Spotlight on the Pharmaceutical industry

Thomson Publications regularly hosts a 'meet-the-press' session at which high-ranking representatives from various sectors are invited to a press conference. They are quizzed by a panel of journalists on their speciality. This month 'meet-the-press' focused on the Pharmaceutical industry.

Innovative pharmaceutical companies which spend vast amounts of time and money on research are in tough competition with imitators and could be forced out of the market if serious measures are not taken to alleviate their problems.

Innovators claim inadequate patent protection has led to imitators marketing generics at lower costs and as a result less research is funded for new products.

With this controversy in mind, Thomson Publications recently organised a meeting of high-powered pharmaceutical executives and a government health representative, the chief state pharmacist.

Background to the inherent dichotomy within the industry

Before they can be marketed, medicines have to be researched. This costs time and millions to the innovator who is granted a patent valid for 20 years.

This patent is granted before research and development begin, which can take an average of between eight to ten years, representing a sizeable bite of the patent period.

Taking registration of the product into account (which can take up to four years depending on the product's presentation), the innovators have a minimal period to market the 'brand name product' and recoup their investment costs as well as providing a financial impetus for the research and development of the next new product.

Once the patent lapses (no patent extensions are granted) the imitators have the right to copy the product formula and market it as a generic product.

It stands to reason that because the immitators have no research costs, they can afford to charge less for the product. Ironically, the imitators generic will be purchased in preference to the brand name product because of its lower cost.

The question now arises — how is the innovator to continue shouldering research and development costs of new products if his return is not enough to justify new research? If stricter controls are not applied, will innovative research become a practice of the past?

This does not mean the imitator should be restricted to the extent where he can no longer operate in the market. The macroeconomy in the pharmaceutical industry exists because of the presence of both imitators and innovators.

The regulatory authorities — the part they play in causing delays.

The MCC (Medicine Control Council) is the South African authority to whom medicines must be submitted for registration. The registration process comprises three basic screening procedures to determine optimum quality, safety and efficacy.

Delay encountered at this stage usurps the innovator's valuable patent period. The shortest delay is about a year for a generic product that is well known but can take up to four years for a new medicine.

There is apparently a chronic shortage of skilled staff at the MCC and 300 applications are known to be awaiting application at any one time. On an annual basis, 150-200 drugs are accepted by the MCC.

A solution, say the innovators, is to reduce the time between patent registration and market launch. In this regard they recommend a period of 16 years patent protection from the market launch date, although they may not be able to match imitators on tender bids.

Local research — is this a viable proposition?

With regard to the viability of local research, the size of the market is the critical factor. For an individual company to conduct its own research and development an annual turnover of R300m is a prerequisite. At present the total turnover in the local pharmaceutical industry is R250m.

The alternative is for a local company to conduct initial research to the point where its resources are no longer capable of supporting research and development. From this point, the larger more self-sufficient companies must handle the remainder of the research.

The public versus the private sector

Mr Donald Bodley, chairman of the PCMA and managing director of an innovatory company, states that more and more of the private sector is being eroded by the public sector. He states in support of his claim that 60% of all drugs are sold to the State with only 34% of the income from drug sales accruing from this sector.

The reason for this imbalance is attributable to the tender system which gives generics a boost over brand name products.

If this system continues, says Mr Bodley, the consequences will be significantly deleterious to the survival of the innovative multinational companies.

A further factor contributing to this erosion is that a large number of people who are able to pay for their medicines are acquiring them for practically nothing. Many people who are already on medical aid are not making use of this facility.

It is also suggested that the Government step in and encourage greater membership of medical aid societies. Hospitals should also be run along business lines and in this regard should conduct stricter means tests.

Mr Retief, the Chief State Pharmacist, countered by saying that the provincial tendering system is democratic in that it is up to the supplier to state his price.

If the prices tendered are rock-bottom, then this is of no concern to the Government.

The dilemma arises, says Mr Retief, because the Government is legally responsible for rendering a health service to the total population but at the same time is restricted by a limited budget in rendering this service. He adds that the Government does not have a deliberate policy to socialise medicine.

The socialisation of medical services leads very quickly to a crisis

situation as occured in Australia. In the latter country multinational innovators are withdrawing from the market because they can no longer afford to survive economically.

If the burning questions discussed above are not resolved soon, then it is very likely that the South African pharmaceutical industry may experience the same crisis which is being experienced in Australia. □