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EDITORIAL : VAN DIE REDAKSIE

THE GREAT HIATUS

The discovery of new drugs has contributed substantially to the great advance in the science and art of medicine that has taken place in recent years. The total effect of these contributions has been a very marked reduction in mortality from many diseases. Since 1930 the death rate in gastro-intestinal infections has been reduced by over 80 per cent, and that in pulmonary infections by nearly 70 per cent. Tuberculosis, meningococcal infections, mastoiditis, syphilis and scarlet fever all show a similar or greater decline in mortality. Taking tuberculosis alone, the annual saving all over the world from the use of the anti-tuberculosis drugs must be calculated in many millions of pounds.

The value of all this is well recognized, but there are nevertheless aspects of the situation which are disconcerting. In line with the rest of the Western World, South Africa is, for instance, wrestling with the problem of a working relationship between the medical profession and the pharmaceutical industry. The only difference is that the hiatus seems to be widening in South Africa. The problem, of course, stems from a rapidly changing world and the difficulty man is experiencing today in revising his preconceived ideas. A quarter of a century ago, 70 per cent of today's prescriptions could not have been written — and it is well to remember that the year was 1935. At that time research was still the prerogative of the universities. Then came the foundations of modern chemotherapy. The first sulpha drug 'prontosil' was discovered in the I.G. Laboratories, and from academic research in the United Kingdom came penicillin. After the Oxford workers had demonstrated the therapeutic effects of this wonderful drug, the industry played its role in the development of mass production. Adrenal studies led to steroid isolation by Reichstein working in the University and Ciba Laboratories in Basle. Whilst the Mayo Clinic 'discovered' cortisone, it took the pharmaceutical industry to develop the modern methods of production. Many more examples can be quoted of the contributions offered to medicine today by the combined efforts of workers in the industrial and academic spheres.

During recent years the pharmaceutical industry has played an increasingly important role in the field of research work. In objective terms, the following figures give some indication of the range of this work: The cost absorbed by the research effort in the UK alone was £7·5 million in 1960; 75 per cent of this expenditure was accounted for by five British firms. The £7·5 million represents 12·5% of National Health Service drug sales. The Medical Research Council, on the other hand, spent £3·8 million in 1958 on research. For Canada and the USA corresponding figures are available.

In this connection it should also be pointed out that in all three countries mentioned above, somewhere in the region of 20 - 25% of research expenditure by the pharmaceutical firms is on fundamental research, i.e. on projects not identified with a specific product or process, but rather with the primary objective of adding to overall scientific knowledge.[1]

If we ask ourselves whether it is correct or advisable for the pharmaceutical industry to take over research work to such a large extent, we must be realistic and accept the fact that under a system of free enterprise any other method is hardly conceivable. We have no doubt, however, that the solution of many important problems in this connection lies in the direction of greater and more effective cooperation between the medical profession and the pharmaceutical industry.

Within the last 30 years, as was pointed out above, new drugs have played an important part in our conquest of disease. In many cases they constitute the most important factor, e.g. antibiotics and biologicals. The successful attack on disease is the result of the combined effects of advances in medical techniques due to medical research in medical schools, medical research institutions and Government medical institutes, which have elucidated a greater understanding of the mechanisms involved in the disease process, and to modern drugs, the majority of which have been discovered and developed by the pharmaceutical industry. The industry is, in essence, a sensitive mechanism for translating the needs of physicians into new research projects. The belief that it will be technically feasible for the laboratory to discover the required agent and the hope of realizing the commercial potential are sufficient to justify the risk of failure.[1]

Under the arresting title 'The premature persuaders', a recent leading article in *The Lancet*[2] draws attention to the absolute necessity for members of the medical profession and the industry to cooperate on a responsible level in, for example, assessing new drugs by conducting controlled trials. The article discusses the inadequacy of some clinical trials and points to the withdrawal of thalidomide and the dangers of triparanol and erythromycin propionate lauryl sulphate, among other examples.

The remedy, *The Lancet* points out, is in the hands of the profession, and the article continues as follows: 'Too often the profession acquiesces in this unsatisfactory situation by failing to call for the results of controlled trials of new drugs. Unfortunately, when many of us were students we were taught little of the difficulties of assessing the results of treatment, and the controlled therapeutic trial had not been devised. This subject should now be taught at all medical schools and should be discussed far more commonly in refresher courses. If doctors were to insist on proper assessment of a new drug before they used it, the demand by the pharmaceutical industry for controlled therapeutic trials would increase greatly. But, if the profession is to encourage this demand, it must be prepared to satisfy it. Even now the majority of manufacturers welcome reliable clinical appraisal of new preparations; but sometimes they have great difficulty in arranging this. One solution would be for a single body to screen new preparations and to decide whether or not to arrange

a clinical trial; but the danger is that such a body might, like other monopolies, become inert or intolerant. The manufacturer should, we believe, have a choice, and he should know where that choice can be exercised: commonly his representatives have to visit successive hospitals before they can prevail on a clinician to test a new product; and the report may be slow in coming and unsatisfactory in quality. We believe that other medical bodies might suitably follow the example of the British Tuberculosis Association whose research committee arranges trials at the request of manufacturers and handles all payments — an important feature, since, where payment is made direct to the clinician testing a drug, the objectivity of his report may (however unjustifiably) be called in question. The truth is that we cannot reasonably grumble about omission to test new drugs unless we provide proper facilities for testing; and in this we have so far failed'.[2]

The time has now arrived — it is in fact long overdue — for the medical profession and the pharmaceutical trade to cooperate in a concerted attempt to discover and evolve a symbiotic relationship which will make it possible for responsible members of both the profession and the industry to strive unfailingly towards achieving the greatest possible benefit for the greatest number of people.

1. Bogue, J. B. (1962): The Pharm. J., 13 Jan., 27.
2. Leading article (1962): Lancet, **1**, 198.