

Understanding the recent changes to the scheduling of medicines

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On 28 July 2017, the Minister of Health, on the recommendation of the Medicines Control Council, published changes to the scheduling of medicines, which came into effect immediately.

Many of the changes are technical, and will probably not affect your practice, so only some of the changes will be reflected in this article. Some changes affect what can be sold by pharmacist's assistants, and in some cases other employees, in a community pharmacy.

Please note that manufacturers will be given a period of time to change their packaging. You may therefore still find stock on the shelves that doesn't comply with the new requirements. It's important for you to be aware of the products that are involved, particularly the schedule 2 products, and to make sure that they are sold in accordance with the new requirements.

Acetylcysteine

E.g. ACC 200, Amuco, Mucatak 200

In the past

- Until recently, it was listed in schedule 2, but without an indication and without a maximum treatment period.
- Acetylcysteine became a schedule 3 substance if it was to be injected, or used to manage paracetamol overdose.

Now

- Schedule 1, for use as a mucolytic in acute respiratory conditions for a maximum treatment period of 5 days
- Schedule 3, when intended for injection or for the management of paracetamol overdose

This means

- It can be sold by any pharmacy personnel, including those not registered as pharmacist's assistants.
- It can be advertised to the public.
- It can only be used in acute respiratory conditions that require a mucolytic.

- The maximum that can be sold at any one time is sufficient for appropriate treatment for five days.
- When the patient asks for more than 5 days' supply, or if the patient returns for more, it should be referred to the pharmacist to discuss whether or not the patient should see the doctor.

Why?

- The only reason that a patient may use a mucolytic without seeing a doctor is for acute respiratory conditions.
- If the condition hasn't improved after 5 days, the patient must discuss the problem with the pharmacist, who will advise him or her to see a doctor if necessary.
- Other conditions, such as cystic fibrosis, require correct diagnosis and management by a medical practitioner, so it then falls into schedule 3.
- Paracetamol overdose is an emergency and must be managed by appropriate medical professionals, so acetylcysteine again becomes a schedule 3 substance.

Diclofenac

E.g. Adco-diclofenac, DicloHEXAL, Panamor, Voltaren

In the past

- Diclofenac when intended for application to the skin was a Schedule 1 substance, and could not therefore be sold in a general dealer's retail outlet.
- In Schedule 2, sufficient diclofenac could be given for a maximum period of 5 days if it was to be used as emergency treatment of acute gout attacks or to treat post-traumatic conditions.
- Schedule 3 conditions applied to all other quantities and uses of diclofenac.

Now

- Schedule 0, when intended for application to the skin and containing 1% m/m or less of diclofenac subject to a maximum pack size of 50 grams

- Schedule 1, when intended for application to the skin and more than 1% m/m of diclofenac
- Schedule 2, when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150mg for a maximum treatment period of 3 days
- Schedule 2, when intended for the treatment of fever or mild to moderate pain of inflammatory origin, subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 days
- Schedule 3, all instances where dose or treatment period exceeds what is stated above, as well as all other indications

This means

- There are now two categories of diclofenac topical preparations, where the lower concentration in a schedule 0 product allows it to be sold in a general retail outlet, and the higher concentration may be sold in a pharmacy as a schedule 1 product by a front shop assistant, because there is a pharmacist present if needed for advice.
- The maximum daily dose for treatment of acute gout attacks was not previously defined, and the treatment period has been reduced from 5 days to 3 days.
- Post traumatic conditions that can now be treated by Schedule 2 medicines have now been described as those exhibiting mild to moderate pain of inflammatory origin. This is a more appropriate description as trauma result in many conditions that cannot be treated in a pharmacy alone. It is important that a post basic pharmacist's assistant, in selling these products, discusses the symptom with the consumer. If the pain is due to a cause that is not related to inflammation, refer the patient to the pharmacist for further counselling.
- Fever has now been included as a symptom which may be treated with these Schedule 2 medicines.
- In the case of both fever and pain of inflammatory origin, products may only be sold with a stipulated maximum daily dose and for a defined treatment period.

Why?

- Products containing 1% m/m or less of diclofenac for topical application are safe for self medication of minor sprains and strains.
- If these products are not effective, the consumer can go to the pharmacy and request either a higher concentration of diclofenac for this purpose, or discuss whether or not to consult a doctor.
- For treatment of acute gout attacks, if the maximum daily dose of 150mg for 3 days was not effective, the patient must be referred to his or her doctor.
- The same applies to the treatment of either fever or mild to moderate pain of inflammatory origin.

Ephedra alkaloids and ephedrine

E.g. Colcleer, Lenazine Forte, Sinucon

In the past

- Schedule 1, when intended for application to the skin, eyes, ears or nose, and containing 1% or less of ephedra alkaloids, and not intended for export
- Oral products containing not more than 30 milligrams of ephedra alkaloids per dose, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, could be sold as a Schedule 2 substance, provided that the maximum pack size was 720 milligrams, individual sales were limited to one pack per customer
- Schedule 6 includes all other indications, doses and quantities

Now

- Schedule 1 remains the same.
- For schedule 2, the maximum daily dose is now stipulated, and the maximum pack size has been halved from 720 mg to 360 mg.
- Schedule 3 remains the same.

This means

- Pharmacist's assistants selling schedule 2 products to the patient will need to check that the maximum daily dose is not exceeded. If it is, they will need to consult the pharmacist on adjusting the dosage regimen, if appropriate. They will also need to check that the pack contains a total of no more than 720 mg. If it does, they should calculate the correct quantity to give. Obviously, if unsure, please discuss it with the pharmacist.

Why?

- The change in schedule 2 is to make sure that patients do not take more than is recommended for a minor self-limiting ailment. If the patient believes that the new requirements are not enough to treat the problem, it is no longer a minor ailment – there may be a different approach with different medicines that is appropriate. On the other hand, it may be a warning that the patient is misusing or abusing the product.

Phenylpropanolamine (norephedrine)

In the past

- Schedule 2, preparations and mixtures where the recommended daily dose for adults does not exceed 100 milligrams and for children 6 to 12 years does not exceed 50 milligrams, when intended for the symptomatic relief of nasal and sinus congestion.

Now

- For sale as schedule 2 products, phenylpropanolamine must now be combined with another pharmacologically

active substance, similar to the requirements for ephedra alkaloids and ephedrine.

- A maximum pack size of 300 mg for adults and 150 mg for children is now required, and sale is limited to one pack per customer.
- All other indications, doses and quantities are now schedule 6, which is the same as other similar substances.

This means

- Once again, pharmacist's assistants selling these products must be vigilant and ensure that the products sold comply with the new requirements.

Why?

- The changes have clearly been made to ensure that the substance is used appropriately. It is also intended to limit overuse and abuse by combining the substance with another pharmacologically active substance, and limiting the maximum pack size and number of packs that consumers can buy.

Pseudoephedrine

In the past

- Schedule 2, oral preparations and mixtures containing not more than 60 milligrams of pseudoephedrine per dose, and

not more than 240 milligrams per day, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer

- Schedule 6, all single ingredient products, those having higher dosages, daily doses and pack sizes, and those which were used for other indications

Now

- Schedule two now makes provision for both immediate-release and controlled-release oral preparations and mixtures
- Schedule 6 remains the same

Why?

- The entry under schedule 2 was confusing as it did not take into account the different contents and dosages of controlled-release preparations and immediate-release preparations. This problem has now been resolved.

Conclusion

It isn't always easy to comply with new scheduling requirements. If in doubt, ask your pharmacist!