

1. **Prescriber Attitudes**

Recent research has shown that physicians feel that funders impinge on their decisions when formularies defined by Pharmaceutical Benefits Managers (PBM) are imposed on them. Specialists especially feel that they have little or no say in how the formularies are compiled and in most cases consideration for the particular drug is based on price alone. Consequently there is an aversion to prescribing generic medicines which comprise the major portion of the formularies.

2. **Consumer Perceptions**

With regard to medicines, patients rely on their doctors in forming attitudes about generic medicines. If the physician is not aware there is general acceptance by the consumer. However it is a known consumer perception in marketing circles that the average person equates quality to price. It is hard for a patient to believe that a medicine costing a third of the price of an original could have the same quality and efficacy as the higher priced medicine.

3. **Intellectual Property**

The NAPM is in agreement with JOPMP in highlighting the challenges provided by intellectual property legislation. The concept of "ever greening" where for trivial changes to the manufacturing processes, patent periods are extended, in the majority of cases there is no extra benefit to patients as the finished product remains unchanged. The NAPM has supported the SA government in its publication of the draft IP policy to ensure patents are only granted for novel inventions through an examinations office.

4. **Regulatory Delays**

An element which affects every one of the NAPM members. The lengthy registration times for generic medicines affect the patients, businesses, and industry. Our members alone have a backlog of more than 1000 dossiers to be evaluated. The members report that on average it is taking about four years to achieve a registration, but because of the long lead times, manufacturing processes have changed and post registration changes can take a further eighteen months.

5. **Pricing Factors**

Input costs are of concern to any business, but in the generics industry the room to manoeuvre is limited. The regulations pertaining to medicines preclude the easy change of suppliers for active ingredients. This prevents shopping around for cheaper alternatives in the short term.

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Michiel R. Leenders



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