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Glyceryl trinitrate and mometasone furoate scheduling proposals

AMA submission to the TGA Advisory Committee on Medicines Scheduling – proposals to permit glyceryl trinitrate advertising and down-schedule mometasone furoate

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The AMA opposes the advertising of glyceryl trinitrate direct to the public and the down-scheduling of certain preparations of mometasone furoate.

Glyceryl trinitrate (GTN)

The AMA continues to oppose the inclusion of GTN in Schedule H of the Poisons Standard.

Patients who need treatment with GTN have a serious medical condition and require medical advice on how to manage it, in the context of their medical history. It should only be used by people who have been diagnosed with angina by their medical practitioner.

Advertising of GTN sprays directly to the public risks diverting patients from proper medical investigation.

Use of GTN is a serious risk if taken at the same time as some other medicines. A common and serious contraindication is the use of GTN with viagra/sildenafil and similar medications used to treat erectile dysfunction.

There appears to be no public benefit in advertising this medicine directly to the public but only potential risks to patient safety with inappropriate use independent of medical advice.

Mometasone furoate

The AMA opposes the application to down-schedule mometasone, in preparations for dermal use containing 0.1% or less of mometasone in packs containing 15g or less, from Schedule 4 to Schedule 3.

Advice from AMA dermatologist and general practitioner members is unanimous that the risks to patients of misuse and prolonged use are high with no apparent advantages to patients.

General practitioners consider it is highly likely that prolonged use will occur, leading to skin atrophy. A fundamental flaw with pharmacist 'prescribing' is that, firstly, pharmacists are not trained to identify skin atrophy, and secondly, as treated areas are generally covered by clothing, pharmacists cannot adequately examine patients.

In addition, the provision into the community of potent corticosteroids will greatly increase the risk of inappropriate family treatment through sharing of an individual's over-the-counter medicine.

Dermatologists' concerns are extensive and summarised below, with references.

Safety

- Mometasone is a mid-strength to potent corticosteroid when used on the skin (depending on the vehicle base).

- It causes the same suppression of adrenal function as other corticosteroids; and indeed more than for the similar product methylprednisolone aceponate[1].

- Studies have shown that it causes skin atrophy with the same potency and over the same time line as other corticosteroids in the same class[1,2].

- Use of potent corticosteroids on the face is a frequent cause of peri-orificial dermatitis[3] and in the experience of dermatologists mometasone is the most frequent culprit.

- The use of potent topical corticosteroids in the napkin area is associated with increased risk of granulomatous reactions[4].

- Used appropriately, in the context of an established diagnosis and management plan, these are invaluable and safe products; but the key is accurate diagnosis. Pharmacists do not have the competency to accurately diagnose skin disease.

- Consequences of incorrect diagnosis can be significant if, for example, a potent steroid is used on an infective condition such as impetigo or a fungal infection[5].

- Treatment of chronic dermatoses requires a clear management plan which may include, but not solely, the appropriate use of appropriately selected topical corticosteroids. The provision of a single increased potency agent would not encourage appropriate usage by pharmacists since many other choices are not available as S3.

Overseas experience

- The application makes the statement that these products have been available overseas for decades, as they have in Australia. It does not state that in most countries they are available as prescription only.

- In India these products are available in an unregulated manner and the consequences of inappropriate use are significant[6,7].

Implications for prescribing doctors

- A daunting problem faced by medical practitioners in sensible management of inflammatory skin disease is 'steroid phobia'. It is usual that S3 drugs (especially topical agents) are sold with the caveat 'cease after one week' but pharmacists fail to give the important message 'if symptoms persist after one week consult your doctor'. This reinforces fear of topical steroids in the community and leads to inappropriate regimens such as 'week on – week off' treatments that contribute significantly to instability in chronic dermatoses.

Implications for patients

- The vast majority of dermatoses that warrant potent topical steroid use are chronic dermatoses. In the case of mometasone, the provision of 'a tube at a time' will only serve to increase costs to patients, especially since PBS Streamlined Authority prescriptions are now available to reduce patient costs and enhance compliance.

- For the acute dermatoses it is unlikely that one-week treatment would be sufficient to see eruptions clearing, meaning that the accepted one-week limit on non-medically supervised therapy would only lead to confusion and poor compliance.

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