

# Prescriber Update

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## Suspension of rosiglitazone (Avandia and Avandamet) in New Zealand

In December 2010 the Medicines Adverse Reactions Committee (MARC) recommended that the consent to distribute rosiglitazone-containing medicines be suspended in New Zealand from **29 April 2011**.

The recommendation follows the MARC review of the benefits and risks of treatment with rosiglitazone. Rosiglitazone has been under regular review by the MARC since 2005.

Of particular concern to the MARC and Medsafe was the potential for rosiglitazone to cause myocardial infarction; a risk not known to be associated with other medicines in the class.

The MARC considered that data from meta-analyses and observational studies demonstrated an increased risk of myocardial infarction and that action was warranted. Although the results from the RECORD study did not show the same risk, this study was limited by its open-label design.<sup>1</sup> For this reason the MARC recommended that the consents for rosiglitazone-containing medicines be suspended rather than revoked.

The suspension will remain in place until the company that developed rosiglitazone identifies a population of patients for whom the benefits of treatment outweigh the risks.

Medsafe has advised patients not to stop taking rosiglitazone; but they should contact their doctor to discuss alternative treatments.

Further information on the rosiglitazone risk:benefit review and the MARC recommendations is available at: <http://www.medsafe.govt.nz/profs/adverse/Minutes144.htm#3.1>

### Summary and key messages:

- The consent to distribute rosiglitazone-containing medicines is to be suspended in New Zealand.
- The suspension will take effect from **29 April 2011** to allow patients enough time to change treatment.
- Patients should not stop taking rosiglitazone, but should contact their prescriber to discuss alternative treatments.

## References

1. Home PD, Pocock SJ, Beck-Nielsen H et al. 2009. Rosiglitazone evaluated for cardiovascular outcomes in oral agent combination therapy for type 2 diabetes (RECORD): a multicentre, randomised, open-label trial. *The Lancet* 373 (9681):2125-35.

## Dextropropoxyphene: FDA advice highlights cardiac risks

Recent action by the FDA to remove dextropropoxyphene from the market in the US has further highlighted the risks associated with the use of medicines in which it is contained.

Following a review of data, the FDA concluded that, even when used at recommended doses, dextropropoxyphene can cause significant changes to the electrical activity of the heart. These changes, which can be seen on ECG, increase the risk of serious abnormal heart rhythms that have been linked to serious adverse effects including sudden death.

Given this finding the FDA concluded that the risks associated with dextropropoxyphene were greater than the benefits of using this medicine. Consequently the FDA recommended that these medicines be removed from the market in the US.<sup>1</sup>

Following a comprehensive risk:benefit review, dextropropoxyphene was withdrawn from New Zealand in August 2010; however Medsafe understands that several patients are still being prescribed this medicine. Prescribers may wish to consider this new information about cardiac risks before continuing treatment with dextropropoxyphene as an unapproved medicine.

### Summary and key messages:

- Dextropropoxyphene is no longer approved for use in New Zealand.
- No new patients should be prescribed dextropropoxyphene-containing medicines.
- Prescribers should be familiar with the requirements associated with prescribing unapproved medicines, e.g. named patient supply, informed consent.
- Prescribers should re-assess the balance of risks and benefits in each patient continuing treatment as an unapproved medicine given the new US data.

Further information about the withdrawal of these medicines in New Zealand is available at: <http://www.medsafe.govt.nz/hot/alerts/Dextropropoxyphene.asp>

## References

1. FDA (2010). Xanodyne agrees to withdraw propoxyphene from the U.S. market. Accessed 16/2/11 from: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm234350.htm>

## Combined oral contraceptives and VTE – putting the risk into perspective

The risk of venous thromboembolism (VTE) associated with combined oral contraceptives (COCs) has been widely reported in the medical literature and mainstream media. Prescribers are reminded that this risk needs to be carefully considered in the context of other risk factors for VTE.

The risk of VTE in women is influenced by endogenous and exogenous hormonal exposure, age, family history of VTE, and lifestyle factors such as weight and smoking.

Data compiled by the World Health Organization (WHO) for developed countries in 1997 suggests that that VTE event rate, among non-pregnant women who are not using COCs, increases with age:<sup>1</sup>

Age	VTE event rate
20 to 24 years	3.2 events per 100,000 woman-years
30 to 34 years	4.6 events per 100,000 woman-years
40 to 44 years	5.9 events per 100,000 woman-years

The estimated risk of VTE in women who are obese (BMI  $\geq 35$  kg/m<sup>2</sup>) varies but studies demonstrate an up to three-fold increase in risk compared to women of normal weight (BMI  $< 25$  kg/m<sup>2</sup>).<sup>1,2</sup> Current smokers of  $\geq 25$ g of tobacco per day have up to a two-fold increase in VTE risk compared to those who have never smoked.<sup>2</sup>

In association with COC use, the risk of VTE is considered to be highest in the first year of therapy. VTE risk also rises with increasing oestrogen dose.<sup>3</sup>

Epidemiological studies suggest the incidence of VTE in women, with no known risk factors, who use low oestrogen dose COCs ( $< 50$   $\mu$ g) ranges from 20 to 40 cases per 100,000 woman-years. This rate equates to a four to eight-fold increased risk of VTE compared with non-pregnant non-users for whom an estimated event rate range is 5 to 10 cases per 100,000 woman-years.<sup>4</sup>

The risk of VTE with COCs is significantly less than the risk during pregnancy, which has been estimated at 60 cases per 100,000 pregnancies.<sup>3</sup> The risk of VTE is highest in the post-partum period, with an estimated two to five-fold increased risk compared to that during pregnancy.<sup>5</sup>

While it is important to consider the risk of VTE when prescribing a COC, it is also important to consider this risk in relation to other risk factors.

## References:

1. Kaunitz A. and Washhoff C. 2008. Combination hormonal contraception and venous thromboembolism risk. *The Journal of Family Practice*. 20(8): Suppl.
2. Holst A., Jensen G. and Prescott E. 2010. Risk factors for venous thromboembolism – Results from the Copenhagen City Heart Study. *Circulation*. 121(17): 1896-1903.
3. Lidegaard Ø., et al. 2009. Hormonal contraception and risk of venous thromboembolism: national follow-up study. *British Medical Journal*. 339(7720): 557-560.
4. MHRA. 2010. Yasmin: Update on risk of venous thromboembolism. *Drug Safety Update*. 3(9): 2-3.
5. Dinger J., Heinemann L. and Kühl-Habich D. 2007. *Contraception*. 75: 344-354.

## Colchicine: Beware of toxicity and interactions

Colchicine is approved for the treatment of acute gout when non-steroidal anti-inflammatory drugs are contraindicated or have previously been unsuccessful.

Colchicine has a low threshold for toxicity and must be used with extreme care. Colchicine is only indicated for intermittent use and patients will often initiate treatment themselves; therefore the potential exists for a severe drug interaction to occur.

Colchicine is metabolised by cytochrome P450 3A4 (CYP3A4) and excreted via the P-glycoprotein (P-gp) transport system. For patients with renal or hepatic impairment, concurrent administration of colchicine with strong CYP 3A4 inhibitors or P-gp inhibitors is contraindicated. For patients with

normal renal and hepatic function a reduction in colchicine dose is recommended when concurrent treatment with a strong CYP 3A4 inhibitor or a P-gp inhibitor is required.

Strong CYP3A4 inhibitors include protease inhibitors, imidazoles and clarithromycin; moderate inhibitors include simvastatin and erythromycin.

Inhibitors of P-gp include cyclosporine, ketoconazole, protease inhibitors, and tarcolimus.

Symptoms of colchicine toxicity may be delayed by up to 12 hours, therefore all patients who are suspected of taking an overdose should be referred for immediate medical assessment. All patients should be monitored for 24 hours. Early symptoms include abdominal pain, nausea, vomiting and diarrhoea. Symptoms occurring after 1 to 7 days include: confusion, cardiac, renal and hepatic impairment, respiratory distress, hyperpyrexia and bone marrow depression.

There is no specific antidote for colchicine toxicity; charcoal may be considered, but treatment is supportive.

#### Key messages:

- The lowest effective dose of colchicine should be used and must not exceed 6 mg over four days.
- Elderly patients and patients with hepatic or renal impairment are at higher risk of colchicine toxicity.
- Colchicine should not be used in patients with hepatic or renal impairment who are also taking CYP3A4 and P-glycoprotein inhibitors.
- Patients need to be informed of the symptoms of overdose and encouraged to seek medical assistance if they have concerns about the amount they have taken.

The Colgout data sheet is currently being updated to provide more information on interactions:

<http://www.medsafe.govt.nz/profs/Datasheet/c/Colgouttab.pdf>

#### References

1. FDA (2006). Drug development and drug interactions: Table of substrates, inhibitors and inducers. Accessed 21/2/11 from: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm081177.htm#PgpTransport>

## Adverse events in children using complementary and alternative medicines

The use of complementary and alternative medicine (CAM) use in children has been associated with serious adverse events, including fatalities, either through the direct effects of use or through failure to seek conventional treatment.

A recent Australian study<sup>1</sup> identified 39 CAM-associated adverse events, including four fatalities, reported by paediatricians between 2001 and 2003. In 64% of cases the adverse event was rated as severe, life-threatening or fatal. In 77% of cases the adverse events were considered to be probably or definitely related to CAM use. Forty-four percent of cases were associated with a failure to use conventional medicine.

The adverse events reported were varied but included constipation, bleeding and allergic reactions. All four reported deaths were related to a failure to use conventional medicine for conditions including epilepsy, chronic eczema and pulmonary emboli. Those at highest risk of adverse events from CAM were infants who had been advised to restrict their diet and children with chronic illness in whom conventional therapies were withdrawn in favour of CAM treatment.

The study also commented that consumers may be less likely to present with an adverse event related to CAM use compared with a similar event associated with conventional therapies. Events may go unreported due to the belief that CAM are natural and therefore safe. Other difficulties to reporting include: information on the product not always being available; CAM products often containing multiple ingredients; and the risk of adulteration with conventional medicines.

Health professionals are reminded that reports for suspected adverse reactions to CAM including herbal medicines, dietary supplements and homeopathic products can be submitted to the Centre for Adverse Reactions Monitoring (CARM) in the same manner as conventional therapies.

Further information on reporting adverse reactions is available at: <http://www.medsafe.govt.nz/profs/adverse.asp> or <http://www.otago.ac.nz/carm>

#### References

1. Lim A, Cranswick N, South M. 2010. Adverse events associated with the use of complementary and alternative medicine in children. *Arch Dis Child*. Published online 22 December 2010.

## Seasonal flu vaccine - an update on spontaneous reporting

### Overview

CARM and Medsafe thank everyone who contributed to the reporting of adverse events to the seasonal flu vaccine last season.

In total, at the end of the season (31 July 2010), CARM had received 396 reports detailing 936 events. This compares with 135 reports submitted in 2009.

Although the reason for the change in reporting pattern is difficult to fully elucidate, the increase in reports is thought to be due to extending the eligibility criteria for funded vaccine (hence more people vaccinated) and stimulated reporting due to publicity of adverse events in Australia.

In 2010 three seasonal influenza vaccines were funded by the Ministry of Health: Influvac, Fluvax and Vaxigrip. Over 1 million doses of vaccine were distributed: 275,000 doses of Influvac; 265,000 doses of Fluvax; with the remainder being Vaxigrip.

The distribution of *suspected* adverse reaction reports per brand of vaccine was: 197 for Fluvax, 119 for Vaxigrip, 52 for Influvac and 28 brand unknown. In children under 9 years of age the majority of reports involved the Fluvax brand while in adults and children over 9 years of age there was an even distribution of reports received for Fluvax and Vaxigrip.

### Reported suspected reactions

The most commonly reported suspected reactions following immunisation were:

- fever (131 reports),
- vomiting (86 reports),
- injection site inflammation (51 reports) and
- headache (48 reports) .

There are also reports of rare neurological or immunological conditions that occurred in temporal association with immunisation with seasonal flu vaccines. However their causal association cannot be confirmed and may reflect coincidence.

Last season CARM received two reports of convulsions (one in a known epileptic) and one report of transverse myelitis (in a patient with alternative causal factors). There was also one report of a sudden death (considered unrelated to immunisation by the coroner).

### Febrile reactions

On 22 April 2010 the cessation of the influenza vaccination programme in children was announced in Australia. This action was taken due to the high number of reports of febrile convulsion in children in Western Australia immunised with seasonal flu vaccine. At that time, in NZ, CARM had received four reports of febrile convulsions; three in association with Fluvax and one brand unknown.

An advisory was issued by the Ministry of Health not to use Fluvax in children, but to continue vaccinating children using other brands. Subsequent to this CARM received a further six reports of febrile convulsions in children. These reports detailed events that had occurred before 22 April 2010 and possibly reflect stimulated reporting.

In summary, of the 10 cases of febrile convulsion: seven were associated with Fluvax, one with Influvac and two were unknown brand. Five of the 10 children who experienced a febrile convulsion had a history of febrile convulsion to previous immunisations.

A crude estimate of the reporting rate of febrile convulsions in New Zealand, in association with Fluvax, did not indicate that the reporting rate of febrile convulsion was above the expected rate for seasonal influenza vaccines of 1 case per 1000 doses. This estimate used preliminary numbers of children under five years of age given funded vaccine.

The 131 reports of fever included 106 reports in children. The majority of reports (81%) were associated with Fluvax. In most cases (89%) the onset of fever was reported to have occurred within 24 hours. However as the temperature was not reported in most cases the presence of fever or the severity cannot be confirmed.

### Conclusions

After analysis of the reports received in New Zealand, CARM considered that although there was an increase in reports the nature of the reports was as expected for vaccine adverse events. The reports of febrile convulsions were in line with expected reports for administration of vaccines in children.

### Next Season

In response to the events in Australia in 2010 the manufacturer of Fluvax is investigating the root cause of the increase in febrile reactions.

As a precautionary measure for the 2011 season, pending the results of these investigations, Fluvax will only be indicated in adults and in children aged five years and above.

Two brands of the seasonal flu vaccine will be funded in 2011: Fluvax and Fluarix.

## Cough and cold medicines – an update

Winter is approaching and with it will come the inevitable increase in cough and colds. Healthcare professionals are reminded of the recent actions taken on the use of cough and cold medicines in children.

The majority of cough and cold medicines are contraindicated in children under six years of age. This action was recommended by the Cough and Cold Review Group due to the absence of evidence of any beneficial effect in children, evidence of serious side effects and the risk of accidental overdose.

A list of the affected medicines is available on the Medsafe website at: <http://www.medsafe.govt.nz/hot/alerts/CoughandCold/AffectedMedicinesOct2009.asp>.

### *Safer use of cough and cold medicines*

To help patients use these medicines safely, labels will now:

- State do not use in children under six years.
- Advise caregivers to consult with a healthcare professional before using these medicines in older children.
- Advise caregivers and patients to seek advice before using more than one cough and cold medicine and not to use other medicines containing the same ingredients.

Healthcare professionals are reminded that cough and colds are self-limiting conditions that do not usually require pharmacological intervention. As many products include more than one active ingredient there is the potential for overdose to occur. In addition it is desirable that patients do not take an antitussive in combination with an expectorant or mucolytic. This is considered to be an illogical combination and theoretically may be detrimental.<sup>1</sup>

Companies have committed to supplying products in the new packs by 1 May 2011.

Consumer Medicine Information leaflets for active ingredients are now available on the Medsafe website at: <http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>

### Footnote

1. Two preparations containing antitussive-mucolytic or antitussive-expectorant combinations are approved for use in New Zealand: Robitussin Cough and Chest Congestion and Duro-Tuss Cough Liquid Expectorant.

## Syringe driver pumps – clearing up the confusion

Medsafe is working with DHBNZ and the Syringe Driver Advisory Group to minimise the disruption associated with the replacement of Graseby syringe drivers.

The inconvenience and confusion caused by having three syringe driver pumps in circulation is unfortunate and unforeseen. Primarily this situation has occurred due to problems that were not anticipated by the manufacturer of the replacement device initially selected.

The supply agreement for replacing Graseby syringe drivers has now been reassigned to REM Systems, supplying the Niki T34 pumps. Medsafe has requested that REM systems ensure all Graseby syringe drivers are replaced by **30 June 2011**. Organisations that have already purchased AD pumps will have these replaced with Niki T34 pumps at no charge.

The June 2011 deadline means Graseby syringe drivers will not be removed without a suitable replacement being available. Once completed all palliative care organisations will be operating on a common hardware platform, which should reduce the potential for user confusion, errors and adverse events.

Medsafe first raised safety concerns about Graseby syringe drivers in 2007. Concerns related to the use of non-standard units of measure leading to errors, and a lack of alarms. The sale of Graseby MS series syringe drivers has now ceased in both New Zealand and Australia.

Healthcare professionals will continue to be regularly updated with information about the replacement of Graseby syringe drivers to prevent any further confusion and misinformation being disseminated.

Any questions or concerns about replacement syringe driver pumps should be directed to Garth Blake, Project Manager, Health Benefits Ltd (garth.blake@dhibnz.org.nz).

## **Changes to the Medicines Regulations – what you need to know**

The Government has agreed to a suite of amendments to labelling, advertising, dispensing, and prescribing requirements under the Medicines Regulations 1984 and, to standing orders, under the Medicines (Standing Order) Regulations 2002.

The amendments are anticipated to come into effect in 2011.

Information on the changes to prescribing and dispensing requirements is outlined below.

### ***Align prescribing rights***

The requirements for dentists to prescribe prescription medicines for dental treatment only and for midwives to prescribe prescription medicines for antenatal, intra-partum or postnatal care only will be removed.

Regulations will stipulate that medical practitioners, dentists and midwives be required to prescribe within their scope of practice as defined by their responsible authorities established under the Health Practitioners Competence Assurance Act, for patients under their care.

### ***Extend period of supply of prescription medicines***

The maximum period of supply on a prescription will be extended from six months to 12 months for oral contraceptives, and from three months to six months for other prescription medicines.

The 10 day limit on supply of a prescription medicine by a dentist will be removed; dentists will be able to prescribe the same quantities as medical practitioners and midwives, within their scope of practice.

### ***Requirements for prescriptions***

Regulations will be amended to require:

- Prescribers to include their physical street address and phone number, in addition to the current requirements (with an exemption for prescribers who do not have a fixed practice address, as long as alternative contact details are provided).

- The given name(s) of the person for whose use the prescription is given.
- The prescriber to specify the total quantity of medicine or total period of supply.

### ***Brand substitution***

Pharmacists will be allowed to substitute an alternative brand of a prescribed medicine provided:

- There are no clinical reasons why substitution should not occur.
- The prescriber has not marked the prescription with a statement such as ‘no brand substitution permitted’.
- The pharmacist records details of the brand substitution on the prescription and informs the patient of the change of brand.

### ***Dispensing requirements***

Prescriptive dispensing requirements will be revoked and replaced with more flexible requirements which allow for electronic technologies and reflect current dispensing practice.

### ***Sale of medicines through vending machines***

The Director-General of Health will be able to specify medicines that may be sold by vending machine and place conditions on their supply (eg pack size, location).

### ***Countersigning standing orders***

The issuer of a standing order will be able to specify the appropriate standing order arrangements (including when countersigning of administration and supply of the medicine is, and is not, required). Where countersigning is not required in every case, a documented monthly audit of a sample of the records of administration or supply under the standing order must be undertaken.

### ***Definitions relating to pharmacy qualifications***

Definitions will be updated and references to old legislation or superseded qualifications removed.

For further information see *Proposed Amendments to Regulations under the Medicines Act 1981 – report of the analysis of submissions and final decisions* ([www.moh.govt.nz/moh.nsf/indexmh/proposed-amendments-regs-medicines-act-submissions-report?Open](http://www.moh.govt.nz/moh.nsf/indexmh/proposed-amendments-regs-medicines-act-submissions-report?Open))

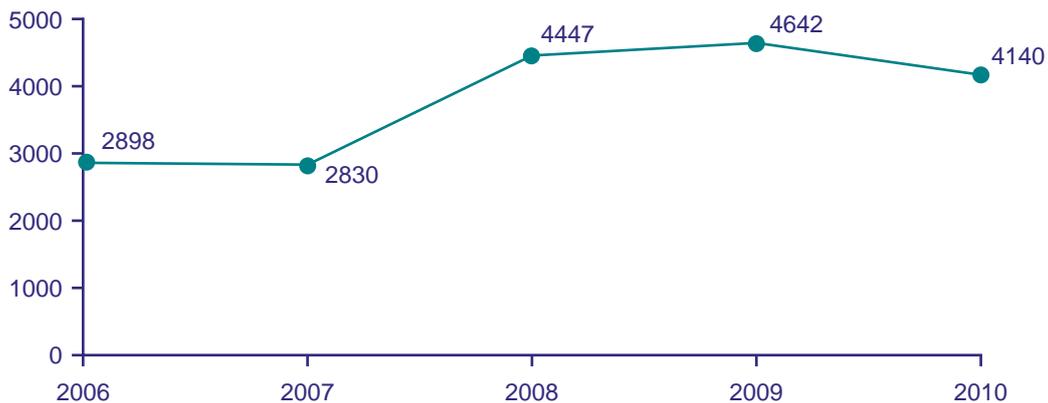
## Adverse reaction reporting – summary for 2010

CARM collects reports of suspected adverse reactions to medicines, vaccines and CAMs in New Zealand.

Adverse reaction reports provide valuable information about the use of medicines in clinical practice. CARM analyses these reports, in conjunction with Medsafe, to look for possible safety signals that require further investigation.

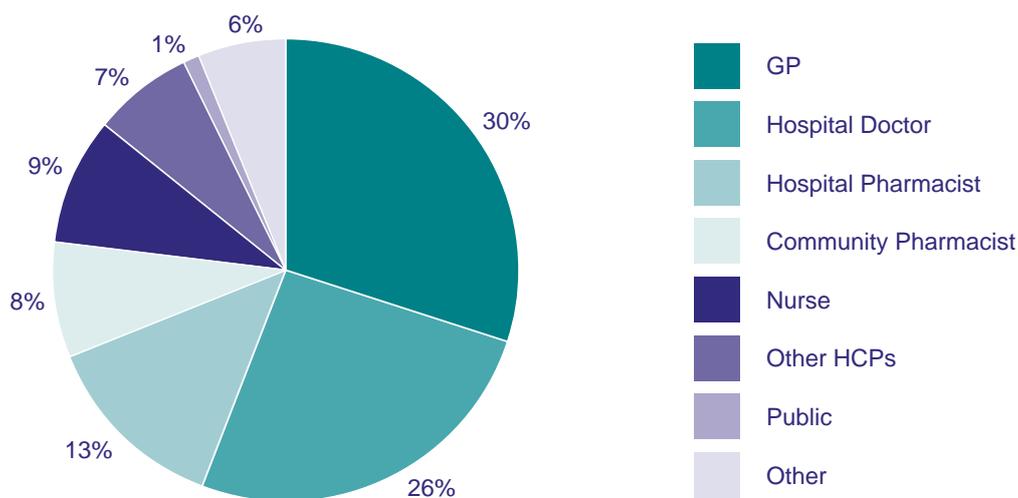
In 2010 CARM received 4140 reports describing suspected adverse reactions to medicines, vaccines or CAMs.

Although reporting has increased overall in New Zealand over the last five years, CARM experienced a slight decrease in adverse reaction reports in 2010 (Figure 1).



**Figure 1: Adverse Reaction Reports Submitted 2006 to 2010**

The majority of reports submitted to CARM came from GPs, with pharmacists and nurses also reporting frequently. Figure 2 summarises the origin of the 83% of total reports received directly from healthcare professionals and consumers in 2010. Reports submitted by pharmaceutical companies have been excluded from this summary.



**Figure 2: Source of Adverse Reaction Reports 2010**

Reactions to medicines continue to make up the majority of reports received by CARM (Figure 3); however reports associated with vaccines are rising (an increase of 315 reports in 2010 compared with the previous year).

Interestingly, the number of reports associated with complementary and alternative medicines (CAM) is very low and remains static. Only 14 reports were submitted to CARM in 2010. Reasons for low reporting may include: that adverse reactions to CAMs are very infrequent; are not well recognised by consumers and healthcare professionals, or there is a lack of awareness that adverse reactions to CAMs can be reported to CARM.



**Figure 3: Percentage of CARM reports by product type per year**

Of the 4140 adverse reaction reports received in 2010, 1046 (25%) were considered to be serious.<sup>1</sup> A further breakdown of serious reports shows that 6% of reports for vaccines were classed as serious, compared to 36% for medicines.

CARM and Medsafe would like to thank all who have contributed to pharmacovigilance in New Zealand by submitting adverse reaction reports and encourage continued support in 2011. Spontaneous adverse reaction reports provide valuable information about the use of medicines in clinical practice and are important in the identification of safety signals. *Prescriber Update* frequently provides feedback and advice based on your reports.

Healthcare professionals are reminded that adverse reactions can be reported by either completing a yellow card, downloading a form from the CARM or Medsafe websites, or completing an online report. An electronic reporting form has also been installed in GP practice software throughout New Zealand.

Further information about adverse reactions and how to submit an adverse reaction report can be found on the CARM website at: <http://www.otago.ac.nz/carm> or on the Medsafe website at: <http://www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Safety-and-Quality-of-Medicines.asp>

#### Footnote

1. A serious adverse event or reaction is one that results in hospitalisation or is life-threatening or fatal, or results in disability or requires intervention to prevent permanent disability, or results in a congenital abnormality. This term should not be confused with severity.

## M<sup>2</sup> MEDICINES MONITORING: Launch of a new scheme

A new medicines monitoring scheme, M<sup>2</sup>, has been launched to promote reporting of adverse reactions to specific medicines of interest.

Stimulating reporting of specific reactions to specific medicines helps CARM and Medsafe to investigate possible safety signals further, decide if there is a causal relationship, and take action if necessary.

M<sup>2</sup> has been developed in collaboration with the MARC and CARM. Further information about the scheme can be found on the Medsafe website at: <http://www.medsafe.govt.nz/profs/M2MedicinesMonitoring.asp>

An evaluation of the safety signal at the conclusion of the monitoring period will be published on the Medsafe website. The medicines and reactions that are being monitored are listed below.



### WE NEED YOUR HELP!

Please send your reports for these potential safety issues\* listed in the table below.

Medicine	Potential safety issue	Active monitoring ends
Rivaroxaban	Atrial fibrillation	1 September 2011
Simvastatin	Joint pain & swelling	1 September 2011
Quetiapine	Cardiomyopathy	1 September 2011

- **M<sup>2</sup>** is a new scheme designed to collect more information on potential safety signals for specific medicines.
- Safety signals are identified from reports of adverse medicine reactions sent to the Centre for Adverse Reactions Monitoring (CARM). For further information see the Medsafe website.
- The **M<sup>2</sup>** scheme does not replace routine adverse reaction reporting. Find out how to report at: <http://www.otago.ac.nz/carm> or <http://www.medsafe.govt.nz>



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\* The appearance of a possible safety issue in this scheme does not mean Medsafe and CARM have concluded that this medicine causes the reaction.

**Reporting form for Adverse Reactions  
to Medicines, Vaccines and Devices  
and all Clinical Events for IMMP**

**PATIENT DETAILS**

**HP3442**

Surname:	First Name/s:	NHI No:	
Address:		Date of Birth:	Sex:
		Ethnicity:	

**ALL MEDICINES IN USE \*ASTERISK SUSPECT MEDICINE/S\*** Include over-the-counter (OTC) and alternative medicines

Medicine or Vaccine+batch no. (and brand name if known)	Daily Dose	Route	Date Started	Date Stopped	Reason for Use

**DESCRIPTION OF ADVERSE REACTION OR EVENT**

Date of onset: \_\_\_\_\_

Recovered  Not yet recovered but improved  Not yet recovered  Unknown  Fatal  - Date of Death: \_\_\_\_\_

Severe? - Yes  No  Rechallenged? - No  Yes  Result: \_\_\_\_\_

**OTHER FACTORS - Please tick or specify as appropriate**

Renal disease  Allergy : \_\_\_\_\_ Other Medical Conditions: \_\_\_\_\_

Hepatic disease  Nutritional Suppl or OTC use : \_\_\_\_\_ Industrial Chemicals : \_\_\_\_\_

**REPORTER - Please tick as appropriate:** Doctor  Pharmacist  Dentist  Nurse  Other : \_\_\_\_\_

Name: \_\_\_\_\_

Address: \_\_\_\_\_ Signature: \_\_\_\_\_

Phone: \_\_\_\_\_ Date: \_\_\_\_\_

**Send completed form to CARM**

Freepost 112002, CARM, PO Box 913, Dunedin 9054 or Fax: (03) 479 7150

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