THE TESTING AND CONTROL OF PHARMACEUTICAL PRODUCTS

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During the year 1950 the South African Bureau of Standards established its test laboratories for pharmaceutical products. In the early days the bulk of the products under test were intravenous fluids. During the years that followed the Bureau has been called upon to prepare specifications, e.g. for intravenous fluids, vitamin preparations, surgical sutures, insulin injections, and other forms of drugs. In some instances certain of the products for which specifications were being prepared had already been prescribed in the *British Pharmacopoeia*. Where this was the case the standard laid down by the *B.P.* was adopted as the basis for the Bureau's specification. In other instances specifications were called for products where no provision had been made either in the *B.P.* or in the *B.P. Codex*. In these instances the basis of the specifications were drawn either from the *United States Pharmacopeia* or other national pharmacopoeias. Where no standard had been laid down the committee was forced to start *de novo* and the information had to be obtained from the manufacturers themselves.

When the Bureau first established its test facilities, there was very little in the way of a pharmaceutical manufacturing industry in South Africa. Today a number of overseas principals have established their own factories in this country or have made arrangements with organizations to manufacture for them. As a result of this increasing industry the Bureau of Standards has been called upon more and more to provide test facilities for a very wide range of manufactured pharmaceutical products, especially ethical preparations.

During these last few years the Union Tender Board has called increasingly upon the services of the Bureau with regard to the testing of products submitted against tender for Government use. From the beginning the Bureau had to submit frequent reports on the failure of many of the preparations submitted for tender or submitted against tender contract. The Bureau has similar experiences on tests conducted on behalf of various provincial authorities and their hospitals.

As the result of these failures an increasing interest was shown in the Bureau's test facilities by the various pharmaceutical manufacturers in South Africa and by the importing agents of overseas companies. As a result more and more products have been, and are continuing to be, submitted by the manufacturing industry to the Bureau for control purposes. The outcome of this is that it has been possible, where specifications exist, to grant the mark to certain manufacturers, thereby ensuring that the medical profession are getting tested products of high quality and performance and, in addition to this, there has certainly been a decrease in the number of failures experienced in tender contracts and other types of supplies to the various tender boards.

The Union Health Department, whose responsibility includes the administration of the Food and Drugs Act and the Therapeutic Substances Act, has been seeking the assistance of the Bureau in the field of testing, and today frequently submits varied samples drawn in terms of the administration of these two Acts. This work from the Union Department of Health continues to show a steady increase.

The pharmaceutical, vitamin and amino-acid assay laboratories of the Bureau of Standards, are we believe, the only laboratories of their kind in South Africa, except certain industrial control laboratories, which are equipped and have the experience to undertake a very wide range of tests and assays necessary in the control of the testing of ethical pharmaceutical products. As a result of this activity by the Bureau, and its very close liaison with large organized buying groups and the industry, both in this country and overseas, considerable improvement has been achieved in the quality of various types of products and in the development of their manufacture.

Before the Bureau established these laboratories, it had been necessary for industry to submit its products to overseas principals in order to have control tests carried out.

The foregoing does not necessarily imply that all is well in the field of manufacture of pharmaceutical products, their supply and usage. It is our experience that only a very limited amount of products are being submitted for test by the various purchasing authorities, and frequently on a selected basis. We believe that it is in the national interest that the various purchasing authorities and the medical profession should encourage greater use of the Bureau's laboratories for this important purpose. When the considerable progress is realized that has been made to date in the field of many of the products tested (with reference to their purity, performance and stability), it will be appreciated that a far better job can be done than is presently being done, if the majority of locally manufactured and imported products were submitted to the Bureau for testing.

We are convinced, although it is very difficult to put it on paper, that the Bureau has involved the country in a considerable amount of saving through the medium of its test facilities. We are likewise convinced that in the same way the Bureau has assisted the medical profession, in the field of the practice of medicine and surgery, as a result of the improvements brought about in the quality of the various products controlled or tested by the Bureau.

We are firmly convinced that if a far wider use were made of the test facilities in the purchasing of pharmaceutical products, considerably more national saving in various fields, i.e. costs, labour, and man-hours, could be made. It is essential for doctors, in carrying out their practices and treating illness and disease, that they should know exactly what they give when administering chemotherapy. This can only be achieved when the purity, performance, and stability of more products can be substantiated by an independent test authority such as the Bureau of Standards. Large purchasers of drugs and pharmaceutical products should always prescribe requirements to a specification and should at all times ensure that they get what they have asked for. Failure to do so must inevitably result in a higher cost of medical treatment than is necessary.

It is not necessary to detail what the Bureau is capable of undertaking. We are confident that in the Pharmaceutical Products Laboratory and the various other laboratories which have been established, we can undertake the test or assay of any pharmaceutical product submitted.

If the present practice of submitting products for testing is increased, we believe that in the years to come it will be possible for South Africa to have either its own national formulary or its own pharmacopoeia, works to which the Bureau could contribute in no small way. We are also sure that more and more branches of industry would voluntarily submit their products to the Bureau mark scheme which is a form of certification and guarantee of performance.