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# Patient Reporting Encouraged during Monitoring of Dapoxetine in New Zealand

The New Zealand Intensive Medicines Monitoring Programme (IMMP) proactively monitors the safety of selected medicines and operates within the New Zealand Pharmacovigilance Centre.[1] The IMMP is currently exploring new methods to improve the amount of safety information obtained for the monitored medicines. The main method by which the IMMP follows up patients who have been dispensed a monitored medicine is by questionnaires sent to the patient's general practitioner (or other prescribing doctor). Other methods of gaining follow-up information include spontaneous reports (yellow cards) sent to the New Zealand Pharmacovigilance Centre, reports on IMMP duplicate prescriptions (or other reports from pharmacists) and linkage to national datasets to identify deaths and serious adverse events resulting in hospital admission.[1] In addition to these multiple 'intensive' methods, the IMMP is now giving patients the opportunity to report directly about their experience with a currently monitored medicine.

Dapoxetine (Priligy®) is a selective serotonin reuptake inhibitor approved for the treatment of premature ejaculation[2] and is being monitored by the IMMP. Follow-up questionnaires returned to the IMMP indicated that doctors often did not know if the patient had experienced any adverse clinical events. Dapoxetine is to be used on an 'as required' basis 1–3 hours prior to sexual activity,[2] and doctors were frequently unaware of when the patient had taken the medicine. Although the product information advises doctors to review the patient after 4 weeks of treatment or six doses,[2] this may not happen in real-life practice. These issues suggested that it may be helpful to invite patients themselves to also report to the IMMP in order to determine if any adverse events had been experienced.

Recently, the IMMP asked all NZ pharmacists to distribute a flyer to patients when dapoxetine is dispensed. This flyer invites patients to tell the IMMP about their experience with dapoxetine by any of the following methods:

- Visit the New Zealand Pharmacovigilance Centre website (www.otago.ac.nz/carm) to complete the patient reporting form (or Google 'IMMP Priligy', which will take you to the form).
- Email immpnz@otago.ac.nz to request a patient reporting form.
- Phone the IMMP on 03-479 7883 or fax 03-479 7150 to request that a patient reporting form be sent out by post and can be returned in a Freepost envelope.

Doctors have also recently been sent an IMMP patient reporting form for new patients for whom they have prescribed dapoxetine/Priligy®. This has been sent in addition to the routine IMMP follow-up questionnaire for dapoxetine/Priligy® and doctors are asked to give the patient reporting form to the patient to complete. Alternatively, doctors may suggest patients complete the IMMP form online as detailed above.

This initiative of inviting patients to report adverse reactions to medicines to a national monitoring programme is not in fact new. The Netherlands Pharmacovigilance Centre has had a website scheme for patients in place since 2003[3] and, in New Zealand, patients may report adverse reactions to any medicine to the Centre for Adverse Reactions Monitoring (see www.otago.ac.nz/carm for more details) if they wish to.

Further information about patient reporting to the IMMP, or any other clinical IMMP issue, may be obtained from the IMMP Director, Dr Mira Harrison-Woolrych at mira.harrison-woolrych@otago.ac.nz.

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