

MEDICINES CONTROL COUNCIL



SCHEDULING MATTERS

RESCHEDULING OF ASPIRIN (*acetyl salicylic acid*)

TO ALL APPLICANTS

Kindly be advised that at a recent meeting of the Medicines Control Council, Council resolved to reschedule aspirin (acetyl salicylic acid) as follows:

Schedule 2 listing

Aspirin (acetyl salicylic acid), when intended for:

- the treatment of children or adolescents; and
- the prophylaxis of cardiovascular disease in adults (S0)

The reasons for the amendment include the following:

- Aspirin use is not recommended for routine analgesic or antipyretic use in children or adolescents with acute febrile illnesses due to the risk of Reyes' Syndrome (SAMF 11th edition, 2014). Use should be restricted to the management of chronic conditions such as juvenile chronic arthritis or rheumatic fever, where the benefits outweigh the risk. These conditions require medical diagnosis, and therefore it would seem appropriate that such indications would be restricted to a pharmacist only Schedule (S2). No aspirin products should therefore be labelled for paediatric use and sold as S0;
- Although aspirin was previously recommended for the primary prophylaxis of cardiovascular conditions in adults, the more recent recommendations are to restrict use to secondary prophylaxis in those patients who have already experienced a cardiovascular event (e.g. a myocardial infarct, coronary artery bypass, coronary angioplasty or stroke). Since this choice also requires a previous medical diagnosis, it would seem appropriate to restrict products specifically marketed for this indication to either prescription-only status (S3 or S4), or to a Schedule which would allow for appropriate professional advice (S1 or S2).

Please be advised that the office of the Registrar is in the process of drafting an amendment to the published Schedules, for consideration by the Minister of Health and publication in the *Government Gazette*.

Yours faithfully

Dr JC GOUWS
REGISTRAR OF MEDICINES