EDITORIAL

Generic Substitution Again

In an editorial[1] the following statement was made:

"Are we not diverting attention away from the real issues in medical care in South Africa by what is possibly a storm in a tea cup?"

For some time now things have been quiet but the Department of National Health and Population Development has published a new Draft Bill for comment.

Essentially we are right back to the same old thing, "to provide for the approval and sale of therapeutic equivalent medicines." In addition other measures are addressed, including regulating "the sale of scheduled substances differently".

It is proposed that:

"2: A pharmacist may not sell a therapeutic equivalent medicine –

(a) if the person who prescribes the medicine states in his own hand on the prescription the words "no substitution" or words to that effect;

(b) in case of an oral prescription, if the prescriber indicated that no substitution shall be made;

(c) if the retail price of the therapeutic equivalent medicine is more than the prescribed medicine"

further

"22a(1) The Minister may, on the recommendation of the council (Medicines Control Council) prescribe the substances which may not be sold by any person other than a medical practitioner, dentist, veterinarian, pharmacist, nurse or practitioner."

Perhaps this is just a follow up on the unsuccessful bid made by the pharmacists in 1984. It is not clear what they, or the patient, can gain from these new proposals. There is no increased profit in it for the pharmacist and a minimal cost saving to the patient, if any. The only people who seem to be possible beneficiaries out of the whole effort, if one looks at it from an economic point of view, are those who make "therapeutic equivalent medicines" which are at times sold at marginally lower prices than the original products.

It is unclear why the Department of National Health and Population Development will want to spend all this energy and money to register and inspect equivalency of medicines as well as their sale by pharmacists. All this work if seriously undertaken, will probably use up many of the few rands that can be saved by the equivalency or generic substitution scheme.

Anyone who is serious about cost savings will put their money and energy where the biggest pay-off can be expected, where patients will not be disadvantaged by the saving strategy. Why not seriously implement primary health care strategies and train people purposefully for this work? Why not make concerted efforts to diminish more costly activities, such as inappropriate referrals to specialist services and unnecessary high investigation and hospital admission rates? If these issues were dealt with, the savings would dwarf into insignificance any proposed gains from generic substitution under any name.

In a position paper[2] on the appropriate use of generic drugs, the American Academy of Family Physicians say the following, "A basic concern ... is that there is no way of knowing that our patient's medication has been 'switched'". They conclude that, "the testing required by the FDA does not document that bioequivalency equals therapeutic equivalency ... There are critical patients, critical drugs, and critical diseases in which there should never be mandatory substitution of a generic drug".

References

1. Editorial. Generic Substitution. S Afr Fam Pract 1984; 5:343.
2. Position Paper. American Academy of Family Physicians 1989: 525-8.

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