

Memorandum – for internal use only					
То	NoSurprises@Pharmac.govt.nz				
cc	TGM, Mental Health; Manager & Team Leader CM;				
From	Trish Mahoney				
Subject	Dexamfetamine tabs 5mg – Potential stock issue				
Date	16/11/2015				

Patient Group	Risk	Issue
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Supplier	PSM t/a API	Brand	PSM
Therapeutic Group	Nervous System	Chemical	Dexamfetamine maleate
Presentation	Tablet	Strength(s)	5mg
Contractual Status	Sole Supply	Date	16/11/2015

Pharmaceutical Use & Original Decision Criteria

Dexamfetamine sulphate 5 mg tablets are indicated in the treatment of well-established and proven narcolepsy. It is also indicated for children with refractory hyperkinetic states under the supervision of a physician specialising in child psychiatry

Background

PSM/API advised 3/11/2015 that it would be OOS of dexamfetamine tabs if an export licence was not received urgently. At that time PSM/API had 4 weeks stock, and suggested limiting orders.

PHARMAC staff contacted Medicines Control to expedite the licence and the licence was received by PSM/API on 10 November 2015. This allowed PSM/API to request manufacture and delivery of the active ingredient (dexamfetamine) which is expected to be received early December, and then manufacture/packaging and delivery of product would take up to 7 days.

This means that there is a potential for there to be stock shortages for some patients in early December 2015 until expected resumption of supply week ending 20/12/2015

PHARMAC staff will be following up around PSM/API's application for licences to ensure that the situation does not arise again.

Usage Data

Units/Month 57,000 tabs	Demographic	00 to 09	147
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			10 to 19	242
			20 to 29	195
			30 to 39	134
			40 to 49	99
			50 to 59	51
			60 to 69	26
			70 to 79	11
			80 to 89	5
			90 and Over	1
Prescriptions/Month	~530 prescriptions; 760 dispensings	Gender	Male & Female	
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Stock Situation

Stock Availability	Potential Out of Stock	Outage From 7/12/2015
Expected Duration	1 - 7 days	Restock Date 11/12/2015
Recall Status	Not Applicable	Recall Level Not Applicable

There appear to be limited alternative the apeutic options for patients. The main alternative option is methylphenidate, however our data indicate that 50%-60% of the patient group has already been prescribed methylphenidate and moved to dexamfetamine. We note that any move to a new medication would require a new Special Authority and/or new prescription and therefore a visit to prescriber.

PHARMAC's Management Plan

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Options	Restrict sales from PSM t/a API, and advise wholesalers of issue to
\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Vimit orders; issue a letter to prescribers asking for Rxs to be amended
	to 15+15 till 1 Jan 2016. Note to pharmacists requesting dispensings
	be restricted.
	PSM/API are preparing a letter for the market for PHARMAC review to
	advise of supply issue.
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Alternate Product 1	4T		
Current Status		Supplier	4T
Comments	4T	I	
Alternate Product 2	4T		
Current Status		Supplier	4T
Comments	4T	,	,

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Other Parties

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Recommendations/Actions/Updates

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FACSIMILE

To All community pharmacies

From **PHARMAC**

Subject TWO ISSUES - dexamfetamine sulfate

tablets & nystatin oral liquid

Date 23 November 2015

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THIS FAX CONTAINS TWO ISSUES FOR PHARMACY INFORMATION

1. Potential supply issue for dexamfetamine sulfate tabs 5 mg

There is currently limited supply of dexamfetamine sulfate 5 mg tablets (PSM).

There is no immediate risk of an out-of-stock situation with dexamfetamine sulfate 5 mg tablets, based on expected usage. However, there is very limited supply and further supplies are not expected until mid-December 2015. The stock issue is due to logistic arrangements, which have been resolved, but there may be a delay in resupply of stock.

There may be instances where you need to dispense dexamfetamine sulfate 5 mg tablets in less than the prescribed volumes. This alteration would need to be endorsed by the prescriber.

We have written to prescribers who have a large number of patients on dexamfetamine to request they modify the dispensing period on their scripts, to dispense in 10 day lots as for other Class B controlled drugs (eg morphine). As a Class B1 controlled drug pharmacists must ensure dexamfetamine sulfate 5 mg tablets are dispensed as instructed by the prescriber in accordance with the relevant legislation.

PHARMAC is working closely with the supplier, PSM (trading as API), to ensure supply is maintained. PSM is managing the supply of dexamfetamine sulfate 5 mg tablets through limiting the quantities purchased through wholesalers. We recommend that you contact PSM directly if you are unable to procure sufficient supply for your patient: **NZ Freephone 0508 776 746**

2. Change in price and subsidy for Aspen nystatin oral liquid 100,000 u per ml (Nilstat)

PHARMAC recently notified of a price change for the Nilstat brand of nystatin oral liquid 100,000 u per ml from 1 December 2015. This price change will now not occur until **1 February 2016**.

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The price and subsidy in Section B and Part II of Section H of the Pharmaceutical Schedule for Aspen Pharma's Nilstat brand of nystatin oral liq 100,000 u per ml will be as follows from 1 February 2016:

Chemical and presentation	Brand	Pack size	Current subsidy (until 31 Jan 2016) (ex-man., ex. GST)	New subsidy (from 1 Feb 2016) (ex-man., ex. GST)
Nystatin oral liq 100,000 u per ml	Nilstat	24 ml OP	\$3.35	\$2.55

Please note that the December 2015 Pharmaceutical Schedule Update will show the price and subsidy decrease for 1 December 2015, but this change has now been revoked.

Thank you for your patience.



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XX November 2015

Name Position Organisation Address line 1 Address line 2 Address line 3

Dear

Dexamfetamine sulfate 5 mg tablets (PSM) limited supply.

We are aware you have prescribed dexamfetamine sulfate 5 mg tablets to at least XX patients in the last few months. There is currently limited supply of dexamfetamine 5 mg tablets (supplied by PSM (trading as API)). This is due to a delay in the arrival of the active ingredient into New Zealand for manufacture.

We are working closely with PSM to ensure stock is manufactured as quickly as possible.

To assist in managing the limited available stock we ask you to:

please specify on any dexametamine prescriptions that it be dispensed in amounts of 10 days supply, like you would for other Class B controlled drugs (ie morphine).

This will help ensure that stock of dexamfetamine sulfate 5 mg tablets continues to be available until the new stock arrives, which is expected mid-December 2015. Pharmacists may contact you to confirm prescription changes if they need to dispense less than the prescribed quantity due to a stock shortage.

The Misuse of Drugs legislation does not allow pharmacists to modify dispensing frequencies on controlled drug triplicate prescriptions, hence our request to you.

If you have any questions regarding supply of dexamfetamine sulfate 5 mg tablets, please contact PSM's customer services on: **NZ Freephone 0508 776 746.**

Thank you for assisting us in managing this stock issue.

Yours sincerely

Nina Sawicki

Deputy Medical Director