

## **New Approach to Benefit-Risk Offers Informed, Tailored Decision-Making for Nonprescription Medicines**

Expert Panel Publishes Framework to Modernise Regulation of OTC  
Medicines in *Clinical Pharmacology & Therapeutics*.

Ferney-Voltaire, France – 11 November 2011 --- As consumers and health systems move toward greater reliance on self-care, regulatory and clinical decision making should be improved through new tools to assess the unique benefits and challenges of self-care nonprescription ('over-the-counter', OTC) products, according to a new White Paper published in the peer-reviewed journal *Clinical Pharmacology & Therapeutics*<sup>1</sup>.

Regulators are working within a complex environment where systems to assess nonprescription medicines and approaches vary from country to country. There is often insufficient distinction between the evaluations of prescription-only and nonprescription medicines. Current approaches focus more on risk, rather than its management, and tend to overlook the particular beneficial features of nonprescription medicines. Often some attributes, like quality of life enhancements and the value of access and convenience, are difficult to incorporate within current regulatory frameworks.

In response to the current situation, Professor Eric Brass (University of California, Los Angeles) has collaborated with Prof. Ragnar Lofstedt (Kings College, London), and Prof. Ortwin Renn (University of Stuttgart) to create a new Benefit-Risk Framework that allows comprehensive identification of relevant benefit and risk features for nonprescription medicines.

The researchers use a "Value-tree Framework" that allows identification of the benefits and risks, and identification of those that are most clinically relevant. The approach facilitates early dialogue and agreement between manufacturers and regulators on the weighting of the most important characteristics, key gaps in the data and the approach to integrated benefit-risk assessment.

To assist with decision-making processes over time, the method also supports alternative formal benefit-risk methods, including multiple criteria analysis. The team used a revised IRGC (International Risk Governance Council) Framework to create a so-called “*OTC Nautilus*” that emphasizes transparency, communication and evidence-based decision making supplemented by balanced expert opinion.

“While today we focus so much on risk mitigation, it is likewise vital for us to ensure there is a thoughtful consideration of the benefits that may be derived from a given product,” said Prof. Lofstedt. “Any risk needs a frame of reference and our approach, using in this case the revised IRGC framework, is designed to give regulators and other stakeholders a more holistic look at a product and its intended use.”

“The right tools can facilitate more fully informed regulatory decisions with a view to enabling appropriate access to effective nonprescription medicines while protecting the public’s health,” said Prof. Brass.

The paper complements wider World Self Medication Industry (WSMI) Modernisation initiatives to enhance appropriate access to non-prescription medicines globally.

“Industry and regulators must unite to advance the way we view and regulate self-care products by embracing new tools such as the new Benefit-Risk Framework that will help ensure the consumer will continue to have access to valuable medicines under appropriate regulatory control,” said Dr David Webber, Director-General of WSMI.

ENDS

**Notes to Editors:**

WSMI supported the White Paper under contract and charter which guaranteed the authors had final editorial control.



**WSMI**

WORLD *self*-MEDICATION INDUSTRY

*The world federation promoting better health  
through responsible self-medication*

*NGO in official relations  
with the World Health Organization*

### About WSMI

The World Self-Medication Industry is a federation of around 50 member associations representing manufacturers and distributors of non-prescription medicines on all continents.

As a Non-Governmental Organization (NGO) in official relations with the World Health Organization, WSMI represents the self-care products industry and contributes to global public health goals through its specialized expertise.

### About the Authors

**Professor Eric Brass** is Professor of Medicine, the David Geffen School of Medicine, UCLA, USA and serves as the Director of the Center for Clinical Pharmacology at Harbor-UCLA Medical Center. Prof Brass is also a former member of the FDA Nonprescription Drug Advisory Committee (NDAC) and Chair; and former member of the FDA's Dietary Supplements Advisory Committee. Prof Brass has authored over 160 original research and review articles since 2001.

**Professor Ragnar Löfstedt** is Professor of Risk Management and Director of the King's Centre for Risk Management. Prof Löfstedt completed a post-doctorate position at the Risk, Society and Policy Group at the International Institute for Applied Systems Analysis (IIASA) in Austria. Prof Löfstedt currently serves on the editorial boards of the International Journal of Risk Assessment and Management, Journal of Health Communication, Risk Analysis and Risk Management. In 2000 Prof Löfstedt was awarded the Chauncery Starr for exceptional contributions to the field of risk analysis by the Society for Risk Analysis (SRA). In 2006 Löfstedt was presented with the Outstanding Service Award from the SRA.

**Professor Ortwin Renn**, University of Stuttgart, Germany is Chair of Environmental Sociology and Director of the Interdisciplinary Research Unit for Risk Governance and Sustainable Technology Development (ZIRN) at the University of Stuttgart. Prof Renn is also Director of non-profit company DIALOGIK, a research institute focusing on environmental policy. Prof Renn is a member of the International Risk Governance Council (IRGC) whose main purpose is to help aid the understanding of emerging global risks that impact on human health, the environment and society at large.



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### About the journal

Clinical Pharmacology & Therapeutics (CPT) is the official journal of the American Society of Clinical Pharmacology & Therapeutics, and a part of the *Nature* publishing group.

CPT is the authoritative cross-disciplinary journal in experimental and clinical medicine devoted to publishing advances in the nature, action, efficacy, and evaluation of therapeutics. CPT provides a forum for perspectives in clinical pharmacology and therapeutics in the context of contemporary scientific, political, economic and social issues. CPT highlights issues transforming the practice of clinical pharmacology, including ethics, education and public policy. In the area of therapeutics, CPT publishes work within the context of clinical applications of basic pharmacology, discovery, translational medicine, and drug development.

### References

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1 Clinical Pharmacology & Therapeutics, 2.11.2011 doi:10.1038/clpt.2011.231;  
<http://www.nature.com/clpt/journal/vaop/ncurrent/full/clpt2011231a.html>