In Print

Latest Issues of New Zealand Doctor Newspaper

25 May

< BACK TO ISSUE OVERVIEW

When the medicines run out: Dealing with drug shortages

Bruce Lee
blee@nzdoctor.co.nz

FEATURE

Few would doubt drug purchasing agency Pharmac has a tough job. To be the sole agency procuring medicines for the public health service comes with responsibilities and the need for accountability. With drug shortages a perennial issue that can alarm and worry those affected, and given the recent shortages of drugs for migraines, blood pressure and antibiotics, questions are being asked about Pharmac's current approach. *New Zealand Doctor* reporter *Bruce Lee* investigates the causes of drug shortages and their impacts

When Jim Taylor gets a migraine, everything stops. Until he has his dose of meds, there is very little he can do besides look for the one thing that can alleviate the pain.

The 75-year-old retiree depends on what he knows as Rizamelt (rizatriptan), and his wife Sue describes the drug working "like magic". So when the former dairy farmer was told the thing he depended on to be free of migraines was not available, the reaction was one of worry and panic.

With his prescription in hand, he went to another pharmacist only to be told the same thing: there simply was no rizatriptan in stock. With his own supply of the drug running out, the only option was to get prescribed another medication so as not to endure the half-dozen weekly migraines with no medication.

Getting another prescription meant another trip to the GP and another trip to the pharmacist, but Mr Taylor was out of options. To complicate matters, it takes two weeks to get an appointment with his GP, and practices are few and far between in rural Kaipara.

The alternative Mr Taylor was eventually prescribed was sumatriptan, which did help, albeit not as quickly as rizatriptan.

“The thing that worried me most was, when I asked the pharmacist if something like this happened often, she replied ‘yes’.”

“It’s a bit over the top and if you ask me, it’s pretty bloody slack.”

Mr Taylor’s story is not an isolated incident. In fact, sumatriptan too was in short supply around the same time he was prescribed. It was only a matter of luck Mr Taylor was able to get the medication, which raises the question of how often drug shortages really happen. The short answer, it seems, is more commonly than might be anticipated.

Pharmac prefers not to release publicly a full list of medications in short supply, citing concerns pharmacists will stockpile the drugs. *New Zealand Doctor* was able to ascertain that as of December 2015, Pharmac was dealing with 39 drug shortages. These included, but were not limited to, cardiovascular, dermatological, antibiotic and chemotherapy drugs. Among the shortages were metoprolol, isotretinoin, amoxicillin and sertraline. (see panel).

List of stock issues during December 2015

THERAPEUTIC GROUP	PRODUCT (CHEMICAL)
Alimentary	ranitidine injection
Alimentary	alfacalcidol
Blood	potassium chloride tab long-acting
Cardiovascular	labetalol injection
Cardiovascular	frusemide tab 500 mg
Cardiovascular	metoprolol succinate – all strengths
Cardiovascular	adrenaline inj 1:10,000
Dermatologicals	permethrin lotion 5%
Dermatologicals	oil in water emulsion cream
Dermatologicals	isotretinoin
Dermatologicals	aqueous cream sls-free 500g
Genito-urinary	oxytocin 5iu/ml
Hormone preparations	testosterone undecanoate cap
Infections	amoxicillin granules for oral liquid
Infections	cefaclor monohydrate cap
Infections	amoxicillin injection
Infections	ceftazidime injection
Infections	phenoxymethyl penicillin cap
Infections	aciclovir tab
Infections	roxithromycin tab
Infections	amoxicillin with clavulanic acid
Musculoskeletal system	ibuprofen oral liquid
Musculoskeletal system	capsaicin cream
NS: anaesthetics/ analgesics/ antinausea	oxycodone hydrochloride injection
NS: mental health	amitriptyline tab
NS: mental health	sertraline hydrochloride tab
NS: mental health	methylphenidate hydrochloride tab
NS: mental health	pericyazine tab

NS: mental health	perphenazine tab
NS: neurology	hyoscine N-butylbromide tab
NS: neurology	sumatriptan succinate injection
NS: neurology	dexamfetamine sulphate tab
Oncology	Bacillus Calmette-Guérin injection
Oncology	epirubicin hydrochloride injection
Oncology	docetaxel injection
Oncology	doxorubicin hydrochloride injection
Respiratory & allergies	cetirizine hydrochloride tab
Sensory organs	chloramphenicol eye ointment
Vaccines	Bacillus Calmette-Guérin vaccine

SOURCE: PHARMAC

PORIRUA GP Bryan Betty knows more than most GPs about the intricacies of drug supply.

As Pharmac's deputy medical director primary care, Dr Betty's role includes providing advice on the drug formulary and on management of budgets for medicines and vaccines.

The plight of patients experiencing a drug shortage notwithstanding, Dr Betty is pleased with how the agency handles shortages and says New Zealand as a country does fairly well.

"If you look at global supply issues, for example, the US, there are 150 medication shortages. Australia has about 60 and New Zealand has just under 40."

Unlike Pharmac, drug shortage lists are freely available in the US. On 10 May this year, the American Society of Health-System Pharmacists (ASHP) listed 153 drugs in short supply, with the longest-standing current shortage having been noted in January this year. The FDA, however, listed only 60 drugs, with another 30 on the list designated as "resolved" for the same date.

This discrepancy between the ASHP and FDA is due to the different sources of information; shortages for the FDA are confirmed by manufacturers, whereas a shortage for the ASHP is reported and confirmed by clinicians, pharmaceutical industry representatives and patients. In short, the FDA's list represents shortages at the manufacturing level and the ASHP's list reflects drug availability at the healthcare provider level.

Pharmac director of operations Sarah Fitt says there are a variety of causes for the global problem of drug shortages, not the least being new FDA regulations governing manufacture and audits, resulting in some manufacturing plants closing temporarily or even permanently, something well beyond Pharmac's control.

"What we're finding is that shortages are a global issue with facilities undergoing audits and losing accreditation with the FDA." She adds changes to production regulations sometimes places extra restrictions and that there are cases where a drug is simply discontinued.

Ms Fitt says Pharmac does what it can to ensure a continued supply of pharmaceuticals, using clauses in the contracts negotiated with suppliers.

The sole supply model, popular with Pharmac, offers an advantage in that when a shortage occurs, New Zealand has a relatively high priority for being restocked and the suppliers are obligated to give very early notice of any expected shortage, Ms Fitt says.

What's more, the onus is on the supplier to find an alternative and resolve the issue in plenty of time, before prescribers and patients are affected, Ms Fitt says.

The exact terms negotiated between a supplier and Pharmac vary, but the accompanying notes to the December shortage list say the list is based on notifications from suppliers and does not contain all potential stock issues reported to Pharmac. In short, it is more analogous to the shortage list published by the FDA than the ASHP. Pharmac's notes elaborate that if a supplier has less than two months' supply in New Zealand, but expects a delivery from the manufacturer within the following week, Pharmac would not include that drug on the list.

Ms Fitt says nine times out of 10, the situation will not get to the point where patients are affected. The sumatriptan and rizatriptan shortages were clearly examples of the one in 10 times where patients were affected.

These cases were considered rare events by Ms Fitt and Dr Betty, who both say Pharmac staff did their utmost to remedy the situation. [see box story]

Case notes – sumatriptan

▶The sumatriptan shortage started in November 2015 when the supplier, Actavis, alerted Pharmac of a global manufacturing issue. At that point, Pharmac began working with Actavis to secure an alternative source, which was air-freighted to New Zealand in early January this year. This shipment was unfortunately compromised, as it was improperly stored, either during transit or before shipping. In the process of finding another shipment to address the unusable batch of sumatriptan, Pharmac also scrambled to secure a temporary measure in the form of sumatriptan vials as opposed to the usual pre-filled auto-injectors.

▶The temporary shipment of 2000 vials from German drug manufacturer Fresenius Kabi arrived in early April. Actavis couriered the vials directly to general practices upon request, free of charge.

PHARMACY GUILD chief executive Lee Hohaia applauds Pharmac's proactive approach in identifying shortages, but says the ongoing feedback to the guild from prescribers, pharmacists and patients alike, decries drug shortages.

In the last year, eformoterol fumarate, permethrin, ibuprofen, potassium chloride and cetirizine were among the medicines with ongoing supply issues, Mrs Hohaia says.

When a drug has a sole supplier, as was the case with rizatriptan, the biggest concern is the supplier not being able to source an alternative if something goes wrong, she says.

The sole supply model has been called into question by Mrs Hohaia, pharmacists and lobby groups, including Medicines NZ. Graeme Jarvis is the general manager of Medicines NZ, the organisation working on behalf of some of the bigger pharmaceutical companies. Mr Jarvis, like Ms Fitt, notes shortages are a global issue. But, he says, the sole supply model can exacerbate the situation; countries where drugs are supplied through multiple channels can often resolve shortages relatively quickly.

While manufacturers have commercial factors to consider, Mr Jarvis says, they do their utmost to meet the needs of patients.

"The last thing we want is for patients to be denied access to their much-needed medication," he says.

Mr Jarvis' sentiments are echoed by Mrs Hohaia, who suggests that if there was a "back-up supplier" for a drug, shortages could be more easily remedied.

KATHY MAXWELL, owner and manager of Hillpark Pharmacy in south Auckland, stands at the front line of drug shortages and is familiar with the attendant frustrations. Ms Maxwell says it's an ongoing challenge; her main concern is for patient safety as shortages can result in pharmacists like herself turning away patients.

If a drug shortage is limited to a certain dose, the medication might be dispensed in the available doses to match the prescription as long as the prescriber is informed and the patient is told of the changes and risks.

"There are additional costs to the patient as well, even though the overall dose is the same," Ms Maxwell says. "For example, you can't give two 95mg tablets when the prescription was originally for a single 190mg. That's not how the claiming works."

Whether or not a different dose of the prescribed drug is available at the pharmacy to replace the patient's original prescription, the patient must be referred back to their prescriber, Ms Maxwell says.

It's clear good communication is essential, not only between the suppliers and Pharmac, but Pharmac and the health sector at large. While it would be assumed those working at the coalface would be told of short ages, either by Pharmac directly or through organisations like the guild, sometimes the message fails to get through.

Ms Maxwell says pharmacists tend to find out only when they go to the wholesaler to order a drug and find they can't.

“From there we approach the GPs and say ‘we can’t get this – prescribe something else’. At the end of the day, it falls on us, since we have the patients standing in front of us. We’re at the coalface and we bear the brunt of patients’ concerns.”

Both Dr Betty and Ms Fitt say Pharmac takes shortages very seriously, and all relevant parties are notified, where necessary – so long as they are part of Pharmac’s notification list.

Pharmac works to keep pharmacists and GPs informed when a shortage is relevant to them. They wouldn’t be notified about the shortage of a hospital drug.

“We are careful not to spam people,” Ms Fitt says, but adds Pharmac publishes regular notices on its website updating people on shortages.

These notices include the name of the drug in short supply, its alternatives, and the expected resolution time frame.

While it would be preferable to tell people when a shortage is likely to be resolved, the complicated and unique nature of each shortage makes promising deadlines for resolution difficult, Ms Fitt says. She emphasises the decision not to have a public list of drug shortages is partly because there are multiple dynamic cases occurring at any given time.

NZMA GP Council chair Kate Baddock says a drug becoming no longer available can have particular impact if the medication is for a very specific problem.

Dr Baddock, a GP at Warkworth Medical Centre, gives the example of Surmontil (trimipramine), which was delisted by Pharmac in May 2003. She adds that even if a generic or alternative is found and given to patients, there could be destabilisation in the form of a change in side-effect profiles.

When asked how long drug shortages have been happening, Dr Baddock responds emphatically: forever.

Shortages under Pharmac’s model have been happening since the early 1990s, Dr Baddock says, but notes Pharmac is doing a superb job in handling its difficult task.

“You’re trying to get the best deal that serves the greatest number of people,” she says. “Rather than saying some people miss out, [it’s more of] the system just doesn’t work as well for some.”

Surprisingly, shortages do not seem to be a big issue in rural areas. Opotiki GP Jo Scott-Jones, who is chair of Rural Health Alliance Aotearoa New Zealand, says drug shortages are not a major concern for rural communities for the most part.

Shortages don’t happen that frequently, and when they do, they are usually fairly temporary, Dr Scott-Jones says.

He goes on to say that while clinicians get word from Pharmac about upcoming drug shortages, whether or not the GP reads the notices are a different matter.

“For me personally, such notices are not on my reading list.”

BEYOND EARLY notification and securing alternative sources for drugs before a shortage begins to affect patients, Pharmac employs other steps to maintain existing supply.

Examples of this in recent months include Pharmac listing products to different pack sizes, and metoprolol succinate dispensed in monthly rather than quarterly amounts.

Drug shortages are not common in the grand scheme of drug purchasing affairs – Pharmac has more than 2100 medications and therapeutic products on its Pharmaceutical Schedule. A total of 1873 items are on the community schedule of which 645 are sole supply formulations. The current processes with the sole supply model and early warning mandates do appear to be successful in keeping the number of drug shortages affecting patients low. But Ms Fitt acknowledges there is always room for improvement. Nevertheless, shortages are, as Ms Fitt says, a fact of life.

Return to homepage

Print Email Share