ISSUES IN MEDICINE

THE MEDICINES REGULATORY SYSTEM IN SOUTH AFRICA — REVIEW AND PROPOSALS FOR REFORM

Review and reform of the South African national drug regulatory authority, the Medicines Control Council, is long overdue. Other countries have benefited in recent years from independent examination of their systems of medicines control, and it was hoped that the same might be achieved for South Africa. There were fundamental issues to be addressed, including the need to decide how to place a regulatory framework for control of complementary medicines, and personnel change in a number of the expert committees of the Council and the secretariat to meet the needs of transformation. (The Council itself did not have that problem, having been appointed by the Minister of Health in 1996.)

WEAKNESSES OF THE MCC

It is inevitable in the adversarial climate of drug regulation that there will be criticism of the national authority. Some of this is justified. For example:

1. Leadership is vested in too few people, given that all the members of the Council have demanding full-time positions in their own institutions. There have been chronic difficulties in recruiting and keeping competent full-time scientists and medically qualified personnel in the secretariat.

2. A formula for successfully communicating results, decisions and explanations for Council policy to the public has not been adequately achieved. It becomes particularly obvious when intensity of public and media interest is high. This is further complicated by the legislative requirements that prevent the Council from divulging details that might compromise intellectual property of the applicants.

3. Perhaps more than anything else, the deficiencies of the Council are reflected in its inability to translate decision-taking into a supportive programme of drug information provision, reactive as well as proactive, for the health professions and the public. Clinics and other primary health care facilities, whose need is greatest, particularly require drug information and advice on rational drug use. This deficiency has been one of resources and inability of the Council to persuade the authorities of the importance of drug information.

What has never been suggested in criticism of the MCC are impropriety, dishonesty, graft, irregularities, lack of fairness, or departure from the principles of natural justice which govern South African administrative laws and thus the operations of the Council.

THE PROPOSED SOLUTION

Over January - March 1998 a review team, appointed by the Minister of Health, considered the difficulties and criticisms under which the MCC currently labours. The review team has proposed as its solution, in place of the MCC, a central management team, linked directly to the Minister of Health and advised by two technical committees dealing with conventional and complementary (traditional) medicines, respectively. The overarching authority will be stronger in management than in science and clinical practice. Review of complementary medicines will fall within the same authority, which has been the preferred approach of the present Council. New senior management and director positions will be created. Training programmes for staff will be strengthened and further developed.

Any proposal for a new drug regulatory authority needs to rest on foundations which have proved in the experience of the Council to be firm.

SPECIAL FEATURES OF THE MCC

Certain features of the MCC have proved to be special to the country, and they have served the nation well. They have been underpinned by a number of foundation principles. These principles include:

1. Emphasis on scientific and clinical principles at every level of decision taking.

2. Inclusion of a broad spectrum of university and clinical personnel, and delegation of the decision-making process to the lowest responsible committee level possible, while allowing adequate opportunity for peer review before final decisions are taken. (Countrywide, more than 120 consultants in pharmacy and medicine serve on expert committees of the Council, representing 11 of the country's universities.)

3. Application of the highest ethical and professional standards at every level of operation of the Council and its secretariat.

4. Flexible central administrative procedures linked to systematic staff training programmes within the secretariat. When regulatory decisions have already been taken elsewhere, an accelerated review system is implemented that enables rapid review, within a short time (weeks to several months), for important new developments. The anti-AIDS drug zidovudine, for example, was approved for use in South Africa within 17 days of its having been filed for registration.

5. Insistence on decision making of the Council at every level being vested in the hands of individuals who themselves are actively involved in the care of patients, teaching and research.

The highest standards have been set for the conduct of

clinical trials. This applies to the requirements for safety, toxicology, quality, scientific integrity and clinical relevance of new chemical entities before they are given to humans for experimental purposes. The MCC also requires independent approval by institutional ethics committees of all clinical trials. It is vital for a developing country that there should be no compromise in the standards of human experimentation, in order to prevent exploitation.

Whenever decisions of the MCC are challenged, this is dealt with by the Council flexibly, rapidly (within 30 days) and without cost to the applicants.

Markers of performance

There are several independent markers of performance of the MCC which the new authority should aim to strengthen in a manner that remains efficient and economical. These include:

1. An overall review time for approval of new medicines (brand products and generic medicines) that has been independently rated as being one of the five shortest in the world.
2. The MCC has served for a number of years as a training centre for drug regulators from developing countries elsewhere, and it is officially designated as such by the World Health Organisation. Many colleagues from throughout the world have received training in drug regulation at the MCC.
3. The MCC has taken a leading role in bringing about a regional plan in southern and East Africa for collaboration in sharing of drug regulatory decisions and policy.
4. The average turnover time for evaluation of clinical trials is 6 weeks, and this has been so for many years despite the ever-increasing number of applications.
5. The system of adverse drug event reporting and safety monitoring of medicines in South Africa has attracted international attention because of its efficiency and its strong emphasis on an academic and clinical approach.

The secretariat of the MCC has established an exceptional system of inspection and quality assurance of manufacturers. It has set the infrastructure for the development of a robust and flourishing local generic industry that provides the main proportion of the country's medicines in the public sector, thus benefiting in particular the poor.

Summary and conclusion

In planning the future national drug regulatory authority in South Africa, it is to be hoped that the pillars of scientific and clinical integrity that have supported the MCC in the past will be preserved.

It is disturbing that the review committee largely ignored the modus operandi and the successes of the MCC, so that the evidence in their report is weak and their recommendations unsuitable to a modern African country. A drugs review body must work in such a way that it makes the best use of the limited manpower and resources available. This will not be achieved by taking on more bureaucrats.

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EDITORIAL

Quinine as unofficial contraceptive — concerns about safety and efficacy

Quinine is extensively used as a contraceptive and sometimes as an abortifacient. In South Africa quinine sulphate (300 mg tablets) is available for unrestricted over-the-counter (OTC) sale in pharmacies. Current recognised uses for quinine are in the treatment of malaria (particularly chloroquine-resistant falciparum malaria), for prophylaxis and management of nocturnal leg cramps, and as a muscle relaxant in myotonia congenita.[1] Quinine is also reported to have been used in the past as an oxytocic to induce and facilitate labour in late pregnancy,[2,3] and in contraceptive pessaries, although its spermicidal action is described as weak.[4,5]

Since the source of oral quinine is from private pharmacies, two surveys (H Govender *et al.* and E A Amra *et al.* — unpublished research projects, University of Durban-Westville, 1993 and 1995) were conducted among 61 pharmacists and their 76 quinine-purchasing clients in KwaZulu-Natal. It was found that approximately 50% of the pharmacists sold quinine to an average of 2 - 6 clients per day. Quinine purchasers were almost exclusively black women, most between 20 and 29 years old. Reasons given for the purchase of quinine were mainly related to 'birth prevention'. Most women took 1 to 2 quinine tablets orally around the time of sexual intercourse, usually postcoitally. These doses are too low to be abortifacient. Few women were concurrently using a conventional contraceptive method. Some women reported side-effects of skin rash, tinnitus, blurred vision, nausea and vomiting.

Focus group discussions were also conducted among women in Cato Crest, an informal settlement in Durban (C Ramoorthy *et al.* — unpublished research project, University of Durban-Westville, 1996). All the women interviewed had knowledge of quinine use in pregnancy prevention, the majority knew of people who were currently taking quinine, and 23% had used quinine themselves. Women generally reported taking a single tablet orally after intercourse. Most regarded quinine as a popular choice of contraceptive and many believed that it was