



THE ORGANISATION  
FOR PROFESSIONALS IN  
REGULATORY AFFAIRS

## **A renewed European Strategy for Pharmaceuticals in Europe:**

**A review and discussion of the European Commission  
10 December 2008 package comprising:**

**Communication to launch reflections on ways to  
improve market access and to develop initiatives to  
boost EU pharmaceutical research.**

**Proposal to tackle the growing issues of Counterfeiting  
and illegal distribution of medicines.**

**Proposals to enable citizens to have access to high-  
quality information on prescription-only medicines**

**Proposals to improve patient protection by  
strengthening the EU system for the safety monitoring  
('pharmacovigilance') of medicines.**

*25<sup>th</sup>-26<sup>th</sup> February 2009*

**Radisson SAS Royal Hotel, Brussels, Belgium**

**A TOPRA MEETING WITH THE CO-OPERATION OF THE EUROPEAN  
COMMISSION**

**Conference working party**

Martin Terberger – Unit F2, European Commission

Irene Sacristan Sanchez – Unit F2, European Commission

Matus Ferech – Unit F2, European Commission

Craig McCarthy – Transcrip Partners LLP, France (Chair)

Alan Hunter – TOPRA President

Brenton E James – Consultant in Strategic Regulatory Affairs in Europe

Axel Wenzel - Pharma Scientific Services, Germany

Paolo Biffignandi - VI.REL Pharma S.a.s. Italy and EU Vigilance Ltd, UK

Supported by TOPRA staff

9:00	<b>Registration and Coffee</b>
9:30	<b>Welcome from TOPRA:</b> Lynda Wight - <i>TOPRA Executive Director</i>
9.40	<b>OPENING ADDRESS:</b> <b>Welcome and Hopes for the Conference:</b> Martin Terberger – <i>Head of Pharmaceuticals Unit (F2)</i> <i>European Commission, DG Enterprise &amp; Industry</i>
9.55	<b>Understanding the EU Legislative Process: Structure, People and Procedures</b> Stephane Lebrun - <i>Unit A3, European Commission, DG Enterprise &amp; Industry</i>
10.40	<b>Coffee</b>
<p><b>SESSION 1: The Development, Purpose and Expected Outcomes of the Pharmaceutical Package and in Particular the Commission Communication of 10 December 2008</b></p>	
<p><i>This session will discuss the reasons behind the Pharmaceutical Package, including the Commission Communication. At the end of this session delegates will have an understanding of the various pressures for these reforms in legislation and also a wider appreciation of the future direction of the Pharmaceutical sector in the EU with non-legislative initiatives</i></p>	
<p><b>Chairpersons:</b></p> <p>Martin Terberger – <i>Head of Pharmaceuticals Unit (F2,)</i> <i>European Commission, DG Enterprise &amp; Industry</i></p> <p>Brenton James – <i>Consultant in European Regulatory Affairs,</i> <i>UK</i></p>	
11.10	<b>Introduction from the chairs</b>
11.15	<b>The Pharmaceutical Package: an Overview of Purpose and Content</b> Irene Sacristan Sanchez – <i>Deputy Head of Pharmaceuticals Unit (F2), European Commission, DG Enterprise &amp; Industry</i>
11.35	<b>The Communication on the Future of the Pharmaceutical Sector</b> Thomas Heynisch - <i>Competitiveness in the Pharmaceuticals Industry and Biotechnology Unit (F5), European Commission, DG Enterprise &amp; Industry</i>
12.05	<b>Speaker Panel with this session's speakers</b> The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you
13.00	<b>Lunch</b>

<b>SESSION 2: COUNTERFEITS</b>	
<p><i>This legislative proposal aims at strengthening EU legislation to better protect EU citizens from the serious threats posed by fake medicines. There is an alarming increase of medicinal products detected in the EU which are false representations of authorised medicines. These products usually contain sub-standard or false ingredients, no ingredients or ingredients in the wrong dosage thus posing a serious threat to human health. The overall principle of the proposal adopted 10 Dec 2008 by the European Commission is to protect the legal distribution chain from the infiltration of fake medicines. This will help to ensure confidence of distributors, health care professionals and patients in the medicinal products they trade, prescribe and purchase in the legal supply chain. This session will discuss the details of this proposal</i></p>	
<p><b>Chairpersons</b></p> <p style="text-align: right;">Stefan Führung - <i>Pharmaceuticals Unit (F2), European Commission, DG Enterprise &amp; Industry</i></p> <p style="text-align: right;">Axel Wenzel - <i>Pharma Scientific Services, Germany TOPRA Board Member</i></p>	
14:00	<b>Introduction by the Chairs</b>
14.10	<b>Ensuring the Safety of the Supply Chain: a Commission Review of the Proposal</b>
	Stefan Führung - <i>Pharmaceuticals Unit (F2), European Commission, DG Enterprise &amp; Industry</i>
14:40	<b>A Manufacturer's View</b>
	Steve Allen – <i>Director Global Security, Pfizer</i>
15.00	<b>The National Agency View</b>
	Michael Deats - <i>Group Manager, Enforcement Group Inspection, Enforcement and Standards Division Medicines and Healthcare products Regulatory Agency (MHRA), UK</i>
15.20	<b>Tea</b>
15.50	<b>View from the Enforcement agencies</b>
	Aline Plancon – <i>Interpol and member of IMPACT</i>
16.10	<b>Brief Presentations from other affected parties:</b>
16.10	<b>Susanne Keitel, EDQM (EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES AND HEALTH)</b>
	<b>Heinz Kobelt, EAEPC (European Parallel Distributors' Association)</b>
	<b>Ruud van Anraat - Director Public Affairs, Teva Pharmaceuticals Europe BV</b>
	<b>Speaker from non-prescription industry</b>
16.50	<b>Speaker Panel with this session's speakers</b>
	The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you.
18.00	<b>Close for day followed by a networking drinks reception</b>

Thursday, 26<sup>th</sup> February 2009  
Day Two

<b>SESSION 3: PHARMACOVIGILANCE</b>	
<p><i>These legislative proposals aim at better protecting patients by strengthening the EU system for the safety monitoring of medicines (pharmacovigilance). The supervision and monitoring of adverse reactions of authorised medicines are done through the EU's pharmacovigilance system. The current system is however complex, leads to duplication of effort as well as potential for confusion of responsibilities. A lack of harmonisation not only interferes with the functioning of the single market in pharmaceuticals but also poses a threat to public health. The Commission's proposals aim at simplifying the current system with the overall objectives of better protecting public health, ensuring the proper functioning of the internal market and simplifying the current rules and procedures</i></p>	
<p><b>Chairpersons:</b></p> <p style="text-align: center;">Irene Sacristan Sanchez – <i>Deputy Head of Pharmaceuticals Unit (F2), European Commission, DG Enterprise &amp; Industry</i></p> <p style="text-align: center;">Paolo Biffignandi - <i>VI.REL Pharma S.a.s., Italy and EU Vigilance Ltd, UK, President-Elect, TOPRA</i></p>	
09.00	<b>Introduction from the Chairs</b>
09.15	<b>A Commission Overview of the Pharmacovigilance Proposals</b>
<p>Lenita Lindström-Rossi - <i>Pharmaceuticals Unit (F2), European Commission, DG Enterprise &amp; Industry</i></p>	
10.00	<b>The Industry Viewpoint</b>
<p>Val Simmons - <i>Lilly QPPV Executive, Global Patient Safety, Lilly</i></p>	
10.30	<b>Coffee</b>
11.00	<b>The National Agency Viewpoint</b>
<p>Doris Stenver - <i>Chief Medical Officer, Consumer Safety Division, Pharmacovigilance Working Party Delegate, Danish Medicines Agency</i></p>	
11.30	<b>The National Agency Viepoint</b>
<p>Thierry Roisin - <i>Conseiller général Division Vigilance, Agence Fédérale des Médicaments et des Produits de Santé, Belgium</i></p>	
11.45	<b>Speaker Panel with this session's speakers</b>
<p>The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you.</p>	
12.45	<b>Lunch</b>

<b>SESSION 4: INFORMATION TO PATIENTS</b>	
<p><i>These legislative proposals aim at ensuring that EU citizens have access to reliable information on medicines available, the grounds on which they have been authorised and how they are monitored. Today EU legislation does not provide for sufficient harmonised rules in this area and as a consequence EU citizens have unequal access to information across the EU. The overall principle of the proposal is to lay down clear rules on information provided by pharmaceutical companies on prescription-only medicines. This proposal is very important for patients as it will help empower EU citizens to make more informed decisions about their health</i></p>	
<p><b>Chairpersons:</b></p> <p style="text-align: center;">Martin Terberger – <i>Head of Pharmaceuticals unit (F2,) European Commission, DG Enterprise &amp; Industry</i></p> <p style="text-align: center;">Alan Hunter – <i>TOPRA President</i></p>	
13:45	<b>Introduction from Alan Hunter, TOPRA President</b>
13:55	<b>Information to Patients: a Review of the Proposals</b>
	Irene Sacristan Sanchez – <i>Deputy Head of Pharmaceuticals Unit (F2), European Commission, DG Enterprise &amp; Industry</i>
14.40	<b>National Authority View</b>
	Christer Backman – <i>Medicines Products Agency (MPA), Sweden</i>
	<ul style="list-style-type: none"> <li>• A national agency's view on the need for the legislative initiative</li> <li>• Pros and cons</li> <li>• The major concerns</li> </ul>
15.00	<b>Tea</b>
15.25	<b>The End User's View</b>
	Ilaria Passarani - <i>BEUC (The European Consumers Association), Belgium</i>
	<p>While strongly supporting the end users right to access high quality information about Prescription only medicines, Consumers Organisations remain sceptical about the provision of such information by Industry, and are urging Commission to nip the proposals in the bud, preferring a comprehensive health information strategy that:</p> <ul style="list-style-type: none"> <li>- puts health interest first</li> <li>- relies on solid sources of information</li> <li>- enables consumers to choose medicine and treatment options</li> <li>- truly addresses inequalities in access of health care information.</li> </ul>
15.45	<b>The Doctor's View</b>
	Lisette Tiddens-Engwirda – <i>Secretary General, Standing Committee of European Doctors, Belgium</i>
	<ul style="list-style-type: none"> <li>• It goes without saying that THE basis for information is the patient-doctor relationship</li> <li>• CPME wants to maintain the ban on direct to consumer advertising of prescription medicines</li> <li>• It is the responsibility of the Pharma industry to inform doctors with accurate and complete information on their drugs. The information should be understandable, objective, of high quality and non-promotional.</li> <li>• In CPME's view, it will amount to indirect advertising if the Pharma industry is allowed to 'inform' patients directly.</li> </ul>
16.05	<b>The Industry View</b>
	Paul Woods - <i>Global Compliance Policy Director, AstraZeneca</i>

	<ul style="list-style-type: none"> <li>• Pharmaceutical companies can play a valuable role, alongside and in partnership with others, in providing high-quality and reliable non-promotional information on the prescription medicines they have researched</li> <li>• The overall objective of the Commission's proposals to establish a harmonised legal framework on how companies make information available for the benefit of all EU citizens and patients should be welcomed.</li> <li>• It is appropriate that reasonable, non-bureaucratic safeguards are put in place to ensure that company information is of high quality and does not promote prescription medicines to the public.</li> <li>• The Commission proposals do not go beyond current national 'best practice' in Europe but they do require some clarification to ensure that all appropriate information provision can continue.</li> </ul>
16:25	<b>Speaker Panel with this session's speakers</b>
	The speakers will take questions from the floor – this is your opportunity to explore topics more fully on issues of interest to you.
17:00	<p><b>Close of meeting:</b>  Ms. Lenka Ticha, Chair of the Council Working Party from the Czech Republic Presidency , Third Secretary Public Health &amp; Pharmaceuticals and Medical Devices</p> <p>Alan Hunter, <i>TOPRA President</i></p>