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From the Uppsala Monitoring Centre

A Review of Viewpoint Part 1 and Part 2

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Abstract

The core task of the Uppsala Monitoring Centre (UMC) is the collection and processing of adverse drug reaction reports from member countries of the WHO Programme for International Drug Monitoring to detect early signals of potential drug hazards. Also a high priority is the communication of information about drug safety issues to the widest possible professional and general audiences in order to improve patient safety and welfare. The publication of the two parts of the publication *Viewpoint* represents a pioneering effort to provide easily accessible information on international pharmacovigilance for lay and specialist readers.

1. Reaching Out On Complex Issues

With its core concerns for patient safety and rational drug use, pharmacovigilance is relevant to everyone who will ever take modern or traditional medicines and to those who care for people taking them; in fact, most of the people on the planet. Considering their importance, relatively little public attention is given to drug safety and rational use (for example, in the education of children).

The two parts of the publication *Viewpoint* provide a serious contribution to remedying this deficiency. Part 1, especially, is written for non-specialist readers and is colourfully presented and technical terms in the pharmacovigilance area are explained. It is written and designed for the widest possible general audience and centres on the obvious, but publicly little-known, truth that no drug is 100% safe for all people in all circumstances. It provides extensive coverage of how hazards can be detected and prevented and of the national and international efforts to improve therapy and its safety.

Basic concepts such as benefit and harm, effectiveness and risk are discussed, and explanations of the process of clinical trials and the limitations of information at the point a drug is first marketed are given. The interpretation of risk statistics is among the topics covered. The importance of adverse drug reaction (ADR) reporting, as a primary source of new intelligence about potential drug hazards, is highlighted along with the vital part observant patients play in the drug safety network.

Part 1 of *Viewpoint* sketches the activities of the Uppsala Monitoring Centre (UMC) and member countries in the WHO Programme for International Drug Monitoring, but Part 2 is an in-depth account of the Programme and the work of the UMC for a more technical specialist audience.[2] Every aspect of ADR reporting is described and illustrated in detail, from the patient's reporting of symptoms and the doctor's diagnosis of an ADR (or failure to recognise an ADR), through to classification of ADRs, methods for assessing cases, the use of the latest neural network techniques for detecting signals in the WHO international ADR database (Vigibase) and the process for disseminating this information. The structure and intricacies Vigibase itself are laid out and the WHO Drug Dictionary (WHO-DD) and the WHO Adverse Reaction Terminology (WHO-ART) – the core tools 646 Hugman

for coding and the analysis of ADR reports – are explained and illustrated.

The issue of drug safety is increasingly important in relation to herbal medicines used, sometimes alongside modern drugs, by a large percentage of the world's population. Part 2 of *Viewpoint* describes some of the pioneering work done by the UMC in the classification of herbals and in the effort to place them within the framework of pharmacovigilance. *Viewpoint* provides a record of the worldwide collaborations that have led to advances in this and many other areas. It also records the many influential publications and training activities in which the UMC has played a leading part (including much of the work of CIOMS).

This 68-page volume, which is attractively designed and in full colour, is a technical reference source for those who want to learn in detail about the science of pharmacovigilance, as well as a comprehensive account of the work of the UMC and its worldwide network of collaborating countries. For anyone who has ever asked 'what does the UMC do?', 'how does it work?' and 'how useful are its activities?', *Viewpoint* provides comprehensive answers.

2. The Objectives of the UMC

Ralph Edwards, Director of the UMC, has strong views about the neglect of drug safety as a topic of concern for lay and professional audiences: "I am sometimes amazed at the low priority given to pharmacovigilance in undergraduate and post-qualification medical training, especially since we know a good deal about the huge costs of its neglect in terms of financial loss and human suffering. But patient education is seriously deficient too and that means we have to try to raise knowledge and awareness among the population as a whole. Critical and

well informed patients have a very important role to play in improving public health and drug safety in general. *Viewpoint* Parts 1 and 2 represent a very serious commitment on our part to spreading the message as widely as possible. I hope they will also shed more light on how we at the Centre go about our vital day-to-day work".

The UMC has played a leading part in raising the profile of communication as a high priority skill in drug safety and it has rapidly risen up the international agenda in recent years. *Viewpoint* is an attempt to model best practice in modern communications and bring complex and unusual knowledge to the public in a form which is attractive and accessible – and will help change behaviour.

Viewpoint Part 1 was published 3 years ago and quickly proved to be popular, to the extent that editions were produced in both French and Spanish, and stocks of the English edition were soon exhausted. At the time of the arrival of Part 2 earlier this year, Part 1 was reprinted and is available again. Both parts are free and can be obtained by request by e-mail (info@who-umc.org); they can also be viewed on the UMC website (www.who-umc.org). The UMC is very keen to improve and extend activities and publications of this kind; suggestions for new projects or improvements in existing ones are always welcome.

References

- Viewpoint. Watching for safer medicines. Part 1. The Uppsala Monitoring Centre: Uppsala, 2002
- Viewpoint. Watching for safer medicines: the scientific story. Part 2. The Uppsala Monitoring Centre: Uppsala, 2005

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