

Pharmaceutical Management Agency

Clinicians' Newsletter



*“Make life easier,
always think generically”*

October 2011

Dabigatran and Patient Safety

Dabigatran

Since the introduction of dabigatran (Pradaxa) on the Pharmaceutical Schedule on the 1st July 2011, there have been some reports of bleeding among patients being transitioned onto dabigatran.

Preliminary analyses of these bleeding reports suggests that elderly patients (age over 75 years), patients with low body weight or impaired renal function are more at risk of bleeding. Some bleeding events were also related to inadequate monitoring of INR before patients were switched from warfarin to dabigatran and the inappropriate use of the higher dose (150mg twice daily) of dabigatran in patients older than 80 years of age.

Before prescribing dabigatran you should ensure that you are fully conversant with the relevant literature including:

- the Medsafe datasheet available on the Medsafe website (www.medsafe.govt.nz);
- information on dabigatran available via the PHARMAC and BPAC websites (www.pharmac.govt.nz/ and www.bpac.org.nz).

If a patient is well controlled on warfarin, there is no particular reason to change to dabigatran at least in the short term.

Extension of varenicline Special Authority approval period

The expiry date of the the varenicline's Special Authority approval will be extended from three to five months from 1 October 2011 to give patients in this situation more time to return to their clinician and get another prescription before the Special Authority expires. This change does not extend the subsidised length of treatment, which remains at a maximum of 3 months' subsidy for each Special Authority approval.

Extending the approval period is in response to PHARMAC receiving a number of requests to grant additional Special Authority approvals for varenicline where the original Special Authority expired prior to the patient's full course of medication being dispensed. In most of these cases the patient's prescription was also no longer valid to access subsidy as more than 90 days had passed, but by the time a new prescription was issued the Special Authority had expired.



Restriction of access

Sulindac

Mylan has increased the price of its sulindac (Daclin) tablets 100 mg and 200 mg from 12 October 2011. The subsidy for these presentations is not increasing to match the price and so patients will have to pay a part charge. However, patients with a valid Special Authority approval will continue to access sulindac fully subsidised.

Out of Stock

Sustanon – out-of-stock situation

Due to a global manufacturing issue Sustanon ampoules (testosterone esters) will be out-of-stock until late 2011. Merck Sharpe and Dohme (MSD) are handling this situation with the help of Pzifer's Depo-Testosterone (testosterone cypionate) long-acting injection. Please note that Depo-Testosterone is a 10 ml multi-dose vial containing 100 mg per ml (1,000 mg per vial) of testosterone cypionate. Full prescribing information is available on the Medsafe website at: <http://www.medsafe.govt.nz/profs/datasheet/d/Depotestosteroneinj.pdf>

For more information and assistance contact MSD's Medical Services Manager Mischa Winnard on (09) 5236107.

Clarithromycin 500mg tablets - pharmacist approval to substitute

To ensure supplies of clarithromycin during stock shortages of the 250 mg tablets of Klacid and Klamycin, pharmacists have been approved to substitute the clarithromycin 500 mg tablets for the 250 mg tablets from 14 September 2011 until further notice. Prescriptions need to be annotated by the pharmacist and will need to be endorsed accordingly. Please refer to the PHARMAC facsimile of 14 September 2011 located on the PHARMAC website for further details. (www.pharmac.govt.nz)

The listing date of Apo-Clarithromycin 250 mg tablets has been brought forward to 1 October 2011. We have been informed that Apotex's stock will be available from mid October.

Other Changes

Special Authority approvals by dietitians

Dietitians will be able to complete initial and renewal applications for Special Authority approvals for patients under their care from 1 October 2011. Dietitians will only be able to apply for Special Authorities for Special Foods listed in Section D of the Pharmaceutical Schedule and multivitamins (Paediatric Seravit) powder and vitamins (Vitabdeck) cap (fat soluble vitamins A, D, E K).

At this stage only manual (paper) applications will be able to be processed. It is anticipated that later this year dietitians will be able to complete electronic Special Authority applications.

General Practitioners who are not yet vocationally registered may reapply for Special Authority applications for their patients under the recommendation of a dietitian. They must include the name of the dietitian and the date contacted on the Special Authority application.

There are no changes for vocationally registered General Practitioners.

Pramipexole hydrochloride - delay in listing

Due to a delay in the production of stock for the New Zealand market, the listing of all strengths of pramipexole hydrochloride (Dr Reddy's Pramipexole) tablets has been delayed until further notice.

Items of Interest

Trastuzumab and sunitinib – amended Special Authority criteria

Some minor amendments regarding clinical definitions have been made to the Special Authority criteria applying to trastuzumab and sunitinib for clarification purposes and are expected to reduce confusion and administrative burden for prescribers and pharmacists. The changes are from 1 October 2011 and are not expected to materially change the funded access to either of these pharmaceuticals. Please refer to the October 2011 Pharmaceutical Schedule Update on the PHARMAC website for further information.

Changes to Schedule Rules

Close Control rule amendment

The Close Control rule in the Pharmaceutical Schedule will be amended from 1 October 2011. PHARMAC and DHBs consulted on proposed changes to the Close Control Rule in February 2011. The resulting changes to the Close Control Rule are relatively minor, and are as follows:

- Removing the need to write "Close Control" or "CC" for monthly dispensing into Community Residential Care and Age Related Residential Care provided the patient's NHI and name of the institution or facility is included on the prescription.
- Allowing patients in Age Related Residential Care or Community Residential Care to have an initial trial period (determined by the prescriber) for new medicines or a change of dose. This is a new issue raised during the consultation process.
- Differentiating the use of Trial Close Control (a one-off shorter dispensing period for new medicines or a change in dose) from ongoing Close Control by annotating the prescription with "Close Control Trial", "CCT" or "Trial Period" and also noting the period of supply specified.
- Amending the format of the current Close Control rule definition to make it easier to read.

These changes will be effective from 1 October 2011. All other aspects of the Close Control Rule remain the same.

Special Authority Forms

Following an influx of out-dated forms, Sector Services have issued a reminder to prescribers to ensure they have the latest Special Authority forms downloaded from the website. Alternatively prescribers can also use the online electronic system. For example Isotretinoin.



PHARMAC Seminar Series – Upcoming Seminars

The PHARMAC Seminar Series provides high quality educational seminars for a range of health professionals. The seminars are held in Wellington and the cost to attend is \$100 + GST. PHARMAC covers the cost of travel, including flights, to and from the seminar and provides catering on the day.

For further information on the seminars below, and to register for a place, head to our website: www.seminarseries.pharmac.govt.nz



inPharmation

PHARMAC publishes a quarterly email newsletter, inPharmation, that includes news and updates on developments around PHARMAC and pharmaceutical issues. If you would like to receive inPharmation, contact simon.England@pharmac.govt.nz.

Dates (2011)	Topic	Description
7 November	Rheumatic Fever (Part II – Invitation Only)	Please note we will be identifying and inviting registrants for these seminars from the relevant high risk areas.
23 November	Palliative Care	All health workers involved in palliative care in the primary care setting, in particular GPs, practice nurses and pharmacists.
1 December	Update on Special Foods	This seminar is suitable for GPs, dieticians, nurses and pharmacists.
2 December	Diabetes, Pre-Eclampsia and Pregnancy Complications	This seminar is a repeat and is aimed towards LMC practitioners or practitioners providing care to women during pregnancy. (This is a repeat seminar).
5 December	Adolescent Health	All health workers involved in caring for young people, but especially relevant for GPs, practice nurses and counselors working in the community. (This is a repeat seminar).

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Special Authority Queries: 0800 243 666
General Questions: 0800 66 00 50 (9am – 5pm Monday to Friday)

Online version of Prescriber newsletter:
<http://www.pharmac.govt.nz/healthpros/CliniciansNews>

InPharmation newsletter:
<http://www.pharmac.govt.nz/patients/ourviews/inpharmation>.

Newsletter feedback: email rochelle.harker@pharmac.govt.nz

Please note this is not a complete reference to all changes occurring from 1 October 2011, for the full reference; please consult your Update to the Pharmaceutical Schedule.

