilars”) needs to be traceable and easily identifiable. The importance of the specific traceability for these products is emphasized due to the complex production process and potential for generating unwanted immune responses that may delay onset of adverse drug reactions.

Subsequently, each biotherapeutic medicine, including similar biotherapeutic products, should be required to have a distinct name that clearly distinguishes it from other biotherapeutic medicines. This would ensure the clear identification, safe prescription and dispensing of medicines to

## Did you miss the Forum?

View Dr Ruiz de Erenchun’s presentation at [http://www.ifpma.org/fileadmin/content/Events/Pharma\\_Forum/20\\_Nov\\_2012/IFPMA\\_Mr\\_Fermin\\_Ruiz\\_de\\_Erenchun.pdf](http://www.ifpma.org/fileadmin/content/Events/Pharma_Forum/20_Nov_2012/IFPMA_Mr_Fermin_Ruiz_de_Erenchun.pdf)

patients, and enable accurate reporting and analysis of adverse drug reactions (i.e. improve traceability).

Under the current WHO criteria for International Nonproprietary Names (INNs) it is possible for multiple biotherapeutic medicines to have the same INN with different clinical characteristics. As a result, there is no clear INN differentiation between similar products. Therefore, IFPMA recommends that the role of INNs in pharmacovigilance be further considered, and WHO should determine on a global level how the current naming system can be applied to retain the goals of the INN system.

Biotherapeutic medicines have unique product characteristics, due to their biological nature and complex structure that require the tracking of adverse drug reactions for individual medicinal products. Additionally, identification and traceability are essential, and all stakeholders have a role in ensuring robust pharmacovigilance for biotherapeutic medicines.

*“Due to their biological nature and complex structure, biotherapeutic medicines have unique product characteristics that require the tracking of adverse drug reactions for individual medicinal products. Additionally, identification and traceability are essential, and all stakeholders have a role in ensuring robust pharmacovigilance for biotherapeutic medicines”*

**Resources:**  
**IFPMA & Biotherapeutic Medicines**  
- [www.ifpma.org/innovation/biotherapeutics.html](http://www.ifpma.org/innovation/biotherapeutics.html)

## Types of pharmaceutical products

Chemically-synthesized small molecule medicines	Biotherapeutic medicines
<ul style="list-style-type: none"> <li>✓ Produced through a step-by-step chemical synthesis process</li> </ul>	<ul style="list-style-type: none"> <li>✓ Produced with a biological synthesis process and derived from proteins and other substances produced by living organisms</li> </ul>
<ul style="list-style-type: none"> <li>✓ Characterized by small molecule composition</li> </ul>	<ul style="list-style-type: none"> <li>✓ Composed by large and complex molecules which are difficult to characterize</li> </ul>
<ul style="list-style-type: none"> <li>✓ Relatively simple organic compounds containing few functional molecular groups</li> </ul>	<ul style="list-style-type: none"> <li>✓ More sensitive to change and the end product is determined by a wide range of factors, including the manufacturing process</li> </ul>
<ul style="list-style-type: none"> <li>✓ Typically prescribed by a primary care physician and self-administered at home</li> </ul>	<ul style="list-style-type: none"> <li>✓ Generally used for the treatment of severe diseases and therefore mostly administered in hospitals with the assistance of medical personnel (with exceptions such as self-administered insulin)</li> </ul>

# Pharmacovigilance: partnering for patient safety



**Mr Jeremiah Mwangi**, *Policy & External Affairs Director, International Alliance of Patients' Organizations (IAPO)*

IAPO believes that both patients and patient groups can make an important contribution to pharmacovigilance. Educating patient groups on pharmacovigilance is the first step toward understanding the critical role that they can play as well as demonstrate how they can participate and provide input at both the local and national levels. IAPO deems both of these elements as critical to raising public awareness on this issue and works to identify and train individuals on outreach and patient safety.

Representing 215 patient organizations, IAPO focuses on building "patient-centered healthcare" through capacity building, advocacy and partnerships, thus creating

## Did you miss the Forum?

View Mr Mwangi's presentation at [http://www.ifpma.org/fileadmin/content/Events/Pharma\\_Forum/20\\_Nov\\_2012/IAPO\\_Mr\\_Jeremiah\\_Mwangi.pdf](http://www.ifpma.org/fileadmin/content/Events/Pharma_Forum/20_Nov_2012/IAPO_Mr_Jeremiah_Mwangi.pdf)

an environment that includes patient engagement and choice. IAPO frequently partners with other health initiatives to ensure that patients are included throughout the whole process.

One example of IAPO's participation is with the Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium (PROTECT). The goal of PROTECT is to "strengthen the monitoring of the benefit-risk of medicines in Europe" with the development of tools and innovative methods to, among other objectives, enhance data collection directly from consumers, conduct pharmacoepidemiological studies and improve early signal detection of potential adverse drug reactions. PROTECT is a European Consortium coordinated by the European Medicines Agency that includes 33 partners from both the public and private sector.

### Resources:

**PROTECT – Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium**  
[www.imi-protect.eu/about.shtml](http://www.imi-protect.eu/about.shtml)

## About IFPMA

IFPMA represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 1.3 million employees research, develop and provide medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

IFPMA manages global initiatives including: IFPMA Developing World Health Partnerships Initiative, which studies and identifies trends for the research-based pharmaceutical industry's long-term partnership programs to improve health in developing countries; IFPMA Code of Practice, which sets standards for ethical promotion of medicines; IFPMA Clinical Trials Portal, which helps patients and health professionals find out about on-going clinical trials and trial results.

"...the essence of patient-centered healthcare is that the healthcare system is designed and delivered to address the needs and preferences of patients, so that healthcare is appropriate and cost-effective"

**IAPO - [www.patientsorganizations.org](http://www.patientsorganizations.org)**

For more information about IFPMA:  
<http://www.ifpma.org>