

WHO News

Recommendations from the first Meeting of the Advisory Committee on Safety of Medicinal Products, 20–22 October 2003, WHO, Geneva *

We are pleased to report that the first meeting of the newly established Advisory Committee on Safety of Medicinal Products was held in October. This meeting was very productive and a number of recommendations were made. A statement was made by this Committee recommending the need to incorporate pharmacovigilance in the WHO strategy to provide antiretrovirals to three million people by 2005. The feature article emphasizes the urgency in evolving a safety strategy for herbal issues as these remain largely un-addressed.

Recommendations

Setting priorities

The Committee raised the following issues as key points in promoting drug safety activities through the WHO International Drug Monitoring Programme.

1. **Advocacy:** There is a real need to convince the public and politicians of the importance and impact of adverse drug reaction (ADR) reporting. An advocacy document should be drafted to outline a common vision for excellence in pharmacovigilance and the positive cost/benefit value of ADR monitoring, with a link to rational drug use around the world.
2. **Development of risk management plans:** A well-designed risk management strategy should be in place, complementing the methods of risk assessment. A workshop should be organized to develop and implement such a strategy.
3. **Alternative approaches to drug safety-monitoring:** Methods such as cohort (prescription event) monitoring should be encouraged, in addition to the current spontaneous ADR reporting system, to account for local situations and practices and thus providing a more complete and comprehensive picture.
4. **Traditional Systems of Medicine:** There needs to be additional focus in special areas such as traditional Chinese medicine.

*This article appeared earlier in the WHO Pharmaceuticals Newsletter, No. 5, 2003, and is published with permission.

Pharmacovigilance in public health

1. Public health programmes could serve as important gateways to introduce and implement pharmacovigilance in countries currently lacking safety monitoring programmes.
2. The draft document on Pharmacovigilance in Public Health: emerging needs' was discussed and the Committee proposed that the document should clearly identify policy makers and public health programme managers as target audiences. The introductory section should stress the vision of the document by including the following:
 - Medicines in public health programmes should be used safely and effectively to achieve the best possible health outcomes.
 - All public health programmes should include a medicine risk management strategy, defined prior to the implementation of a project.
 - All public health programmes should promote pharmacovigilance in the countries in which they operate.
3. Progress in pharmacovigilance for antimalarials:
 - Following the initial launch of the programme to monitor artemisinin combination therapy (ACT) in the five countries of Burundi, DRC, Mozambique, Tanzania and Zambia, the initiative will be rolled out to include other countries in Africa.
 - The Committee acknowledged the rapid progress made with this initiative, recognizing the significance of what has been achieved to date. The Committee recommended that this important activity should be endorsed by WHO, extended and used as a model for other disease-driven projects such as HIV and TB.
4. Pharmacovigilance in lymphatic filariasis:
 - Experience from national programmes on filariasis will be reviewed by a subgroup of the committee and later discussed at the next meeting of the Advisory Committee.
5. Pharmacovigilance in parasitic disease programmes:
 - Further data on praziquantel use in pregnancy should be reviewed.
 - The initial surveillance of triclabendazole in fascioliasis (foot-borne trematode) should be followed by an ongoing monitoring.
6. Pharmacovigilance in herbal medicines:
 - The Committee's approval of the proposed WHO Guidelines on Safety Monitoring and Pharmacovigilance of Herbal Medicines is solicited.
 - Committee members will provide written comments to WHO by mid-December prior to further revision and wider consultation in early 2004.

Pharmacovigilance for antiretrovirals

1. The Committee unanimously recommended that the issue of patient safety as an aspect of the 3 by 5 initiative is of paramount importance.
2. The Committee prepared a document detailing the challenges, specific safety concerns and proposals to address these issues and enhance the success of the programme.

Current safety issues

1. Chlorproguanil/dapsone: use in African countries.
A statement was drafted and will be published at a later date.
2. Isotretinoin: teratogenicity.
The committee agreed that a review of isotretinoin should be undertaken but limited to its inappropriate or illicit use, with a request for information circulated via Vigimed; it may be necessary to consult with external agencies (e.g., police departments, enforcement groups, etc.) at the national level.
3. Thalidomide: current status of registration.
The current status of review of thalidomide at the EU level, availability of any evaluation reports and the proposal for monitoring thalidomide within the 'Steps' programme will be investigated. The outcome will determine future needs to commission an expert review of available evidence-base for concerns associated with thalidomide use, including the Cochrane database.
4. Kava-kava: traditional use.
 - The Committee endorsed the recommendation to obtain data/assessments from countries from whom kava use associated adverse reaction reports are available, including comprehensive literature reviews.
 - The WHO Collaborating Centre for International Drug Monitoring would help compile the available data on kava-products and their safety as well as re-evaluate all data thereafter.
 - The investigation, comparison of extraction and analysis procedures across the various kava preparations could be undertaken possibly as a PhD project in a suitable location.