

**EDITORIAL**

**VAN DIE REDAKSIE**

## The Drugs Control Council

Arising from the recommendations of the Commission of Enquiry into the High Cost of Medical Services and Medicines, the Drug Control Act No. 101 was passed in 1965. In terms of this Act the Drugs Control Council was established and has been in operation since July 1968. Its function is the registration of all drugs intended for human use. A drug is defined in the Act as 'any substance used in the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man, or restoring, correcting, or modifying any somatic or psychic or organic function in man'. While the Council's basic function is the registration of all drugs before they are marketed, for practical reasons registration has virtually been confined to 'new' drugs, that is, drugs that have been introduced since registration became a statutory requirement. The Council, in common with similar bodies round the world, has only touched the surface of the vast task of reviewing the qualities and claims of all 'old' drugs that were on the market before registration became statutory, since the registration of 'new' drugs has exercised the Council's resources to their full capacity.

In its application for registration of a drug, a pharmaceutical company must submit evidence of the quality of the ingredients both active and inactive, the containers, the preparation and presentation, proof that the final product contains what it purports to contain, and evidence of its pharmacological, toxicological and possible teratogenic properties as well as clinical trials in support of the claims of safety and efficacy. A new formulation or a new dosage form of a drug, 'old' or 'new', registered or unregistered, must be processed as a 'new' drug by the Council but data required in respect of a new formulation or a new dosage form of an 'old' drug such as aspirin need be far less comprehensive than what is required for a truly new antibiotic. The applicant must submit a draft package insert, the information pamphlet

which all too frequently is not seen by the prescribing doctor, and which, in the form approved by Council must be enclosed in every separate package leaving the factory, whether that package contains 20, 100 or 1 000 dosage forms. The package insert, *inter alia*, must specify the indications, contra-indications if any, side- and toxic effects, the recommended dosage and the Council's registration number. Advertising matter distributed by any means whatsoever may include only claims which are specified in the approved package insert which is virtually the passport to marketing.

The Council conducts its business through its permanent staff, which include pharmacists and at present one medical practitioner, and a number of expert committees which operate by correspondence. The Council, under the chairmanship of Professor H. W. Snyman, must include one or at the most two registered physicians, and there must be not less than one general practitioner, one pharmacologist, one pharmacist and an officer of the Department of Health. The Council meets every 3 months and the Executive monthly. The expert committees, each under the chairmanship of a Council member, and each consisting of 7 members with special knowledge appropriate to their committee's function, cover analytical protocol, presentation and preparation, efficacy, safety, advertisement and information and adverse reactions. Each chairman is responsible for reporting the opinions of his fellow members to Council. A small scheduling committee advises on the scheduling of each registered drug. The schedules are at present under major revision. Finally, there is an inspectorate of pharmacists who inspect Republic-situated factories of companies who have made application for registration of a drug or drugs. The inspectorate also visits any factory that Council for one reason or another deems it necessary should be inspected. Companies are informed of the reports and are required to rectify any deficiencies.

The Council has no laboratories of its own but occasionally refers analytical problems to State, provincial or university laboratories. It relies mainly on its own analysis of the evidence, laboratory or clinical, which is submitted with an application for registration, and if dissatisfied it refers back for further evidence and may ask that a claim be either withdrawn or else substantiated by additional submissions. The Act requires that Council furnish information concerning registered drugs to the medical, dental and pharmacy professions. Unfortunately cost and administrative problems have to date prevented the implementation of this requirement but the approved package insert is available for the asking.

The Act makes provision for exemption from registration. Section 21, for example, empowers the Council, after due scrutiny of evidence submitted by the company in accordance with a set

formula, to authorize the use of unregistered drugs in man, usually for the conduct of 'pre-registration' clinical trials in the Republic, the results of which may later be submitted in support of registration of a drug. Occasionally, at the request of a company, exemption under Section 21 is authorized for the use of a specified unregistered drug on a particular patient by the doctor who initiated the request.

The Council has been in operation less than 3 years. There have been regular meetings between the Executive of the Council and of the Pharmaceutical and Chemical Manufacturers' Association which have provided opportunity for frank discussion of problems that have arisen in respect both of interpretation of the Act and also of practical issues relating to registration procedures. This co-operation has certainly assisted in accelerating the achievement of competence.

## Die Wêreld Mediese Vereniging

Die 25ste vergadering van die Wêreld Mediese Vereniging is gedurende September in Ottawa gehou. Soos vantevore, was dit 'n luisterryke byeenkoms waar 34 ledeverenigings verteenwoordig was. Die Mediese Vereniging van Suid-Afrika het 'n afvaardiging van 3 verteenwoordigers en 1 alternatiewe verteenwoordiger gestuur. Sulke internasionale byeenkomste word altyd gekenmerk deur die nouer samewerking wat na afloop van die vergadering tussen die ledelande ontwikkel, en dit is sekerlik waar om te sê dat, afgesien van die werklike besprekings, sulke kontakte met kollegas uit ander wêrelddele van onskatbare waarde is.

Afgesien van die roetienewerk wat deur die Wêreld Mediese Vereniging-vergadering hanteer is, en wat onvermydelik jaarliks behartig moet word, was die hooftemas onder bespreking die toenemende vraagstuk in verband met die misbruik van verdowingsmiddels, die opleiding en gebruik van doktersassistente en, gedurende die tradisionele redakteurskonferensie, die probleme verbonde aan mediese kommunikasie.

Verskeie lande se verteenwoordigers het hul standpunte oor die misbruik van gewoontevormende middels gestel en dit het duidelik geblyk dat, hoewel die probleem sekerlik reeds in Suid-Afrika sy intrek geneem het, dit gelukkig nog nie hier die omvang aangeneem het wat in ander lande die geval is nie. 'n Aantal formele besluite

is uiteindelik deur die vergadering geneem en een van die belangrikstes was die feit dat die misbruik van verdowingsmiddels hoofsaaklik as 'n gesondheidsprobleem liefs as 'n geregtelike probleem gesien moet word. Een van die Suid-Afrikaanse afgevaardigdes het die vergadering daarop gewys dat so 'n besluit egter nie die implikasie mag inhou dat die wêreld se sosio-ekonomiese moeikhede nou uitsluitlik op die dokters se skouers gepak moet word nie.

Die hele aangeleentheid van die verligting van die huidige mediese mannekragtekort deur middel van die opleiding van doktersassistente is deeglik bespreek. Dit is ook 'n onderwerp wat steeds voor die Mediese Raad dien.

Gedurende die redakteurskonferensie het verskeie ervare joernaliste hul sienings oor moontlike verbetering van mediese tydskrifte uiteengesit. Tegnieese detail in verband met styl en dies meer, asook breër beginselsaangeleenthede is bespreek. Die presiese regte en pligte van die redakteur is ook onder die soeklig gebring en verskeie senior mediese redakteurs van nasionale algemene mediese tydskrifte het hieroor stelling ingeneem.

Die volgende vergadering van die Wêreld Mediese Vereniging vind in September 1972 in Amsterdam plaas en daar is rede om te verwag dat dit 'n ewe belangrike en leersame byeenkoms sal wees.