MINISTRY OF HEALTH
MANATŪ HAUORA

133 Molesworth St
PO Box 5013
Wellington 6145
New Zealand
T+64 4 496 2000

[redacted]
Health Reporter
New Zealand Herald
[redacted]

Ref: H201800256

Dear [redacted]

Response to your request for official information

Thank you for your request of 24 January 2018 under the Official Information Act 1982 (the Act) for

> *"Information on Primidos.*
>
> *This should include:*
> ** All correspondence within the Ministry of Health, to the Minister of Health and with the Centre for Adverse Reactions Monitoring about Primodos, how to handle reports of reactions to Primidos and media strategy around the issue in 2017*
> ** The number of reports received last year from people who used the drug and how many believed they had an adverse reaction to it.*
> ** All correspondence between Schering and the Ministry regarding Primidos".*

The information relating to this request is itemised in the table below, with copies of documents attached. Under section 9(2)(a) and section 9(2)(g)(i) of the Act, I have decided to withhold some information to protect the privacy of natural persons and to maintain the effective conduct of public affairs through free and frank expression of opinions. I have also decided to withhold information that is outside the scope of your request. Specific grounds are noted in each document where information has been withheld.

Please note that Medsafe has received other requests under the Act on hormonal pregnancy tests, including Primodos. The responses to these requests are publicly available at: www.medsafe.govt.nz/publications/OIAContents.asp. As you will see from previous requests, the regulation of medicines in New Zealand at the time that Primodos was in use was very different to the current situation.

Request	Response
All correspondence within the Ministry of Health, to the Minister of Health and with the Centre for Adverse Reactions Monitoring about Primodos, how to handle reports of reactions to Primidos and media strategy around the issue in 2017.	A number of documents within the scope of your request were identified. These documents have been grouped into two broad groups and you will find them attached: 1. H201800256 Correspondence 2. H201800256 Media.
Number of reports received last year from people who used the drug and how many believed they had an adverse reaction to it.	The Centre for Adverse Reactions Monitoring (CARM) received 10 adverse reaction case reports in 2017 where it was thought that a hormonal pregnancy test was the suspect medicine — Primodos was one of the hormonal pregnancy test products available during the 1960s and 1970s. Because of the length of time now elapsed the reports have little confirmed detail, including whether Primodos was actually taken. In order to provide you with the full information set, a summary of all reports that could possibly be relevant is detailed in the table below. Please note that due to problems with identifying the actual medicine involved, these reports have not been able to be fully assessed by CARM but the detail for each case has been retained by CARM in case of future need. There was one additional case received in 1973 and this is also detailed in the table below (CARM case number 004018).

Date of report	Baby M/F	Mother's age at administration (years)	Reported reaction(s) in baby	Reported reaction(s) in mother
Mar 1973	-	42	-	Hemiplegia
Mar 2017	F	-	Bone development abnormal, Radial head dislocation	-
Mar 2017	-	24	Stillbirth, Skull malformation, Brain malformation, Head deformity	-
Mar 2017	M	37	Multiple congenital abnormalities	-
Mar 2017	M	22	Tracheal stenosis Case published and publicly available: ANZ J Surgery 1991:61(10);801-4 http://onlinelibrary.wiley.com/doi/10.1111/j.1445-2197.1991.tb00156.x/full	-
Mar 2017	F	18	Death neonatal	-
Mar 2017	M	28	Micropenis	-
Apr 2017	F	20	Spina bifida, Kidney malformation	-
Apr 2017	M	Approx 25	Congenital muscle absence	-
Apr 2017	F	Approx 20	Congenital bladder anomaly, Joint dislocation	-
May 2017	M	29	Low birth weight baby	Placenta abnormalities

All correspondence between Schering and the Ministry regarding Primidos.	Please refer to pages 3 to 6 of the attached document titled 'H201800256 Correspondence' for recent correspondence with Bayer (previously Schering). All historical correspondence was previously requested under the Act (H201701896) and is publicly available along with other similar requests under the Act: www.medsafe.govt.nz/publications/OIAContents.asp.

I trust this information fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review my decision to withhold information under this request.

Yours sincerely

[redacted]

Group Manager
Medsafe

Sent by: Chris James/MOH

24/03/2017 03:53 p.m.

To: Janelle Ashton [redacted],
cc: Michael Tatley [redacted] Section 9(2)(a) [redacted] uth Savage [redacted]
bcc:

Subject: Re: Primodos

Hi Janelle

The info we have is on the website as I mentioned to Ruth (on the front page).

From my perspective this is simple in that callers may wish to discuss possible ADRs to a medicines - just happens to be a medicine they may have taken 50 years ago.

Happy to have a teleconference next week if you like. I can update you with what we are doing.

Thanks

Chris

Chris James | Group Manager | Medsafe | Ministry of Health | Section 9(2)(a) [redacted]

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

[redacted]

Janelle Ashton Hi Chris Further to the evolving week... 24/03/2017 01:23:30 p.m.

From: Janelle Ashton [redacted]
To: [redacted]
Cc: Section 9(2)(a) [redacted] Michael Tatley [redacted], Ruth Savage [redacted]
Date: 24/03/2017 01:23 p.m.
Subject: Primodos

Hi Chris
Further to the evolving week...
At this point in time, CARM has now been contacted by 5 people (which includes one who emailed Medsafe and was referred to CARM and the person you asked Ruth to phone). In light of previous events (eg: Section 9(2)(g)(i) [redacted]) I have been putting together an operational SOP for handling of various scenarios in preparation for Michael's review on his return on Monday. I would suggest that we then consider a teleconference with you to discuss/finalise if necessary.

At this point I have received emails and phone calls. I have acknowledged the emails with "Thank you for advising your details to our Centre. CARM is collecting these details and working with the Ministry of Health. I will update you further in due course."
The phone calls I have advised the same detail verbally.

Questions I have at this point are:

1. Do you have anything further that you would want added to these standard initial

responses?

2. Have you any plan of actions to be taken by the Ministry ? This question is to ensure that if you have particular plans then CARM may need to record something extra to accommodate them and it is easier to do this from the start.
3. Do you want regular updates/reports prepared ? Is so, what do you want to know?

Just thought this would give you a "heads up" and time to think about what you might require from us.
Janelle

Janelle Ashton | Manager Information Systems | New Zealand Pharmacovigilance Centre [https://nzphvc.otago.ac.nz]
NZPhvC, PO Box 913, Dunedin 9054, New Zealand | DDI: Section 9(2)(a)

This page all section 9(2)(a)

Sent by: [redacted]

To: [redacted]
cc:
bcc:

28/03/2017 02:06 p.m.

Subject: Information regarding Primodos

Dear Mr James,

Please find attached information regarding Primodos as requested.

Please let me know if you have any further questions,

Best Regards

[redacted]

Medical Director Bayer Australia/New Zealand

Science For A Better Life

Bayer Australia Ltd
Pharmaceuticals Division
875 Pacific Highway, Pymble, NSW, 2073, Australia

[redacted]

Web: www.bayer.com.au

Letter to Medsafe.pdf

Chris James
Group Manager
Medsafe
Ministry of Health
PO Box 5013
WELLINGTON NZ 6145

28 March 2017

Bayer Australia Limited
ABN 22 000 138 714

875 Pacific Highway
Pymble NSW 2073
Australia

Postal Address
PO Box 182
Gordon W 2072
Australia

Ph: (61) 2 9391 6000
Fx: (61) 2 9988 3311
www.bayer.com.au

Dear Mr James

Re: Primodos

Thank you for your message. You have asked whether we have details on the use of Primodos and relevant safety data either for New Zealand or globally. We have noted the contents of your website statement of 20th March 2017 on Primodos.

You will readily appreciate that, given the passage of time we are not in a position to give you detailed information about a product last marketed by Schering in New Zealand over thirty years before Schering became part of Bayer in 2006. However, we can confirm that you are correct in saying that the Department of Health in New Zealand asked manufacturers of Hormone Pregnancy Tests ("HPTs") then on the market in New Zealand (Amenorone Forte from Roussel and Primodos from Schering) to withdraw their products from the market. We understand that both companies agreed to do so. Similar action was taken by the Australian authorities in 1976.

You have asked us about the level of sales in New Zealand. We cannot provide such data but understand that, given the availability of in vitro urine tests, by 1975 the sales of Primodos in New Zealand were low. During the period when Primodos was marketed, adverse event data was not collected as comprehensively as it is today. We can say from the adverse event data that we have reviewed related to Primodos, we have not found any New Zealand cases recorded. However, the UK's yellow card system for spontaneous adverse event reporting was viewed at the time as relatively advanced and we note from the CSM's publication mentioned above that the CSM had received only a "small number" of reports raising a possible association between the use of any product containing sex hormones in pregnancy and the subsequent delivery of a child with congenital malformations. In 1978 litigation was started in the UK by families who believed their child had been injured by HPTs. It concerned HPTs from several manufacturers but two "test cases" against Schering concerning Primodos were selected by lawyers acting for the families. The claimants' cases were fully funded by the UK's public legal aid scheme. The litigation became the focus for a major investigation, over several years, of all of the safety information relevant to HPTs and exposure in pregnancy to other products containing sex hormones. The claimants and Schering presented expert evidence from a very large number of international experts across many disciplines. Supplementary reports were exchanged in 1982, just prior to the scheduled date for trial.

Following this exchange, the claimants' lawyers re-evaluated the merits of their case and in July 1982 applied to the English court to discontinue the proceedings on the grounds that there was "no reasonable prospect - indeed, no real prospect - that we can establish as a matter of probability that Primodos causes congenital malformations". On this basis the Court gave permission to the claimants to discontinue the litigation.

As regards the specific safety information examined, the claimants explained to the Court that the totality of the voluminous epidemiological evidence did not afford any real possibility that it could be established that a causal association existed between the use of Primodos and congenital malformations. In addition, the data on biochemical mechanisms that might account for such an association were not viewed as supporting the claimants' original case that plausible mechanisms for the development of malformations existed. Finally, the claimants' advisors believed that the animal testing data did not indicate that Primodos was teratogenic at dosages used in pregnancy tests. Animal tests in various primate and non-primate species had been conducted or commissioned by Schering and these revealed no teratogenic effects.

Bayer has undertaken a full review of all scientific literature relevant to the effects of sex hormones in pregnancy that have been published since 1982 and this shows that there are no new data that could properly be viewed as having changed the state of scientific knowledge, as compared with the knowledge available to the claimants' advisors in 1982.

You refer in your statement to the review by the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom of all scientific literature on this issue. Please allow us to clarify that this scientific review is not directly conducted by the MHRA but by an Expert Group of the Commission on Human Medicines (CHM). The MHRA in its own assessment from 2014 came to the conclusion "that the data are not sufficient to conclude that there is a causal association between the use of Primodos (or any HPT) and congenital abnormalities" [1]. It is our understanding that the Expert Group would review all currently available evidence relating to whether use of various oral HPTs previously available on the UK market was causally associated with an increased incidence of birth defects and would consider whether the conclusions of that review have any implications for currently licensed medicines. In this context, Bayer has cooperated with the MHRA in its collection of available scientific information.

We hope this information is helpful and meets your current needs.

Yours sincerely,

Section 9(2)(a)

Section 9(2)(a)

Medical Director Bayer Australia/New Zealand

References:

1. MHRA, March 2014, Assessment of historical evidence on Primodos and congenital malformations – a synopsis

This page all section 9(2)(a)

Sent by: Chris James/MOH
04/04/2017 08:08 a.m.

To: Rowan Pollock/MOH@moh,
cc:
bcc:

Subject: Re: Primodos

Hi can you please organise a response? May need referral to CARM.
Chris

On 4/04/2017, at 7:19 AM, Info MOH <info@health.govt.nz> wrote:

Hi Chris

Another email via info@health.

Thanks
Janine

Ministry of Health
PO Box 5013
Wellington 6145
Free phone: 0800 855 066
Phone: (04) 496 2000
Healthline: 0800 611 116
Email: info@health.govt.nz
Website:www.health.govt.nz

----- Forwarded by Janine Pickering/MOH on 04/04/2017 07:18 a.m. -----

From: [redacted]
To: ""Ministry of Health"" <info@health.govt.nz>,
Date: 03/04/2017 06:21 p.m.
Subject: RE: Primodos

Dear Sir/Madam,

[redacted] went to [redacted] who gave pregnancy testing pill [redacted] daughter who had classic ectopia vesicae & bilateral dislocated hips.
This was in [redacted]

Section 9(2)(a)

Regards

Section 9(2)(a)

This page all section 9(2)(a)

Sent by: Rowan Pollock/MOH

04/04/2017 03:22 p.m.

To: [redacted]
cc:
bcc:

Subject: Fw: Primodos

Dear [redacted]

Thank you for your email.

I appreciate you getting in touch to let us know about your experiences with Primodos and I'm sorry to hear of [redacted]

You may have seen the Medsafe website or comments in the media. In case not, this is what we know so far about use in New Zealand:

- Primodos first appeared on the New Zealand market in 1966.
- In May 1975 the then Department of Health decided to withdraw Primodos from the New Zealand market. This was due to reports received overseas that birth defects have occurred when hormonal pregnancy tests have been taken in early pregnancy.
- Stock was also removed from pharmacies in June 1975 so there should have been little to no stock left in the market to be prescribed after this date.

Medsafe is aware there is a Primodos working group review currently underway in the UK, the outcome of which we will be following closely.

I would also recommend getting in touch with the Centre for Adverse Reactions Monitoring (CARM) in Dunedin to discuss your concerns, if you have not done so already. CARM is part of the University of Otago and is contracted by the Ministry of Health to collect information about possible adverse reactions to medicines and then to provide that analysis to us. CARM has medical staff who are able to discuss with you your experiences and help you to register a report of an adverse reaction if you wish to. CARM can also provide advice on adverse reactions already reported for these products.

CARM can be contacted on (04) 479 7247 or by email at nzphvc@otago.ac.nz

CARM's website is https://nzphvc.otago.ac.nz/

Thank you for getting in touch. The information you have provided helps us to get more information about the use of Primodos in New Zealand.

Kind regards

Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

This page all section 9(2)(a)

From: [redacted]
To: "'Ministry of Health'" <info@health.govt.nz>,
Date: 03/04/2017 06:21 p.m.
Subject: RE: Primodos

Dear Sir/Madam,

[redacted] went to [redacted] who gave pregnancy testing pill [redacted] daughter who had classic ectopia vesicae & bilateral dislocated hips.
This was in [redacted]

Regards
[redacted]

This page all section 9(2)(a)

Sent by: Rowan Pollock/MOH

06/04/2017 10:49 a.m.

To: OIA Requests/MOH@MOH,
cc: Rosie Maltas/MOH@MOH,
bcc:

Subject: Fw: RE: Amenorone Forte

Hi team

Can this please be logged as an OIA?
Request is for Amenorone Forte archival records.

Thanks
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

----- Forwarded by Rowan Pollock/MOH on 06/04/2017 10:47 a.m. -----

From: [redacted]
To:
Date: 05/04/2017 06:57 p.m.
Subject: RE: RE:

Dear Rowan

Thankyou for your e mail.
You are the third person to reply to my e mails so Im just wondering exactly who you are and why my information is being passed around your organisation?
Could you please provide the archival records that you refer to in your e mail.
Regards [redacted]

From: [redacted]
Sent: 5 April 2017 3:12 p.m.
To: [redacted]
Subject: Fw: RE:

Dear [redacted]

I am writing to follow up on your query about Amenorone Forte. According to archival records, Amenorone Forte was available in New Zealand from mid-1968 and was withdrawn at the same time as Primodos (1975).
There was one report to the Centre for Adverse Reactions Monitoring (CARM) in relation to this product, with limited details.

Thank you for getting in touch and I hope this information is helpful.

Kind regards
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | Section 9(2)(a)

This page all section 9(2)(a)

Sent by: Rowan Pollock/MOH

06/04/2017 10:57 a.m.

To: [redacted]
cc:
bcc:

Subject: RE: RE:

Dear [redacted]

Thank you for your email and request for Amenorone Forte archival records.

I have submitted your request under the Official Information Act (OIA) 1982. You can find more information about the OIA process here:
www.health.govt.nz/about-ministry/contact-us/official-information-act-requests

We will respond to you as soon as practicable and in any case not later than 20 working days after the day the request was received.

Kind regards
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

[redacted] Dear Rowan 05/04/2017 06:57:08 p.m.

From: [redacted]
To: <Rowan_Pollock@moh.govt.nz>,
Date: 05/04/2017 06:57 p.m.
Subject: RE: RE:

Dear Rowan

Thankyou for your e mail.
You are the third person to reply to my e mails so Im just wondering exactly who you are and why my information is being passed around your organisation?
Could you please provide the archival records that you refer to in your e mail.
Regards [redacted]

From: [redacted]
Sent: 5 April 2017 3:12 p.m.
To: [redacted]
Subject: Fw: RE:

Dear [redacted]

This page all section 9(2)(a)

I am writing to follow up on your query about Amenorone Forte. According to archival records, Amenorone Forte was available in New Zealand from mid-1968 and was withdrawn at the same time as Primodos (1975).
There was one report to the Centre for Adverse Reactions Monitoring (CARM) in relation to this product, with limited details.

Thank you for getting in touch and I hope this information is helpful.

Kind regards
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

From: [redacted]
Date: 4 April 2017 at 6:53:04 AM NZST
To: [redacted]
Subject: RE: RE:

Hi Chris

I have been in contact with [redacted] the spokesperson in the UK for children effected by pregnancy testing and she has suggested to me that there was also another hormone pregnancy testing drug called Amenerone Forte, which was 3 tablets.(See my e mail below re [redacted] tablets given to [redacted] birth defects.
Could you please advise if this drug or its equivalent was introduced to NZ –when and its side effects?
Regards [redacted]

From: [redacted]
Sent: 22 March 2017 8:23 a.m.
To: [redacted]
Subject: Re: RE:

Dear [redacted]

I certainly will keep your email on file. Medsafe is seeking further information from the pharmaceutical company to ensure we know when this product was in New Zealand.

Thanks again for getting in touch.

Chris

This page all section 9(2)(a)

On 21/03/2017, at 9:33 PM, [redacted]:

Dear Chris

Thanks for your prompt reply I will look at that website ,however in the meantime please keep my e mail on file as you may find that like Britain it was introduced here a lot earlier than 1966 as it could have been made available as samples.
If your advertising and media campaign draws more people out with similar defects born in years prior to 1966 it would suggest that further investigation was required.
Regards [redacted]

From: [redacted]
Sent: 21 March 2017 5:41 p.m.
To: [redacted]
Subject:

Dear [redacted]

Thank you for your email. I appreciate you getting in touch to register your concerns.

From the information we have to hand, it appears Primodos was available in New Zealand from 1966 - 1975. However, after reading your email about [redacted] blue pills I think it is worth getting in touch with the Centre for Adverse Reactions Monitoring in Dunedin (CARM). The centre has medical staff who you can discuss your concerns with and produce an adverse reaction report if you wish.

CARM's website details are: https://nzphvc.otago.ac.nz/
They can also be contacted on 03 479 7247

Kind regards

Chris

Chris James | Group Manager | Medsafe | Ministry of Health | [redacted]
<image001.gif>

From: [redacted]
To: <info@health.govt.nz>,
Date: 21/03/2017 06:50 a.m.
Subject:

To Whom it May Concern
Primodos
I have heard about the birth defects caused by Primodos.
[redacted] lack the development of the radial head and the [redacted] radio ulnar

This page all section 9(2)(a)

joints being both dislocated [redacted] . [redacted] undeveloped middle and terminal phalanges [redacted] .
[redacted] blue pills given to [redacted] by [redacted]
After reading about Primodos tonight I would like to register my concerns that this may have been a drug used in the late 1950s .... And would be interested in who I would contact to discuss further.
Yours faithfully

[redacted]

[redacted]

This page all section 9(2)(a)

Sent by: Becci Slyfield/MOH

06/04/2017 12:44 p.m.

To: Rowan Pollock/MOH@MOH, Chris James/MOH@MOH, Alison MacDonald/MOH@MOH,
cc:
bcc:

Subject: Fw: Primodos

Any takers for this?

MEDSAFE

----- Forwarded by Becci Slyfield/MOH on 06/04/2017 12:43 p.m. -----

From: [redacted]
To: askmedsafe@moh.govt.nz,
Date: 05/04/2017 12:00 p.m.
Subject: Primodos

Hello
Reading and hearing about this tablet given to check for a pregnancy - has reminded me of when [redacted] prescribed this tablet [redacted] tablet - [redacted] boy was born in [redacted]
However- [redacted] has a missing pectoral muscle [redacted] if [redacted] prescribed primodos - [redacted] tablet.
Is there a link here [redacted]
Many thanks
[redacted]

This page all section 9(2)(a)

Sent by: Rowan Pollock/MOH

06/04/2017 02:17 p.m.

To: [redacted]
cc:
bcc:

Subject: Fw: Primodos

Dear [redacted]

Thank you for your email.
I appreciate you getting in touch to let us know about your experiences with Primodos and I'm sorry to hear of [redacted]

The following summarises what we know so far about use in New Zealand:

- Primodos first appeared on the New Zealand market in 1966.
- In May 1975 the then Department of Health decided to withdraw Primodos from the New Zealand market. This was due to reports received overseas that birth defects had occurred when hormonal pregnancy tests had been taken in early pregnancy.
- Stock was removed from New Zealand pharmacies in June 1975 so there should have been little to no stock left in the market to be prescribed after this date.

Medsafe is aware there is a Primodos working group review currently underway in the UK to investigate this further, the outcome of which we will be following closely.

From the information we hold Primodos was in a pack of two tablets, one tablet to be taken once a day for two days. However, it is very possible that this is what you were prescribed back in 1972-1973.

To ensure we get information on the use of Primodos in New Zealand I would recommend getting in touch with the Centre for Adverse Reactions Monitoring (CARM) in Dunedin to discuss your concerns, if you have not done so already. CARM is part of the University of Otago and is contracted by the Ministry of Health to collect information about possible adverse reactions to medicines and then to provide that analysis to us. CARM has medical staff who are able to discuss with you your experiences and help you to register a report of an adverse reaction if you wish to. CARM can also provide advice on adverse reactions already reported for these products.

CARM can be contacted on (04) 479 7247 or by email at nzphvc@otago.ac.nz
CARM's website is https://nzphvc.otago.ac.nz/

Thank you for getting in touch. The information you have provided helps us to get more information about the use of Primodos in New Zealand.

Please don't hesitate to contact me again should you have any further questions or queries.

Kind regards
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

This page all section 9(2)(a)

From: [redacted]
To: askmedsafe@moh.govt.nz,
Date: 05/04/2017 12:00 p.m.
Subject: Primodos

Hello
Reading and hearing about this tablet given to check for a pregnancy - has reminded me of when [redacted] prescribed this tablet [redacted] tablet - [redacted] boy was born in [redacted].
However- [redacted] has a missing pectoral muscle [redacted] if [redacted] prescribed primodos - [redacted] tablet.
Is there a link here [redacted]
Many thanks
[redacted]

This page all section 9(2)(a)

Sent by: Rowan Pollock/MOH

11/04/2017 12:21 p.m.

To: [redacted]
cc:
bcc:

Subject: Amenorone Forte

Dear [redacted]

You may be aware that there has been recent public interest regarding the product Primodos. Medsafe has been investigating the use of hormonal testing preparations for pregnancy and is aware that Amenorone Forte (norethisterone and ethinylestradiol) was also available during this time.

I note that Roussel NZ Ltd, the company that supplied Amenorone Forte, is now sanofi-aventis.

The records for Amenorone Forte have been retrieved from archives and within this file it is noted that the average monthly sales during 1974 was 252 units for New Zealand. In keeping the public informed about this, I would like to seek permission from sanofi-aventis that this information is included in the next update.

Additionally, Medsafe has also been requested, under the Official Information Act 1982, to release records relating to correspondence about the withdrawal of this product.

Please forward this to the most appropriate contact if you are not involved in this or alternatively please contact me as soon as practicable to discuss further.

Kind regards
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

Sent by: Rowan Pollock/MOH

20/04/2017 11:06 a.m.

To: [redacted] Amanda Taylor/MOH@MOH,
cc: Susan Kenyon/MOH@MOH, Geraldine Hill/MOH@MOH, Lily Chan/MOH@MOH, Jo Prankerd/MOH@MOH,
bcc:

Subject: CARM-Medsafe teleconference (minutes)

20 April 2017
Present: Michael, Ruth, Amanda and Rowan

[redacted]

Hormonal pregnancy tests: another query re: Primodos

Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

This page all section 9(2)(a)

Sent by: Chris James/MOH
26/04/2017 08:07 a.m.

To: Rowan Pollock/MOH@moh,
cc:
bcc:

Subject: Fwd: Exposure to hormone pregnancy tests shown to increase risk of testicular cancer in males.

Hi Rowan
Can you please respond?
Thank
Chris

Begin forwarded message:

From: [redacted]
To: [redacted]
Subject: Exposure to hormone pregnancy tests shown to increase risk of testicular cancer in males.

Dear Chris and [redacted]

I have been doing research on HPTs and have come across data which shows that sons of mothers who took HPTs and other oestrogen/progestin drugs have a much higher incidence of testicular cancer. Daughters have a variety of reproductive anomalies and infertility and while I have yet to research that, there is plenty of discussion by daughters on the UK Facebook page *Primodos (The Forgotten Thalidomide) ACDHPT.*

I enclose a robust published study, *Exposure During Gestation and Risk of Testicular Cancer (1983), by Robert H. Depue, Malcolm C. Pike,and Brian E. Henderson.* To quote this study; *"Hormone administration during pregnancy was a significant risk factor in this study, with 9 mothers of cases and only 2 mothers of controls receiving such exposure during the first 3 months*

The ongoing health of children who were exposed to HPTs is of great concern when reading studies that have been conducted, yet no follow up has been actioned in New Zealand. The above study on testicular cancer was printed 34 years ago in 1983. The history of HPTs and the continued silence and inaction from our health authorities as to the long term effects on the victims is malignant.
Nothing short of an Inquiry is going to satisfy.

Yours sincerely
[redacted]

Estrogen Exposure During Gestation and Risk of Testicular Cancer Depue 1983.pdf

Estrogen Exposure During Gestation and Risk of Testicular Cancer[1,2]

Robert H. Depue,[3] Malcolm C. Pike,[4] *and* Brian E. Henderson[4,5,6]

ABSTRACT—In this case–control study of 108 cases of testicular cancer in men under 30 years of age, cryptorchidism was a major risk factor [relative risk (RR)=9.0]. Low birth weight was also associated with increased risk (RR=3.2). Having severe acne at puberty was protective (RR=0.37). Interviews with mothers of cases revealed that exposure of the mother to exogenous estrogen during pregnancy created a significant risk in the son (RR=8.0). In first pregnancies, excessive nausea indicated an increased risk of testicular cancer (RR=4.2). Increased body weight in the mother also increased the risk. The relation between these factors and testicular hypoplasia is discussed. Severe perimenopausal menorrhagia was a factor in the mother associated with reduced risk of testicular cancer in the son (RR=0.10). A modified hormonal milieu in the mother appears to be important in the later development of testicular cancer in her sons.—JNCI 1983; 71:1151–1155.

The age-specific incidence curve of testicular cancer shows a broad peak between ages 20 and 40 years (*1*). The major known risk factor for testicular cancer is cryptorchidism (*2–4*). These two features suggest that gestational and/or early childhood periods are probably critical in the pathogenesis of this disease.

In our first case–control study of testicular cancer, we found that, in addition to cryptorchidism, both excessive nausea and vomiting and exogenous hormone use during the index pregnancy were risk factors for testicular cancer (*5*). The current case–control study was explicitly designed to obtain further information on these factors. It was limited to cases under 30 years of age to maximize the number of mothers available for interview.

MATERIALS AND METHODS

The patients were white men first diagnosed with a germ cell carcinoma of the testis between the years 1973 and 1979. Such men between 16 and 30 years of age at the time of diagnosis were eligible for interview, provided they were a resident of Los Angeles County when diagnosed; were born in the United States; and had a mother who was alive, living in the United States, and willing to be interviewed. Patients who had died were not eligible for the study. The patients were identified by the University of Southern California Cancer Surveillance Program, the population-based cancer registry for Los Angeles County (*6*).

The University of Southern California Cancer Surveillance Program identified 261 patients, of whom 59 were deceased and 202 were eligible for interview. The attending physician refused permission to contact 21 of them. Of the remaining 181 patients, 8 declined to participate; 31 could not be located; and for 19 patients, the natural mother had moved out of the United States or had died. The number of successfully completed mother–son interviews was 124.

For each completed mother–son patient interview, an attempt was made to locate a nearest white male neighbor, matched for date of birth, to serve as a control. For cases aged 18 years and under at diagnosis, the matching for date of birth was ±2 years, for cases aged 19 years it was ±3 years, for cases aged 20 years it was ±4 years, and for older cases it was ±5 years. The controls had to be born in the United States with a mother who was alive, living in the United States, and willing to be interviewed.

We selected controls by visiting neighborhood houses in a pattern designed to avoid the block of the case residence, until an eligible and willing control was located. If no one was home at the time of the visit, an explanatory letter was left with a form to be returned by mail, indicating whether there was an eligible control living at the address or another eligible family member who had lived there at any time since the time of diagnosis of the case. If this form was not returned, a follow-up letter was sent enclosing another form. If the follow-up letter was not returned, up to three attempts were made to contact the residence by telephone. The first eligible control found in the neighborhood visiting pattern was used. Up to 40 residences were visited in an attempt to obtain a control. We successfully completed 108 mother–son matching control interviews. Because of refusals, 33 controls interviewed were not the first eligible. A total of 39 potential control sons and 5 potential control mothers refused interview.

All interviews were conducted by telephone either by one of us (R.D.) or by one of two trained interviewers. Information was obtained from cases and controls on socioeconomic, reproductive, and medical histories. Socioeconomic questions were on level of education attained and occupation. Reproductive history included years married, number of children, and history of fertility problems in either partner. Medical history included questions on height, weight, puberty (ages at first shaving

ABBREVIATIONS USED: DES=diethylstilbestrol; EC=embryonal cell carcinoma; RR=relative risk; S=seminoma; SHBG=sex hormone-binding globulin; T=teratoma.

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and voice change, as well as severity of acne), childhood infectious diseases, hormone usage, X-ray exposure, urologic diseases and malformations, and any treatments for these. These telephone interviews were about 15 minutes in length.

The mother's questionnaire included a complete menstrual and reproductive history, including menstrual disorders and their treatment. Special attention was paid to disorders of pregnancy, including nausea, preeclampsia, spotting, and threatened abortion. Questions on drug usage during pregnancy specifically included estrogens, progestins, insulin, thyroid, antinauseants, antibiotics, stimulants, analgesics, tranquilizers, and sedatives. Information about specific treatment for threatened abortions was also sought. Inquiries were made about any chronic or serious diseases or malformations, especially urologic, in her children. Height and weight at the time of the index pregnancy was recorded. The length of the mother interviews ranged from 30 to 50 minutes, depending on the number children the woman had had.

Standard methods, including multivariate logistic regression methods for individually matched case–control studies, were used for statistical analysis (*7, 8*). Because the odds ratios estimated from such analyses closely approximate the related RR, the term RR was used in the text for clarity of presentation. All significance tests (*P*-values) quoted were one-sided.

RESULTS

The histologic elements of germ-cell cancers of the testis are EC, T, and S; however, most cases were of mixed histology. In our 108 cases the histologic classifications were: EC (22 cases), T (7 cases), S (28 cases), EC&T (25 cases), EC&S (16 cases), and EC&T&S (9 cases).

The mean difference between the dates of birth of the cases and controls was only 0.3 years, and the socioeconomic status of the patients was similar to that of the controls as was to be expected from the method of control selection. Of the cases studied 30% were college graduates, an additional 39% had some college education, and only 7% did not complete high school. This educational distribution is distinctly higher than expected when compared to the 1970 Los Angeles white census population ($P<0.001$) (*9*), thus reflecting the positive, socioeconomic risk gradient that has been found for testis cancer (*10*).

No differences were noted in the type of industry or job classification of the cases and controls. The ages of the mothers at interview were well matched—the mean age of the cases' mothers exceeded that of the controls' mothers by only 0.5 years; and both the mothers' and fathers' educational levels were also well balanced, cases to controls, by the neighborhood control selection process.

The risk factors that emerged from the analysis of the 108 patient–mother and matched control–mother questionnaires are shown in table 1. As expected, there was an excess risk associated with cryptorchidism (RR=9.0). Hernia before 13 years of age occurred more frequently in the cases (RR=2.7), but it was not a statistically significant risk factor. The cases also tended to be first-born children more often than the controls (RR=1.6), but the result was again not statistically significant. The cases reported significantly less acne that had been treated by a physician (RR=0.37). However, there was no significant difference between the cases and controls in the ages when shaving began and when the voice changed, in the frequency of shaving, in the proportion married (RR=1.2), or in the proportion having had a child (RR=0.83).

An index of fertility was constructed for each married case and control by calculation of the number of children each had before the age of diagnosis and by division by the number of years the male subject was married before his diagnosis age. No difference was found in this fertility index between cases and controls (0.24 children/yr in

TABLE 1.—*Relative risks calculated from the patient's and the mother's questionnaires*

Questionnaire	Cases[a]	Controls[a]	Matched RR	95% confidence limits	One-sided *P*-value
Patient's					
Cryptorchidism	9/98	1/107	9.00	1.5–54.9	0.01
Hernia before 13 yr of age	9/98	4/104	2.67	0.44–6.3	0.11
First born	44/64	34/74	1.62	0.89–3.0	0.08
Treated for acne	15/92	27/80	0.37	0.16–0.85	0.01
Mother's					
Mothers Quetelet's Index before index pregnancy[b]	10	18	1.00		0.02[c]
	53	62	1.60	0.70–3.7	
	45	28	2.86	1.1–7.3	
Exogenous hormone exposure during first trimester of index pregnancy	9/97	2/105	8.00	1.3–49	0.02
Treated nausea during index pregnancy	20/87	15/89	1.36	0.68–3.1	0.22
Treated nausea during index pregnancy for first birth	10/33	2/30	4.24[d]	0.89–20.2	0.03[d]
Birth weight index pregnancy, <6 lb	17/90	7/99	3.20	1.2–8.4	0.01
Surgery for menorrhagia	4/102	22/85	0.10	0.03–0.39	<0.001

[a] When two numbers are given in the column, they are positives/negatives.
[b] Three levels, <19, 19–21, 22+.
[c] Test for trend (7).
[d] These values are calculated after fitting the first born.

cases vs. 0.23 children/yr in controls), and no case–control difference was found in response to questions about wives having trouble getting pregnant. Thus there was no evidence for any deviation from normal fertility among the cases before diagnosis of the testicular cancer.

The mothers of cases had a significantly greater Quetelet's Index (weight in kg/square of height in m) at the time of conception with the index pregnancy. Exposure to exogenous hormones during the first trimester of the index pregnancy was also a significant risk factor for testicular cancer in the offspring (RR=8.0). The details of the hormone exposure in these 9 case and 2 control pregnancies are shown in table 2. Mothers of 2 cases received DES; the mother of 1 case, an estrogen preparation; and the mother of 1 case, a progestin. Mothers of 5 cases and of 1 control reported receiving a pregnancy test that involved taking an estrogen–progestin preparation. All of the hormone exposures of the mothers of cases started in the first 2 months of gestation.

No difference was seen in the frequency of reported nausea during the index pregnancy between the mothers of cases and the mothers of controls. There was, however, a slight, but not statistically significant, excess of nausea that required medical treatment among the mothers of cases (RR=1.4). All of the excess risk from treated nausea was confined to cases who were first children (RR=4.2).

Low birth weight (<6 lb) was a significant risk factor (RR=3.2). Two related risk factors were being one of a set of twins (RR=5.0; 5 cases, 1 control) and delivery by caesarian section (RR=6.0; 6 cases, 1 control). Both of these factors tend to produce lighter infants; the three risk factors were not independently statistically significant when a multivariate analysis was performed.

The menstrual histories of the mothers were otherwise unremarkable except for a much lower incidence in cases' mothers having menorrhagia, which was surgically treated (RR=0.10). This menorrhagia occurred mainly at perimenopausal ages, years after the index pregnancies, so that it was only a "risk factor" in the sense of indicating some possible underlying menstrual difference between the mothers of cases and the mothers of controls. The RR was unity for menorrhagia that did not require surgery. Of the 22 control mothers, 9 did not know the exact diagnosis resultant from the surgery, 7 reported benign tumors (fibroids or polyps), and 6 reported miscellaneous diagnoses—postpartum bleeding (2 women), endometrial hyperplasia (1 woman), ovarian cysts (2 women), and uterine malposition (1 woman). The 4 cases reported miscellaneous diagnoses—one each for break-through bleeding, ovarian cyst, endometrial hyperplasia, and postpartum bleeding; none reported benign tumors.

TABLE 2.—*Hormone usage during first trimester of index pregnancy*

Mothers of:	Hormones used	No. of mothers	Mo of pregnancy when usage started	Duration, wk
Cases	DES	2	2, 2	2, 12
	Estrogen	1	1	36
	Progestin	1	2	13
	In pregnancy test[a]	5	1–2	
Controls	Estrogen	1	3	1
	In pregnancy test[a]	1	2	

[a]Mothers took estrogen–progestin preparation as a pregnancy test (*see* text).

The risk factors in table 1 were analyzed jointly by multiple logistic regression (*7*). None of the estimated risks changed appreciably when other factors were included in the model.

The frequency of mixed cell types indicated to us that separate analyses were inappropriate. Elimination of the pure S-cases from the analyses presented here did not materially change the results. The number of pure S-cases were too few for results to be meaningful.

DISCUSSION

The results of this case–control study generally substantiate our earlier findings (*5*). The RR of 9.0 for cryptorchidism agrees reasonably well with our earlier estimate of 5.0 and the results of others who have reported risks of 14.0 (*3*), 2.8 (*4*), and 9.0 (*11*).

Inguinal hernia, although often accompanying cryptorchidism, was not a statistically significant risk factor for testicular cancer in this study, although the RR was 2.7. RR estimates of Morrison (*11*) at 2.9 and of Henderson et al. (*5*) at 2.0 are consistent with the 2.7 we find here. Only Morrison's result was statistically significant. If we combine the results here with the results of our previous study (*5*), the RR is 2.2 (P=0.03) (*8*).

The validity of the study is supported by the fact that the estimated risk ratios for cryptorchidism and for inguinal hernia agree with published values. Attempts were made independently to validate maternal drug exposures, but physician and hospital maternity records were no longer available after 18–30 years since childbirth. There were no case–control differences in maternal responses to questions about use of other drugs unlikely to be related to testis cancer, such as antibiotics and analgesics.

Hormone administration during pregnancy was a significant risk factor in this study, with 9 mothers of cases and only 2 mothers of controls receiving such exposure during the first 3 months of the index pregnancy (table 2). We previously found a fivefold-increased risk of testicular cancer associated with hormone administration during the index pregnancy (*5*), but that result was not statistically significant. Schottenfeld et al. (*4*) also found a nonstatistically significant RR of 2.8 for use of DES or other hormones during pregnancy. None of the mothers of cryptorchid subjects were exposed to exogenous hormones during the index pregnancy.

Particularly interesting is that 5 of the cases' mothers in this study had a single hormone injection as part of a pregnancy test. Hormone pregnancy tests generally employ mixtures of an estrogen and a progestin, most commonly ethinylestradiol and norethindrone, but sometimes mestranol and norethynodrel. Torfs et al.

(*12*) found an elevated rate of cryptorchidism in sons born to mothers who had such a pregnancy test (RR=1.93; 3/109 vs. 7/490), but the result was not statistically significant. These preparations are almost identical in composition to oral contraceptives, and Rothman and Louik (*13*) found an elevated risk of cryptorchidism in sons of women who had used oral contraceptives during the pregnancy (RR=1.77; 11/1448 vs. 27/6275). Their result also was not significant; but when these 2 sets of results are considered together, the difference reaches conventional statistical significance (RR=1.80; P=0.03) (*8*).

Estrogen administration can produce testis cancer in mice (*14*); and DES has produced incomplete male genital development, including maldescent and testicular hypoplasia, when administered to pregnant experimental animals or humans (*15–19*). Hormone administration during early pregnancy thus fits well with cryptorchidism as a risk factor for testicular cancer.

We previously found excessive nausea during the index pregnancy to be associated with a fourfold-increased risk of testicular cancer (*5*). In the present study, excessive nausea, as indicated by treatment with drugs, was associated with only a slight increase in risk; but when we confined attention to treated nausea in first-born pregnancies, the RR rose to 4.6. Treated nausea in second or subsequent index births was not associated with any increase in risk. When we reexamined the data from our first study, we found that the risk from excessive nausea was higher in first-born sons in that study too (in first births: 4 of 38 cases' mothers vs. 0 of 38 controls' mothers; in second and subsequent births: 4 of 40 cases' mothers vs. 2 of 40 controls' mothers).

In our first study, the occurrence of excessive nausea was volunteered as a complication of pregnancy, and it was especially difficult to know to what extent the result may have been due to selective recall bias. In the study reported here, incidence of nausea in pregnancy was specifically asked in structured questions about each pregnancy; and, as we noted above, no difference was found between the cases' mothers and the controls' mothers in overall frequency of this complication. It is difficult to separate the risk of severe nausea from the risk of the drugs used to treat it; but epidemiologic studies of antinauseants have not found any increase in risk of teratogenicity (*20, 21*), and the fact that the risk appears to be confined to first births argues strongly for the severe nausea itself being the risk factor. The true level of RR in first-born males is probably lower than that observed here, since the observed proportion of the controls' mothers who were treated for nausea is lower for first births than for subsequent births. This result is contrary to clinical experience and to the observation that hyperemesis gravidarum, the most severe form of nausea in pregnancy, is more common in first pregnancies (*22*).

The cause of nausea of pregnancy is not definitely known (*23*), but it almost invariably starts in the first 2 months of gestation when estrogen levels rapidly rise in the mother. This rise has been suggested as the event inciting nausea because exogenous estrogens commonly produce nausea. Nausea as a risk factor may thus be related to the risk factor of hormone administration. The observed higher proportion of first-born cryptorchid cases and controls is consistent with this reasoning.

That the mother's nausea should be a risk factor only in first-born sons suggests that the first pregnancy is endocrinologically different from subsequent pregnancies. It is the mother's first experience with very high estrogen levels. In addition to the steep estrogen rise that occurs, a pregnant woman must produce much more SHBG, which rises fivefold to tenfold by midpregnancy (*24*). SHBG is an estrogen-inducible protein synthesized by the liver, and perhaps its production lags behind the increasing estrogen synthesis in some women for about the first 12 weeks of pregnancy, the critical period for urogenital differentiation. Such an effect would be expected to be greatest and most frequent at a first pregnancy. The increase in SHBG synthesis would be expected to proceed more rapidly in subsequent pregnancies, a phenomenon akin to the anamnestic response in antibody production.

Siiteri and his colleagues (*25, 26*) have suggested that reduced SHBG binding may be a risk factor for breast cancer, a cancer for which the risk is lowered by an early first birth (*27*). Women with endometrial cancer have also been shown to have higher free 17β-estradiol levels due to much lower SHBG levels (*28*). The sharply lower SHBG is completely a function of the greater body weight of women with endometrial cancer. Similarly, we find that a high body weight in the mother is a risk factor for testis cancer in the son. This risk, therefore, also may be related to elevated free estrogen mediated by the strong inhibitory effect that overweight has on SHBG production (*29, 30*).

The protection against testicular cancer associated with a mother's having surgically treated menorrhagia is difficult to understand. Little is known of the etiology of benign uterine tumors. Spellacy et al. (*31*) found that women with fibroids have a higher growth hormone response to hypoglycemic challenge, and Ylikorkala et al. (*32*) found that follicle-stimulating hormone levels were depressed in such women. We are unable to relate these observations to our results. We did note, however, that only 3 (14%) of the 22 controls who were later surgically treated for menorrhagia were nauseated during the index pregnancy, compared to 21 (24%) of the 86 remaining controls. This result is not statistically significant, but does relate this observation on benign uterine tumors to the other risk factors we observed.

The clearest risk factor, aside from cryptorchidism, at the time of the birth of the case was low birth weight. This low birth weight was, of course, related to twinning and early delivery. Premature delivery was noted to be a risk factor in our previous paper. Children born underweight have a higher risk of being cryptorchid (Depue RH: Unpublished observation).

The lower incidence of severe acne among cases may be related to other risk factors for testis cancer. The appearance of acne is associated with increasing testos-

terone levels (*33*), and its absence could indicate testicular hypofunction in testis cancer patients. Rajfer and Walsh (*34*) provided evidence that testicular descent is under the control of dihydrotestosterone produced by the testes. Furthermore, both testes in unilateral cryptorchid patients are thought to be hypofunctional (*35–37*). This evidence is consistent with the fact that the contralateral testis in unilateral cryptorchids has an elevated risk of cancer (*3*).

Estrogen administration at the critical time in pregnancy may produce cryptorchidism and hypofunctional testes (*13, 14, 17–19*). Thus all of the risk factors for testicular cancer—estrogen administration in early pregnancy, severe nausea of pregnancy, low birth weight, absence of severe acne, and cryptorchidism—can be related directly or indirectly to each other.

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Sent by: Rowan Pollock/MOH

27/04/2017 09:34 a.m.

To: [redacted]
cc:
bcc:

Subject: Fw: Death of baby from Primodos[redacted]

Dear [redacted]

Thank you for your email.

I am sorry to hear of about [redacted]. It must have been a very difficult time for you and your family, and I appreciate that you have been able to get in touch to share your experiences with Primodos.

I can understand that you would like to be informed of any developments. You may have seen the Medsafe website or comments in the media, but in case not what is known is that Primodos first appeared on the New Zealand market in 1966. In May 1975, the then Department of Health decided to withdraw Primodos from the New Zealand market due to reports received overseas that birth defects had occurred when hormonal pregnancy tests were taken in early pregnancy. Stock was also removed from pharmacies in June 1975.

A working group has been established in the UK to review international information relating to these hormonal pregnancy tests. Medsafe and the Ministry of Health will be closely following the review to learn what implications there might be for women who may have received these products in New Zealand. Medsafe will receive information directly from the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), and Medsafe is also happy to make available to the working group any and all information from New Zealand which may be useful.

I would recommend getting in touch with the Centre for Adverse Reactions Monitoring (CARM) in Dunedin to discuss your concerns. CARM is part of the University of Otago and is contracted by the Ministry of Health to collect information about possible adverse reactions to medicines and then to provide that analysis to us. CARM has medical staff who are able to discuss with you your experiences and help you to register a report of an adverse reaction if you wish to. CARM can also provide advice on adverse reactions already reported for these products.

CARM can be contacted on (04) 479 7247 or by email at nzphvc@otago.ac.nz
CARM's website is https://nzphvc.otago.ac.nz

Thank you again for getting in touch, the information you have provided helps us to get more information about the use of Primodos in New Zealand.

Kind regards

Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

----- Forwarded by Rowan Pollock/MOH on 27/04/2017 08:59 a.m. -----

From: [redacted]

This page all section 9(2)(a)

To: info@health.govt.nz,
Date: 25/04/2017 10:15 a.m.
Subject: Death of baby from Primodos1974

To whom it may concern

I wish to register my interest with those who are concerned about the negative health effects on babies and children by the drug Primodos.

In [redacted]
a packet with [redacted] pills [redacted]
[redacted] baby was born very small [redacted] placenta
hadn't developed properly.
[redacted]

Please keep me informed of any developments with others who may be concerned with the negative effects possibly caused by Primodos..

For research purposes:
...[redacted]
....The date of birth [redacted]
My name is [redacted]
My address is.....[redacted]
Telephone no [redacted]
Cell Phone no [redacted]

This page all section 9(2)(a)

Sent by: Rowan Pollock/MOH

27/04/2017 03:32 p.m.

To: [redacted]
cc:
bcc:

Subject: Fw: Exposure to hormone pregnancy tests shown to increase risk of testicular cancer in males.

Dear [redacted]

Thank you for your email.

As you are aware a working group has been established in the UK to review international information relating to these hormonal pregnancy tests. Medsafe and the Ministry of Health will be closely following the review to learn what implications there might be for women who may have received these products in New Zealand. Medsafe will receive information directly from the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), and Medsafe is also happy to make available to the working group any and all information from New Zealand which may be useful.

Thank you also for providing a copy of the study by Depue et al (1983). This will be reviewed in conjunction with the findings from the working group.

Kind regards
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health |

Begin forwarded message:

From: [redacted]
To: [redacted]
Subject: Exposure to hormone pregnancy tests shown to increase risk of testicular cancer in males.

Dear Chris and [redacted]

I have been doing research on HPTs and have come across data which shows that sons of mothers who took HPTs and other oestrogen/progestin drugs have a much higher incidence of testicular cancer. Daughters have a variety of reproductive anomalies and infertility and while I have yet to research that, there is plenty of discussion by daughters on the UK Facebook page *Primodos (The Forgotten Thalidomide) ACDHPT.*

I enclose a robust published study, *Exposure During Gestation and Risk of Testicular Cancer (1983), by Robert H. Depue, Malcolm C. Pike,and Brian E. Henderson.* To quote this study;

"Hormone administration during pregnancy was a significant risk factor in this study, with 9 mothers of cases and only 2 mothers of controls receiving such exposure during the first 3 months

The ongoing health of children who were exposed to HPTs is of great concern when reading studies that have been conducted, yet no follow up has been actioned in New Zealand. The above study on testicular cancer was printed 34 years ago in 1983. The history of HPTs and the continued silence and inaction from our health authorities as to the long term effects on the victims is malignant.

Nothing short of an Inquiry is going to satisfy.

Yours sincerely

Section 9(2)(a)

Estrogen Exposure During Gestation and Risk of Testicular Cancer Depue 1983.pdf

Sent by: Rosie Maltas/MOH

23/05/2017 11:22 a.m.

To: OIA Requests/MOH@MOH,
cc: Rowan Pollock/MOH@MOH, Chris James/MOH@MOH,
bcc:

Subject: Fw: Official Information Act request

Hello,

Please can you process the below as a new OIA request and allocate to Rowan Pollock's team.

Thanks,
Rosie

Rosie Maltas | Team Administrator | Medsafe | Ministry of Health | Section 9(2)(a)

From: Section 9(2)(a)
To:
Date: 23/05/2017 10:40 a.m.
Subject: Official Information Act request

Chris James Group Manager Medsafe

23rd May, 2017

Dear Chris

Request for information under the Official Information Act 1982

Re. Hormone Pregnancy Tests (HPTs)

I would be pleased if you would provide copies of the following: documents, emails, hand-written notes, minutes, texts and telephone conversations regarding:

1. Requests from the Medicines and Healthcare Products Regulatory Agency (MHRA) to provide New Zealand information to them and/or the Expert Working Group (EWG) Inquiry into HPT products, including but not limited to Primodos.
2. Reports or other information from the MHRA regarding HPTs including but not limited to Primodos.
3. Correspondence to and from Schering/Bayer regarding the withdrawal of Primodos from the market.
4. Actions recorded and correspondence with Schering/Bayer to ensure compliance with the withdrawal of the drug under existing statutory regulations in addition to any other

requirements made by the Department of Health.

5. Evidence to demonstrate how the NZ Department of Health "....removed stock from pharmacies", *Medsafe Publications, 20th March, 2017.*
6. All notifications to General Practitioners and/or their regulatory body regarding the withdrawal of HPTs including but not limited to Primodos.
7. All notifications to The Chemist Service Guild, Wholesalers and Retailers regarding the withdrawal of HPTs including but not limited to Primodos.
8. Documentation to show the process implemented to ensure that no stock remained in the possession of General Practitioners or Pharmacies.
9. Notices for publication in the NZ Gazette regarding the introduction and revocation of HPTs including but not limited to Primodos.
10. Notices for publication in the NZ Gazette regarding the introduction and revocation of intramuscular HPTs including but not limited to Duogynon and Primodos.
11. Minutes of meetings or other correspondence that shows what (if any) actions were considered by the Department of Health to research the histories of, or contact women (or their General Practitioners) who were prescribed HPTs, including but not limited to Primodos.

Thank you for your assistance.

Yours sincerely

Section 9(2)(a) Medsafe OIAR 23 May 2017.pdf Section 9(2)(a)

This page all section 9(2)(a)

Sent by: Rowan Pollock/MOH

04/05/2017 10:09 a.m.

To: [redacted]
cc:
bcc:

Subject: Re: UK working group information

Dear [redacted]

The group referred to is the Commission on Human Medicines' Expert Working Group on Hormone Pregnancy Tests.

Medsafe is considering how best to make available the relevant information. Once information has been provided then your request will be granted.

Kind regards
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

[redacted] Hello Rowan I am hoping you can clari... 03/05/2017 04:55:45 p.m.

From: [redacted]
To:
Date: 03/05/2017 04:55 p.m.
Subject: Re: UK working group information

Hello Rowan

I am hoping you can clarify a few things for me.

When you say, "the UK working group", are you referring to the parliamentary expert working group (PEWG)?

If that is not the case then what is the makeup of the "UK" working group you refer to, and to whom does it report?

When you say the report has not yet been provided but that, "we will inform you once it has", does that mean I will receive a copy of the report also as per my request, or merely that I will be informed that the report has been sent?

Kind regards

[redacted]

On 3/05/2017, at 1:27 PM, [redacted] wrote:

Dear [redacted]

Information has not yet been provided to the UK working group, but we will inform you once it has.

Kind regards

This page all section 9(2)(a)

Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]
<Mail Attachment.gif>

From: [redacted]
To: [redacted]
Date: 28/04/2017 09:05 a.m.
Subject: UK working group information

Good morning Rowan

Thank you for your reply. Can you please advise whether the information Medsafe is providing to the UK working group has been sent or when it is likely to be sent?

I would welcome a copy of the documents that Medsafe is providing to the UK working group. Can you please either email or send via post to:

[redacted]

Regards

[redacted]

On 27/04/2017, at 3:32 PM, [redacted] wrote:

Dear [redacted]

Thank you for your email.

As you are aware a working group has been established in the UK to review international information relating to these hormonal pregnancy tests. Medsafe and the Ministry of Health will be closely following the review to learn what implications there might be for women who may have received these products in

New Zealand. Medsafe will receive information directly from the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), and Medsafe is also happy to make available to the working group any and all information from New Zealand which may be useful.

Thank you also for providing a copy of the study by Depue et al (1983). This will be reviewed in conjunction with the findings from the working group.

Kind regards
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health |
<Mail Attachment.gif>

Begin forwarded message:

From: [redacted]
To: [redacted]
Subject: Exposure to hormone pregnancy tests shown to increase risk of testicular cancer in males.

Dear Chris and [redacted]

I have been doing research on HPTs and have come across data which shows that sons of mothers who took HPTs and other oestrogen/progestin drugs have a much higher incidence of testicular cancer. Daughters have a variety of reproductive anomalies and infertility and while I have yet to research that, there is plenty of discussion by daughters on the UK Facebook page *Primodos (The Forgotten Thalidomide) ACDHPT.*

I enclose a robust published study, *Exposure During Gestation and Risk of Testicular Cancer (1983), by Robert H. Depue, Malcolm C. Pike,and Brian E. Henderson.* To quote this study; *"Hormone administration during pregnancy was a significant risk factor in this study, with 9 mothers of cases and only 2 mothers of controls receiving such exposure during the first 3 months*

The ongoing health of children who were exposed to HPTs is of great concern when reading studies that have been conducted, yet no follow up has been actioned in New Zealand. The above study on testicular cancer was printed 34 years ago in 1983. The history of HPTs and the continued silence and inaction from our health authorities as to the long term effects on the victims is malignant.

Nothing short of an Inquiry is going to satisfy.

Yours sincerely

[redacted]

This page all section 9(2)(a)

Sent by: Rowan Pollock/MOH

04/05/2017 12:37 p.m.

To: [redacted]
cc:
bcc:

Subject: RE: Primodos the second Thalidomide

Dear [redacted]

Medsafe does not monitor the practice of healthcare professionals. To obtain information about the requirements of Plunket nurses I suggest you contact Plunket directly or the Nursing Council of New Zealand.

At the time hormonal pregnancy tests were withdrawn in 1975 Medsafe is aware of two products being available in New Zealand, Amenorone Forte and Primodos. With respect to other medicines that may have been available and the oversight and control of samples by the then Department of Health during the 1950s, given a period of 60 years has lapsed, Medsafe has been unable to locate any additional information from its archives.

The regulation of medicines 60 years ago is very different to the extent of regulation that occurs now in regards to the data reviewed prior to approval of medicines and ongoing controls and monitoring.

Kind regards
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

[redacted] Hi Chris 03/05/2017 08:46:17 p.m.

From: [redacted]
To: ,
Cc:
Date: 03/05/2017 08:46 p.m.
Subject: RE: Primodos the second Thalidomide

Hi Chris

I sent you the e mail below and I note that you haven't replied to my questions which were:
Were Plunket nurses required to keep medical records and where would those records be kept when the drugs were administered and what controls and monitoring were placed on Plunket nurse?
What was the ministry of health doing to monitor Plunket nurses.?
In addition to these questions I have the following questions that I would appreciate answered:
What drugs were available in NZ both in pill and injection form which were or could be used as a means of pregnancy testing from 1955 onwards?
What overseeing did Medsafe have over drugs used by Bayer that may have been supplied by GPs or nurses including Plunket nurses in the late 1950s?

What control did Medsafe have over samples released here in NZ for pregnancy testing and how easy was it for samples to come into the country?
Look forward to your response.

Regards [redacted]

From: [redacted]
Sent: 6 April 2017 8:01 p.m.
To: [redacted]
Cc: [redacted]
Subject: RE:

Hi Chris

Thankyou for your e mail.

I just want to explain to you and Rowan how very disturbing it is to find that there were hormonal drugs being used and that [redacted] birth defects could have been a result of [redacted] being given [redacted] tablets by [redacted]
To be fobbed off by your e mail Rowan Thank you for getting in touch and I hope this information is helpful. No that information wasn't helpful and no further comment as to what you as a ministry intend to do about it..helpful not in the least.

To be told that I need to produce [redacted] medical records to confirm this is very upsetting when it was a [redacted] who gave [redacted] the tablets.
Were Plunket nurses required to keep medical records and where would those records be kept when the drugs were administered and what controls and monitoring were placed on Plunket nurse?
What was the ministry of health doing to monitor Plunket nurses.?

I saw [redacted] ago and his comments in the report that I have kept state that [redacted]

and then [redacted] ago [redacted] from the Genetics division who in his report states that [redacted]

As a govt dept in my opinion you need to act independently and with due care and consideration of the people involved.

One look at the Sky News report shows what a cover up – so it is little wonder that hardly anyone has come forward – why would they after all these years and to have to have the energy to fight a drug company without any govt support.

Let me tell you that when [redacted] you don't and neither does the drug company who would have made huge

This page all section 9(2)(a)

profits from the live human guinea pigs.

The three people who I have had correspondence with are :
Chris [redacted]
Janinepickering [redacted]
Rowan-pollock [redacted]

Regards [redacted]

From: [redacted]
Sent: 6 April 2017 9:42 a.m.
To: [redacted]
Cc: [redacted]
Subject:

Dear [redacted]

I am writing to reassure you that your details have not been forwarded throughout the organisation.

Upon receiving your email I asked Rowan Pollock to respond to you as she will be helping me with any correspondence and ongoing monitoring of the use of these products in New Zealand. Rowan is the Manager of the post market monitoring team at Medsafe that works closely with CARM in Dunedin, who I understand you have also been in touch with. Rowan is also a practising pharmacist so is bound by patient confidentiality requirements and maintaining privacy of patient details. I have not forwarded or provided a copy of your email to anyone else in the organisation. You mention in your email you have heard from three people from the organisation - do you mind letting me and/or Rowan know who that was?

In hindsight I should have informed you that Rowan would respond on my behalf, I hope this hasn't caused any undue alarm. I understand Rowan will respond to you about obtaining a copy of the records.

Thank you for getting in touch.

Kind regards

Chris

Chris James | Group Manager | Medsafe | Ministry of Health | [redacted]

From: [redacted]
To:
Date: 05/04/2017 06:57 p.m.
Subject: RE: RE:

Dear Rowan

Thankyou for your e mail.
You are the third person to reply to my e mails so Im just wondering exactly who you are and why my information is being passed around your organisation?
Could you please provide the archival records that you refer to in your e mail.
Regards 9(2)(a)

This page all section 9(2)(a)

Sent by: Rowan Pollock/MOH

17/05/2017 08:17 a.m.

To: [redacted]
cc:
bcc:

Subject: Fw: Primodos/Duogynon

Dear [redacted]

Thank you for forwarding these newspaper articles about hormonal pregnancy tests.

Kind regards
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health [redacted]

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

[redacted]

----- Forwarded by Rowan Pollock/MOH on 17/05/2017 08:11 a.m. -----

From: Chris James/MOH

From: [redacted]
To: <info@health.govt.nz>,
Date: 16/05/2017 11:39 p.m.
Subject: Fw: Primodos/Duogynon

Hi

Please find papers regarding the drug Primodos.

Regards

[redacted]

Virus-free.
www.avg.com

(See attached file: scan0024.jpg)(See attached file: scan0025.jpg)(See attached file: scan0026.jpg)(See attached file: scan0027.jpg)(See attached file: scan0028.jpg)

4 The Sydney Morning Herald, Sat. Jan 11, 1975 4

Pregnancy te may cause palate defect

By SHAUN McILRAITH,
Medical Correspondent

A Perth doctor has associated a congenital abnormality, cleft lip and palate, with the child's mother having one kind of pregnancy test.

In 10 per cent of cases of the abnormality in Western Australia between 1963 and 1974, the mother had had a pregnancy test involving taking a combined progestogen-oestrogen hormonal drug, he says.

In 22 of the 222 cases of cleft lip and palate during the period, the mother had taken the pregnancy test between the fifth and eighth weeks of gestation.

Doctor's research

Dr W. F. Brogan, of Princess Margaret Hospital for Children in Perth, reports the finding in a letter to the Medical Journal of Australia.

He says that because most cases of cleft lip and palate are thought to be due to the

14 JAN. 1975
SYDNEY HERALD

Govt acts on baby test pill

MELBOURNE, Monday. — The Federal Government has asked for a complete withdrawal of pregnancy test pills. Research indicates the pills are contributing to defects in babies.

It was reported on Saturday that research had shown oral pregnancy tests were associated with cleft lips and palates.

The Federal Health Department is cancelling import licences for the pills.

The three Australian companies marketing the pills have been asked to halt all sales.

The action follows a recommendation from the Federal Drug Evaluation Committee.

A Health Department spokesman said today: "We have

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written to three companies that market hormonal pregnancy testing tablets.

"The companies are being asked to withdraw the tablets from sale.

"All import licences have been cancelled.

"The measures are designed to have immediate effect.

"The action is on the basis of questionable safety."

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COURIER MAIL

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MELBOURNE. — The Federal Governm
ordered the complete withdrawal from
pregnancy testing pills.

Research indicates that the pills have con
deformities in babies.

The Health Department is cancelling import
the three Australian companies marketing them have
their sales.

A Brisbane gynaecologist last night said many doctors had dropped this form of pregnancy testing some years ago.

He was not aware of any abnormalities attributed to it in Queensland.

"It is not normally used because most doctors consider it wise to give a pregnant woman as few drugs as possible," he said.

bodies, but some recent work was done by a doctor at Perth's Princess Margaret Hospital for Children.

This doctor reported late last week that the hormonal pills could cause penile defects.

Worried

Some doctors are worried that a second type of pill — for birth control — is causing male features in female babies.

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Drink the pill for a day
or two, then took a double
dose.

The problem with withdrawal was that it caused tremendous alarm, when the drug was only suspected of being responsible.

Immediate

The Government action follows a recommendation from the Federal Drug Evaluation Committee.

A Federal Health Department spokesman said yesterday: "We have written to three companies that market hormonal pregnancy testing tablets.

"The companies are being asked to withdraw the tablets from sale. The measures are designed to have immediate effect. The action is on the basis of questionable safety."

The Drug Evaluation Committee chairman, (Dr. Stanley Goulston) said the recommendation to stop Australian marketing followed receipt of detailed research mate-

The Australian College of Gynaecologists is worried that young girls could become infertile.

The college president (Mr. Ian McDonald) said yesterday: "Hormonal testing has been used quite extensively."

On the birth control pill, Mr. McDonald added that indications were emerging that a popular component of many such pills could cause a type of male genital characteristic in females.

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The Sun, Tuesday, Jan.

PREGNAN
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By MICHAEL WILKINSON

THE Federal Government has ordered withdrawal of a pregnancy testing pill.

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SYDNEY MORNING HERALD

Hormone drugs under scrutiny

MELBOURNE, Tuesday. — Royal College of Obstetricians and Gynaecologists in Australia has begun a national investigation into the effects of drugs on unborn children.

The investigation, to cover about 80 per cent of all Australian births, is expected to last for many years. All drugs, including those related to sex hormones, will come under close scrutiny and progress reports will be published from time to time.

A controlled survey in New York last year showed that children were more likely to be born with limb deformities if their mothers had been exposed to hormonal pregnancy tests, or had "breakthrough" pregnancies while on oral contraceptives.

The college's Australian president, Mr I. A. McDonald, said he did not think hormone pregnancy test pills or contraceptives containing 19-norethisterone should be taken off the market until long-term investigations had shown a definite link to deformities.

"Our earliest impressions are that the link between

WITHDRA CHEMICA TESTS NA

CANBERRA, Tuesday. — A number of hormone pregnancy-testing preparations which the Federal Government has ordered withdrawn were named today by the Minister for Health, Dr Everingham.

They are Duogynon, Duogynon Simplex, Duogynon Oral (Schering Pty Ltd), Amenorone Forte (Roussel Pharmaceutical Pty Ltd) and Seerodyl (Allen and Hanbury's).

Dr Everingham said the Australian Drug Evaluation Committee had recommended that systemic hormonal formulations for pregnancy testing be withdrawn because of their questionable safety, and the fact that there were adequate and reliable methods available which did not involve the

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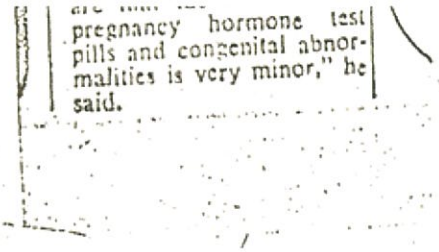


pregnancy hormone test pills and congenital abnormalities is very minor," he said.

Sent by: Amanda Taylor/MOH

02/06/2017 08:58 a.m.

To: Lily Chan/MOH@MOH,
cc:
bcc:

Subject: Re: Fw: OIA for DDG sign-out H201701896 Due: 21/06/2017 - Peer review please

Hey Lily

The letter looks fine. I just played around with the formatting a little but it is up to you which you prefer.

I just have one page on both the released documents to talk to you about so will come over in a bit.

Cheers

Amanda

Response letter (peer).docx

Amanda Taylor | Senior Advisor Pharmacovigilance (Part-time: Wednesday, Thursday, Friday) | Clinical Risk Management | Medsafe | Ministry of Health | Section 9(2)(a)

Lily Chan Hi Amanda I'm putting together a resp... 01/06/2017 11:15:56 a.m.

From: Lily Chan/MOH
To: Amanda Taylor/MOH@MOH,
Date: 01/06/2017 11:15 a.m.
Subject: Fw: OIA for DDG sign-out H201701896 Due: 21/06/2017 - Peer review please

Hi Amanda

I'm putting together a response to an OIA regarding hormone pregnancy tests (ie, Primodos and Amenorone Forte).

Rowan has given me all the information we hold on both these products. I see that you have peer reviewed a previous OIA for Rowan regarding Amenorone Forte and wondered if you could please peer review this one for me?

Attached are:
1.) Draft response letter
2.) Redacted documents for Primodos
3.) Redacted documents for Amenorone

Pretty much releasing everything we hold for both these products. Any suggestions on how to display this information in the table are welcome!

There's no hurry for this. Response is due to Rosie on 14 June.

Thank you,
Lily

[attachment "Response letter (draft).docx" deleted by Amanda Taylor/MOH] [attachment "Primodos Redacted.pdf" deleted by Amanda Taylor/MOH] [attachment "Amenorone Forte Redacted.pdf" deleted by Amanda Taylor/MOH]

Lily Chan | Senior Advisor Pharmacovigilance | Clinical Risk Management | Medsafe | Ministry of Health |
Section 9(2)(a)

----- Forwarded by Lily Chan/MOH on 01/06/2017 11:07 a.m. -----

From: Rowan Pollock/MOH
To: Lily Chan/MOH@MOH,
Date: 24/05/2017 02:48 p.m.
Subject: Fw: OIA for DDG sign-out H201701896 Due: 21/06/2017

Hi Lily

This OIA has now been logged etc.

Thanks
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | (04) 819 6812 |

----- Forwarded by Rowan Pollock/MOH on 24/05/2017 02:48 p.m. -----

From: OIA Requests/MOH
To: Rowan Pollock/MOH@MOH, Rosie Maltas/MOH@MOH,
Cc: OIA Requests/MOH@MOH
Date: 24/05/2017 02:46 p.m.
Subject: OIA for DDG sign-out H201701896 Due: 21/06/2017
Sent by: Ashley Goodwin

Hi Rowan

This OIA has now been logged and allocated

Thanks

Ashley

oiagr@moh.govt.nz | OIA
Government Relations | Ministerial, Executive and Government Services | Office of the Director General

MINISTRY OF HEALTH
MANATŪ HAUORA

http://www.health.govt.nz

Please find attached an **OIA request for immediate action by your team**. Please copy in the OIA inbox when you allocate the request to a staff member. OIAs are time sensitive and must be completed within 20 working days under the Official Information Act 1982.

OIA H201701896	**OIA for DDG Sign-out**
Received By: Ministry of Health to reply	**Received On:** 23/05/2017
Final Draft Due (day 8):	**Due to Requestor:** 21/06/2017

- Guidance on responding to OIA requests is available on the intranet: http://intranet.moh.govt.nz/knowledge-services/oia-brag/official-information-act-oia-request-rules-and-guidelines

- Please note that the covering letter and OIA responses, as well as being a factual reply to the request made, should be used as an opportunity to provide relevant context to help tell the Ministry's story on that particular topic or issue. Without this, we risk others using our information to tell a story of their own.

- If you think you will be unable to provide a full response within the first 20 working days, please contact Government Relations (GR) to discuss the options available in advance of the 20 day deadline.

- To support the Ministry's monitoring and external reporting on the timeliness of OIAs:

  - **Update** GR on progress or changes to the OIA (e.g. if an extension is required or if the request is transferred)
  - **Notify** GR when OIAs go to the Minister's office and send us an e-copy for our records (including the Audit Trail)
  - **Provide** GR with an e-copy of the signed and dated response to the requestor as soon as possible so that the request can be closed in Quill.

If you or your staff have questions about the OIA process that can't be answered by the Ministry's online guidance, please contact GR. It is important that the Ministry's complies with its obligations under the OIA and to ensure the timeliness and quality of responses.

Please contact the OIA Co-ordinator in GR ASAP if you consider this request has been allocated to your team incorrectly.

Many thanks,
Government Relations

133 Molesworth Street
PO Box 5013
Wellington 6145, New Zealand
T +64 4 496 2000

Section 9(2)(a)

Ref: H201701896

Dear Section 9(2)(a)

Response to your request for official information

Thank you for your request of 23 May 2017 under the Official Information Act 1982 (the Act) for

"…copies of the following: documents, emails, hand-written notes, minutes, texts and telephone conversations regarding:

1. *Requests from the Medicines and Healthcare Products Regulatory Agency (MHRA) to provide New Zealand information to them and/or the Expert Working Group (EWG) Inquiry into HPT products, including but not limited to Primodos.*
2. *Reports or other information from the MHRA regarding HPTs including but not limited to Primodos.*
3. *Correspondence to and from Schering/Bayer regarding the withdrawal of Primodos from the market.*
4. *Actions recorded and correspondence with Schering/Bayer to ensure compliance with the withdrawal of the drug under existing statutory regulations in addition to any other requirements made by the Department of Health.*
5. *Evidence to demonstrate how the NZ Department of Health "....removed stock from pharmacies", Medsafe Publications, 20th March, 2017.*
6. *All notifications to General Practitioners and/or their regulatory body regarding the withdrawal of HPTs including but not limited to Primodos.*
7. *All notifications to The Chemist Service Guild, Wholesalers and Retailers regarding the withdrawal of HPTs including but not limited to Primodos.*
8. *Documentation to show the process implemented to ensure that no stock remained in the possession of General Practitioners or Pharmacies.*
9. *Notices for publication in the NZ Gazette regarding the introduction and revocation of HPTs including but not limited to Primodos.*
10. *Notices for publication in the NZ Gazette regarding the introduction and revocation of intramuscular HPTs including but not limited to Duogynon and Primodos.*

11. *Minutes of meetings or other correspondence that shows what (if any) actions were considered by the Department of Health to research the histories of, or contact women (or their General Practitioners) who were prescribed HPTs, including but not limited to Primodos."*

The information relating to this request is itemised below, with copies of documents attached.

I have decided under section 9(2)(a) of the Act to withhold information to protect the privacy of natural persons. Specific grounds are noted in each document where information has been withheld.

Request	Response
1. Requests from the Medicines and Healthcare Products Regulatory Agency (MHRA) to provide New Zealand information to them and/or the Expert Working Group (EWG) Inquiry into HPT products, including but not limited to Primodos.	This request is refused under section 18(e) of the Act as the document(s) alleged to contain the information requested does not exist.
2. Reports or other information from the MHRA regarding HPTs including but not limited to Primodos.	This request is refused under section 18(e) of the Act as the document(s) alleged to contain the information requested does not exist.
3. Correspondence to and from Schering/Bayer regarding the withdrawal of Primodos from the market. 4. Actions recorded and correspondence with Schering/Bayer to ensure compliance with the withdrawal of the drug under existing statutory regulations in addition to any other requirements made by the Department of Health.	Attached are: 1. Letter dated 4 June 1975 2. Letter dated 30 May 1975 with recall letter 3. Handwritten note dated 27 May 1975 4. Letter dated 26 May 1975 5. Letter dated 19 May 1975 6. Handwritten note dated 21 May 1975 7. Letter dated 1 May 1975 8. Handwritten note dated 29 April 9. Handwritten note dated 14 April 1975 10. Letter dated 10 April 1975 with Australian permit to import 11. Document with information from the World Health Organization 12. Letter dated 2 April 1975 13. Handwritten note dated 24 March 14. Letter dated 18 March 1975

	15. Handwritten note dated 11 March 16. Letter dated 6 March 1975 17. Information from the Medical Journal of Australia 18. Letter dated 18 February 1975 with information from the World Health Organization and the Medical Journal of Australia
5. Evidence to demonstrate how the NZ Department of Health "....removed stock from pharmacies", Medsafe Publications, 20th March, 2017.	Attached are documents regarding Amenorone Forte: 1. Letter dated 26 June 1975. 2. Letter dated 13 June 1975. 3. Letter dated 18 June 1975. 4. Letter dated 26 May 1975. 5. Letter dated 9 May 1975. 6. Letter dated 1 May 1975 with information from the World Health Organization. 7. Letter dated 4 April 1975. 8. Letter dated 21 March 1975. 9. Handwritten note. 10. Document dated 19 March 1975. 11. Letter dated 13 March 1975 with information from the Medical Journal of Australia and the World Health Organization. Please also refer to documents regarding Primodos provided in response to questions 3 and 4.
6. All notifications to General Practitioners and/or their regulatory body regarding the withdrawal of HPTs including but not limited to Primodos.	This request is refused under section 18(e) of the Act as the document(s) alleged to contain the information requested does not exist.
7. All notifications to The Chemist Service Guild, Wholesalers and Retailers regarding the withdrawal of HPTs including but not limited to Primodos.	Attached are documents regarding Amenorone Forte: 1. Letter dated 19 June 1975. 2. Letter dated 9 June 1975.
8. Documentation to show the process implemented to ensure that no stock remained in the possession of General Practitioners or Pharmacies.	Please refer to documents regarding Primodos provided in response to questions 3 and 4. Please refer to documents regarding Amenorone Forte provided in response to question 5.

9. Notices for publication in the NZ Gazette regarding the introduction and revocation of HPTs including but not limited to Primodos.	This request is refused under section 18(e) of the Act as the document(s) alleged to contain the information requested does not exist.
10. Notices for publication in the NZ Gazette regarding the introduction and revocation of intramuscular HPTs including but not limited to Duogynon and Primodos.	This request is refused under section 18(e) of the Act as the document(s) alleged to contain the information requested does not exist.
11. Minutes of meetings or other correspondence that shows what (if any) actions were considered by the Department of Health to research the histories of, or contact women (or their General Practitioners) who were prescribed HPTs, including but not limited to Primodos.	This request is refused under section 18(e) of the Act as the document(s) alleged to contain the information requested does not exist.

I trust this information fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review my decision to withhold information under this request.

Yours sincerely

Section 9(2)(a)
Group Manager
Medsafe

This page all section 9(2)(a)

Sent by: Chris James/MOH
20/06/2017 08:33 a.m.

To: Rowan Pollock/MOH@moh,
cc:
bcc:

Subject: Fwd: Primodos

Hi Rowan
FYI below. One for direct reply. I think we have replied to this person before.

Kind regards
Chris

Begin forwarded message:

From: "Liz McMillan" [redacted]
Date: 20 June 2017 at 7:42:42 AM NZST
To: "Chris James" [redacted]
Subject: Re: Fw: Primodos

Hi Chris

This looks fine to be dealt with as a direct reply.

Regards

Liz McMillan
Manager | Government Relations | Ministerial, Executive and Government Services | Office of the Director-General of Health | [redacted]
MINISTRY OF HEALTH
MANATŪ HAUORA
[redacted]

http://www.health.govt.nz
mailto: [redacted]

Chris James---19/06/2017 04:43:20 p.m.---Hi Liz We've received the email below which seems to be from an MP? How should this be dealt with? O

From: Chris James/MOH
To: Liz McMillan/MOH@MOH,
Cc: Rowan Pollock/MOH@MOH
Date: 19/06/2017 04:43 p.m.

This page all section 9(2)(a)

Subject: Fw: Primodos

Hi Liz

We've received the email below which seems to be from an MP? How should this be dealt with? Ok for direct reply?

Chris

Chris James | Group Manager | Medsafe | Ministry of Health | [redacted]

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

[redacted]

----- Forwarded by Chris James/MOH on 19/06/2017 04:42 p.m. -----

From: Info MOH/MOH
To: Chris James/MOH@MOH,
Date: 19/06/2017 03:11 p.m.
Subject: Fw: Primodos
Sent by: Janine Pickering

Hi Chris

Another query.

Thanks
Janine

Ministry of Health
PO Box 5013
Wellington 6145
Free phone: 0800 855 066
Phone: (04) 496 2000
Healthline: 0800 611 116
Email: info@health.govt.nz
Website:www.health.govt.nz

----- Forwarded by Janine Pickering/MOH on 19/06/2017 03:11 p.m. -----

From: [redacted]
To: "'info@health.govt.nz'" <info@health.govt.nz>,
Date: 19/06/2017 03:06 p.m.

Subject: Primodos

This page all section 9(2)(a)

Good afternoon,

Our office has been visited this afternoon by a constituent who believes [redacted] given Primodos, [redacted] son was born prematurely, with dislocated hips and other medical issues in [redacted] received injections from [redacted]

Who [redacted] to contact to discuss this further or find out more about whether this was indeed what [redacted]

I have attached a permission slip signed by her at our office this afternoon.

Thank you for your assistance with this.

Kind regards,

[redacted]
MP for Botany and Chief Government Whip
Tel: [redacted]
PO Box 230109 | Botany | Auckland 2163
309 Botany Road | Botany | Auckland 2015

[attachment "img-170619155646-0001.pdf" deleted by Liz McMillan/MOH]

This page all section 9(2)(a)

Sent by: Rowan Pollock/MOH

20/06/2017 04:25 p.m.

To: [redacted]
cc:
bcc:

Subject: Fw: Primodos

Dear [redacted]

Thank you for your enquiry about Primodos on behalf of a constituent, [redacted]. I am sorry to hear of her experiences and her son's ongoing medical issues.

Primodos first appeared on the New Zealand market in 1966. In May 1975, the then Department of Health decided to withdraw Primodos from the New Zealand market due to reports received overseas that birth defects had occurred when hormonal pregnancy tests were taken in early pregnancy. Stock was also removed from pharmacies in June 1975.

Primodos was administered orally as a hormonal pregnancy test, one tablet daily for two days, and was not administered as an injection. [redacted] would need to contact her GP practice for her individual health records to find out what she received during this time period.

Should [redacted] wish to report an adverse reaction, then I would recommend getting in touch with the Centre for Adverse Reactions Monitoring (CARM) in Dunedin. CARM is part of the University of Otago and is contracted by the Ministry of Health to collect information about possible adverse reactions to medicines and then to provide that analysis to us. CARM has medical staff who are able to discuss with her experiences and help her to register a report of an adverse reaction. CARM can also provide advice on adverse reactions already reported for these products.

CARM can be contacted on (04) 479 7247 or by email at nzphvc@otago.ac.nz
CARM's website is https://nzphvc.otago.ac.nz

Please let me know if you require any further information.

Kind regards
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

From: [redacted]
To: "'info@health.govt.nz'" <info@health.govt.nz>,
Date: 19/06/2017 03:06 p.m.
Subject: Primodos

Good afternoon,

This page all section 9(2)(a)

Our office has been visited this afternoon by a constituent who believes [redacted] given Primodos, [redacted] son was born prematurely, with dislocated hips and other medical issues in [redacted] received injections from [redacted]

Who [redacted] to contact to discuss this further or find out more about whether this was indeed what [redacted]

I have attached a permission slip signed by her at our office this afternoon.

Thank you for your assistance with this.

Kind regards,

[redacted]
MP for Botany and Chief Government Whip
Tel: [redacted]
PO Box 230109 | Botany | Auckland 2163
309 Botany Road | Botany | Auckland 2015

img-170619155646-0001.pdf

This page all section 9(2)(a)

Authorisation to release personal information

1. My full name is [redacted] (the applicant).
To help distinguish me from other people, my date of birth is [redacted].

I hereby authorise representatives of the following institutions and government agencies / departments:

- ACC • WINZ • Medsafe • Womens Health Action

to disclose information to Jami-Lee Ross, or the office of Jami-Lee Ross which will help them assist me with my enquiry.

My ACC client number is _____

2. *If you would like us to reply to you through a friend or family member (eg. for translation convenience etc.) please write their name below:*

I hereby authorise Jami-Lee Ross, or the office of Jami-Lee Ross to disclose any information obtained from the above institutions and government agencies / departments
to _____ (my contact person).

3. **Signed** [redacted] **Date** 19/6/17

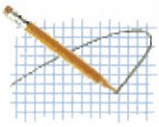
4. *Applicant's Details:* *Contact Person's Details (if applicable):*

Phone [redacted]
Mobile
Address
Email

5. Please return this form to us along with:
   i) a brief written description of your problem and
   ii) copies of any relevant documentation *(eg. doctors certificate, court documents, correspondence from government agency etc.)*

Email: botanymp@parliament.govt.nz
Post: PO Box 230 109, Botany, Auckland 2163

This page all section 9(2)(a)



Sent by: Chris James/MOH
16/08/2017 12:38 p.m.

To: Rowan Pollock/MOH@MOH,
cc:
bcc:

Subject: Re: DES Injections - Diethylstilbestrol

Hi thanks for the heads up.

Kind regards
Chris

On 16/08/2017, at 12:06 PM, Rowan Pollock [redacted] wrote:

> Hi Chris
>
> Just letting you know that another request was received from [redacted] who had previously enquired about Primodos. I've drafted a response.
>
> I've included the email trail below for your information, however this will not be included in the final response.
>
> ---
>
> Dear [redacted]
>
> Thank you for your follow up email up behalf of a constituent, [redacted]
>
> Diethylstilboestrol or DES is a synthetic form of the hormone oestrogen and was also known as stilboestrol.
>
> Information included in the following attachment, which was published in 1994, notes that stilboestrol was prescribed for pregnant women in the 1940s, 1950s and 1960s in the belief that it would reduce the risk of miscarriage. It was subsequently found to have a higher risk of some adverse effects in the women who took stilboestrol, as well as in sons and daughters who were exposed *in-utero* . These effects are outlined in the below attachment as well as a *Prescriber Update* article published on DES in 2006 (www.medsafe.govt.nz/profs/PUarticles/DES2006.htm).
>
> *(See attached file: Stilboestrol use in pregnancy.pdf)*
>
> Product detail for stilboestrol, including approval lapsed date and dose form, can be found on the Product/Application Search on the Medsafe website:
> www.medsafe.govt.nz/regulatory/dbsearch.asp
>
> I hope this information is helpful.

Please note I have been advised that in future these requests must be directed through the Minister's office.

Kind regards
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

<0.101C.gif>

----- Forwarded by Rowan Pollock/MOH on 15/08/2017 02:34 p.m. -----

From: Medsafe/MOH
To: Rowan Pollock/MOH@MOH,
Date: 15/08/2017 01:39 p.m.
Subject: Fw: DES Injections - Diethylstilbestrol
Sent by: Becci Slyfield

Hi Rowan

Would we have some publically available information about this?

Thanks

Becci

<0.3E20.gif>

----- Forwarded by Becci Slyfield/MOH on 15/08/2017 01:38 p.m. -----

From: Melissa Buckle [redacted]
To: [redacted]
Cc: "'askmedsafe@moh.govt.nz'" <askmedsafe@moh.govt.nz>
Date: 15/08/2017 12:51 p.m.
Subject: RE: Fw: DES Injections - Diethylstilbestrol

Hi Liz,

These kind of questions should be coming through our office not directly to Medsafe. If Medsafe has a publicly available link that's fine but when they respond can they put in a line saying that in future these requests must come through the Minister's office? Thanks.

Kind regards,

This page all section 9(2)(a)

Melissa Buckle
Private Secretary (Admin) I Office of the Hon Dr Jonathan Coleman
Minister of Health, Minister for Sport and Recreation

From: [redacted]
Sent: Tuesday, 15 August 2017 12:37 p.m.
To: Melissa Buckle
Cc: askmedsafe@moh.govt.nz
Subject: Re: Fw: DES Injections - Diethylstilbestrol

Hi Melissa

Do you want to see this or can Medsafe just provide the publically available info?

Regards

Liz McMillan
Manager I Government Relations I Ministerial, Executive and Government Services I Office of the Director-General of Health I [redacted]

<0.70F6.gif>

http://www.health.govt.nz
mailto: [redacted]

From: Medsafe/MOH
To: Liz McMillan/MOH@MOH,
Date: 15/08/2017 12:11 p.m.
Subject: Fw: DES Injections - Diethylstilbestrol
Sent by: Becci Slyfield

Hi Liz

Catherine Marnane said you might be able to help me with this. I look after our generic askmedsafe inbox and whe have received this email which appears to have come form a Government MP.

Is there a process for this do you know? Or should I just find somebody here at Medsafe to respond.

Thanks for your help.

Becci

<0.967E.gif>

----- Forwarded by Becci Slyfield/MOH on 15/08/2017 12:07 p.m. -----

From: [redacted]
To: "'askmedsafe@moh.govt.nz'" <askmedsafe@moh.govt.nz>,
Date: 14/08/2017 01:56 p.m.
Subject: DES Injections - Diethylstilbestrol

Good afternoon,

We have been visited by a constituent who is querying injections given [redacted]

You have responded to us previously regarding Primidos, as this was given orally and not administered via injection. Having contacted [redacted] given DES injections? [redacted] given meds from [redacted] son was born prematurely, with dislocated hips and other medical issues in [redacted]

Any information you can offer on DES would be greatly appreciated.

Kind regards,

[redacted]
MP for Botany and Chief Government Whip
Tel: [redacted]
PO Box 230109 | Botany | Auckland 2163
309 Botany Road | Botany | Auckland 2015

****

Statement of confidentiality: This e-mail message and any accompanying attachments may contain information that is IN-CONFIDENCE and subject to legal privilege.

This page all section 9(2)(a)

Sent by: Chris James/MOH
07/09/2017 12:16 p.m.

To: Susan Kenyon/MOH@MOH, Jo Prankerd/MOH@MOH,
cc:
bcc:

Subject: Fw: UK PM speaks out against Primodos cover up

FYI - will need to include comment to cover this in OIA response

Chris

Chris James | Group Manager | Medsafe | Ministry of Health | [redacted]

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

[redacted]

----- Forwarded by Chris James/MOH on 07/09/2017 12:15 p.m. -----

From: [redacted]
To:
Date: 07/09/2017 12:08 p.m.
Subject: UK PM speaks out against Primodos cover up

Dear Chris

I enclose a link to video of Theresa May answering questions about toxic Hormone Pregnancy Tests given to women in the 1960's and 70's.

In the video May says that the MHRA are due to release their report into Hormone Pregnancy Tests and the actions of the Health Department (of the time), in October this year.

British MPs are calling for an inquiry.

I would like to know what the Ministry of Health's intentions are with regard to the effects of HPTs on women and babies in New Zealand.

http://news.sky.com/story/primodos-pm-says-we-need-to-recognise-impact-of-deformity-drug-11023269

Regards

[redacted]

Sent by: Jo Prankerd/MOH

03/10/2017 08:53 a.m.

To: Lily Chan/MOH@MOH, Susan Kenyon/MOH@MOH, Geraldine Hill/MOH@MOH, Amanda Taylor/MOH@MOH, Maria Storey/MOH@MOH,
cc:
bcc:

Subject: Primodos documents

Hi everyone

Just FYI I have put a blue folder of Primodos related documents and correspondence in the cabinets between compliance and product reg (relating to OIAs H201703568 and H201701896).

I'm not sure if it will be of any use again but thought it could be good to keep it until at least after the UK inquiry has concluded in case we get further OIAs.

Jo

Jo Prankerd | Senior Advisor Pharmacovigilance | Clinical Risk Management | Medsafe | Ministry of Health | Section 9(2)(a)

Status:	Closed		Min Office Ref	1701123
Database Number	3703678	**Ministerial** Routine	Responsibility of:	Michael Pohl/MOH

Subject	MINS: Historical hormone pregnancy tests
Writer	Section 9(2)(a) View writer's address
Due Date	20-Dec-2017
Minister's Office Reference Number	1701123
Section	Protection Regulation and Assurance, Medsafe, Product Regulation
Extension	Granted

Ministerial

Letter Date	07-Sep-2017	**Date Received by MOH**	18-Se
Complexity Rating	3		
DHB			

Minister	Hon Dr David Clark
Interim Reponse Date	

Minister's Office Reference Number	1701123
Records Reference Number	
Created Date	20-Sep-2017
Created By	John Bell

Correspondence

Response Document

1701123.docx HB Notes. Information available from the OIA linked below, main source there for drafting, go back to the te
for info to Jamie Harknett 28.09 due back COB 05.10
allocated to Susan Kenyon 29.09
info received from Jo Prankerd 29.09
30/11 closed by agreement with Minister's office (correspondence addressed to previous Minister).

22/12 Letter sent to requester asking to write again as prev correspondence not transferred to new Min

Original Correspondence

1701123 MIN.pdf

Notes

From: Jo Prankerd/MOH
To: John Bell/MOH@MOH,
Cc: Jamie Harknett/MOH@MOH, Susan Kenyon/MOH@MOH
Date: 29/09/2017 09:49 a.m.
Subject: Fw: Min 1701123 (Hughes) request for information by COB 05.10 please

Hi John

Robyn also sent her email to the Minister to Chris James on 7 September so a response to this question has already bee see response to question 16 in link below).

Please let me know if anything else is needed.

Thanks

Jo

					Ref Number	Writer	Subject	Complexity	Assign
						Section 9(2)(a)	**OIA MOH:Follow up request in relation to OIA H201701896 for information regarding Hormone Pregnancy Tests (HPTs) Requestor has asked that the Ministry revisit her original questions and provide information to an additional set of supplementary questions Original questions: I would be pleased if you would provide copies of the following: documents, emails, hand- written notes, minutes, texts and telephone conversations regarding: 1. Requests from the Medicines and Healthcare Products Regulatory Agency (MHRA) to provide New Zealand information to them and/or the Expert Working Group (EWG) Inquiry into HPT products, including but not limited to Primodos. 2. Reports or other information from the MHRA regarding HPTs including but not limited to Primodos. 3. Correspondence to and from Schering/Bayer regarding the withdrawal of Primodos from the market. 4. Actions recorded and**	0	Susan I

								correspondence with Schering/Bayer to ensure compliance with the withdrawal of the drug under existing statutory regulations in addition to any other requirements made by the Department of Health. 5. Evidence to demonstrate how the NZ Department of Health "....removed stock from pharmacies", Medsafe Publications, 20th March, 2017. 6. All notifications to General Practitioners and/or their regulatory body regarding the withdrawal of HPTs including but not limited to Primodos. 7. All notifications to The Chemist Service Guild, Wholesalers and Retailers regarding the withdrawal of HPTs including but not limited to Primodos. 8. Documentation to show the process implemented to ensure that no stock remained in the possession of General Practitioners or Pharmacies. 9. Notices for publication in the NZ Gazette regarding the introduction and revocation of HPTs including but not limited to Primodos. 10. Notices for publication in the NZ Gazette regarding the introduction and revocation of intramuscular HPTs including but not limited to Duogynon and Primodos. 11. Minutes of meetings or other correspondence that shows what (if any) actions were considered by the Department of Health to research the histories of, or contact women (or their General Practitioners) who were prescribed HPTs, including but not limited to Primodos. Supplementary questions 1. When was Medsafe first aware of the MHRA Inquiry into Primodos and other HPTs? 2. How was Medsafe made aware of the MHRA Inquiry given that Medsafe's response tomy original question 2, was that no such documents existed. Please provide this and "2 of 3"other documentation outlined in my original OIA request. 3. Why did Medsafe wait for over 2 years from the time the MHRA called for information, to action the call for information from those who may have taken the drugs in New	

								Zealand? 4. Provide a copy of Medsafe's report to the MHRA about Primodos and other HPTs use in NZ or advise the status of the report. 5. Provide a copy of the Clinical Services Letter No. 150 and any other documents thatshow the actions taken by the Department of Health before and after withdrawal of HPTs as outlined in my original OIA questions 6 and 7. 6. Provide minutes of the Department of Health committee(s) responsible for the health and well being of women who were prescribed HPTs and their children, from March 1975 to December 1975, including those of the Medicines Advisory Committee.		

Jo Prankerd | Senior Advisor Pharmacovigilance | Clinical Risk Management | Medsafe | Ministry of Health | Section 9(2)(a)

From: Jamie Harknett/MOH
To: Susan Kenyon/MOH@MOH,
Cc: Catherine Marnane/MOH@MOH, John Bell/MOH@MOH
Date: 29/09/2017 09:10 a.m.
Subject: Fw: Min 1701123 (Hughes) request for information by COB 05.10 please

Hi Susan,

Please see below for Min 1701123 which requires your comment by COB 5 October.

Cheers,

Jamie Harknett
Team Administrator
Corporate
Medsafe
Protection Regulation and Assurance
Ministry of Health
DDI: Section 9(2)(a)
Fax:

From: John Bell/MOH
To: Jamie Harknett/MOH@MOH,
Cc: Catherine Marnane/MOH@MOH
Date: 28/09/2017 03:57 p.m.
Subject: Min 1701123 (Hughes) request for information by COB 05.10 please

Hi Jamie

please provide information bullet points to assist me to draft a response to the ministerial below.
By COB 05.10 please.

				Dt Due	Ref Number	Writer	Subject	Assig
				18/10/2017	1701123	Section 9(2)(a)	**MINS: Historical hormone pregnancy tests**	John

Thanks and kind regards,

John Bell
Advisor
Government and Executive Advisory
Government Services
Office of the Director-General
Ministry of Health
DDI: Section 9(2)(a)

Workflow

Section	Protection Regulation and Assurance, Medsafe, Product Regulation on 20/09/2017 Change Section Assigned
Analyst	Michael Pohl/MOH
Awaiting Information From	Susan Kenyon/MOH
Peer Review Comments	☐ Peer Review Sighted
Peer Reviewer	
Editor	
Ministry Approver	
Ministry of Health Sign-off	
Date sent to Minister	
Minister's Sign-off	Passed
Date Signed out	30/11/2017

Status Change To:	Assigned By:	Assigned To:	Assigned Date:
Closed	Michael Pohl	Michael Pohl	30/11/2017 3:43:
With Analyst (drafting)	Hamish Brodie	Michael Pohl	13/11/2017 3:17:
With Analyst	Hamish Brodie	Michael Pohl	13/11/2017 3:17:
With Analyst (drafting)	John Bell	Hamish Brodie	6/10/2017 4:04:4
With Analyst	John Bell	Hamish Brodie	6/10/2017 4:04:3
With Analyst (drafting)	John Bell	John Bell	29/09/2017 10:2:
Awaiting Information	John Bell	Susan Kenyon	29/09/2017 9:38:
Awaiting Information	John Bell	Jamie Harknett	28/09/2017 3:58:
With Analyst	John Bell	John Bell	20/09/2017 1:24:
With Section	John Bell	John Bell	20/09/2017 1:23:

Peer Review History

Rejection History (Previously rejected by Minister 0 times)
n/a

Section Assignments
20/09/2017 Protection Regulation and Assurance, Medsafe, Product Regulation

From: Melissa Buckle [redacted]
To: "'Briefings@moh.govt.nz'" <Briefings@moh.govt.nz>,
Date: 18/09/2017 03:50 p.m.
Subject: Min for logging 1701123

Hi,

Min for logging please

Ref: 1701123

Routine

Kind regards,

Melissa Buckle
Private Secretary (Admin) I Office of the Hon Dr Jonathan Coleman
Minister of Health, Minister for Sport and Recreation

From: Melissa Buckle
Sent: Monday, 18 September 2017 3:50 p.m.
To: [redacted]
Subject: RE: UK PM speaks out about use of Hormone Pregnancy Tests and effects on women and children in the 1960's and 70's

Dear [redacted]

On behalf of Hon Dr Jonathan Coleman, Minister of Health, thank you for your email of 7 September 2017 about toxic Hormone Pregnancy Tests given to women in the 1960's and 70's.

The Minister has asked Ministry of Health officials to advise him on the matters you have raised. We will endevour to get a personal response to your correspondence before the general election on 23 September 2017. In the event that this is not possible you will receive a response once a new government is formed.

Kind regards,

Melissa Buckle
Private Secretary (Admin) I Office of the Hon Dr Jonathan Coleman
Minister of Health, Minister for Sport and Recreation

From: [redacted]
Sent: Thursday, 7 September 2017 12:12 p.m.

To: Hon. Dr. Jonathan Coleman
Subject: UK PM speaks out about use of Hormone Pregnancy Tests and effects on women and children in the 1960's and 70's

Dear Dr Coleman

I enclose a link to video of Theresa May answering questions about toxic Hormone Pregnancy Tests given to women in the 1960's and 70's.

In the video May says that the MHRA are due to release their report into Hormone Pregnancy Tests and the actions of the Health Department (of the time), in October this year.

British MPs are calling for an inquiry.

I would like to know what the National's intentions are with regard to the dramatic effects of HPTs on women and babies in New Zealand.

http://news.sky.com/story/primodos-pm-says-we-need-to-recognise-impact-of-deformity-drug-11023269

Regards

Section 9(2)(a)
Section 9(2)(a)

MINISTRY OF HEALTH
MANATŪ HAUORA

PO Box 5013
Wellington 6145
New Zealand

22 December 2017

Section 9(2)(a)

Dear Section 9(2)(a)

Thank you for your email to the former Minister of Health, Hon Dr Jonathan Coleman, received on 18 September 2017.

Hon Dr Coleman was unable to reply to you before leaving office and your correspondence was not transferred to the new Minister, Hon Dr David Clark's office.

Should you wish the current Minister of Health, Hon Dr David Clark, to consider the issues you raised in your correspondence to Hon Dr Coleman, please write to Hon Dr Clark.

Yours sincerely

Liz McMillan
Manager, Ministerial Services
Office of the Director General

This page all section 9(2)(a)

Fw: FYI : Questions re: Primodos
Charlotte Gendall to: Lily Chan 30/01/2018 10:17 a.m.

Charlotte Gendall
Senior Advisor - Media
Office of the Director-General
Ministry of Health - Manatû Hauora
DDI: [redacted]
MOB: [redacted]

----- Forwarded by Charlotte Gendall/MOH on 30/01/2018 10:17 a.m. -----

Charlotte Gendall/MOH wrote on 19/03/2017 05:13:11 p.m.:

> From: Charlotte Gendall/MOH
> To: "Angela Kenealy" [redacted]
> Date: 19/03/2017 05:13 p.m.
> Subject: FYI : Questions re: Primodos
>
> HI Angela - FYI I've checked out the Primodos connection to NZ and
> can go back to [redacted] with the following tonight.
>
> It will be necessary to work through Medsafe paperwork to be
> accurate and definitive so essentially, I have to tell him we'll
> get back to him ASAP - hopefully tomorrow.
>
> What I am seeing is that there are no signs of support groups or
> similar awareness here in NZ, as there was with thalidomide.
>
> Charlotte
>

>
> DRAFT RESPONSE - please attribute to a spokesperson
>
> Medsafe understands that this product was used in the UK in the
> 1960s and 1970s before being withdrawn.
>
> In terms of the New Zealand context, Medsafe will utilise archival
> material to ascertain the extent of use in this country, if any.
>
> Medsafe has a memorandum of understanding with the Medicines &
> Healthcare products Regulatory Agency (MHRA) in the United Kingdom
> and will receive any relevant information from its review as it
> becomes available.
>
> ENDS

>

This page all section 9(2)(a)

> Charlotte Gendall
> Senior Media Advisor
> Ministry of Health
> DDI: [redacted]
> MOB: [redacted]
>
> http://www.health.govt.nz
>
> ----- Forwarded by Charlotte Gendall/MOH on 19/03/2017 05:07 p.m. -----
>
> From: [redacted]
> To: "media@moh.govt.nz" <media@moh.govt.nz>,
> Date: 19/03/2017 02:58 p.m.
> Subject: Questions re: Primodos
>
> Hi there,
>
> I am interested in whether is any fallout in NZ from findings in the
> UK about the pregnancy test Primodor:
> http://www.telegraph.co.uk/news/2017/03/18/new-evidence-claims-
> against-pregnancy-test-drugs-linked-birth/
> http://www.dailymail.co.uk/health/article-4327024/New-thalidomide-
> scandal-1960s-pregnancy-test-pill.html
>
> Has the ministry had any advice on this?
>
> Was the drug prescribed in NZ?
>
> And if so, how prevalent was it and will there be any follow up
> investigation here?
>
>
> Regards,
>
>
> [redacted]
> Political Reporter
> The New Zealand Herald
> Parliamentary Press Gallery
> [redacted]
> [redacted]
>
>
> _____
>
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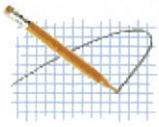
This page all section 9(2)(a)



Sent by: Chris James/MOH
20/03/2017 08:19 a.m.

To: Rowan Pollock/MOH@moh,
cc:
bcc:

Subject: Fwd: New Zealand / Primidos story - document below

Hi rowan
Need your teams help with this. Stewart also thinks we may need to go back to the old tt60 hard copy files since this was used in the 60s and 70s. I'm hoping someone like Catherine can help us also with this system.
Can discuss when I get in.
Chris

Begin forwarded message:

From: "Charlotte Gendall" [redacted]
Date: 20 March 2017 at 7:31:36 AM NZDT
To: [redacted]
Cc: "Peter Abernethy" [redacted], "Deidre Mussen" < [redacted]
Subject: Re: New Zealand / Primidos story - document below

Hi [redacted] - this is what I can provide at this time:

RESPONSE - please attribute to a spokesperson

Medsafe understands that this product was used in the UK in the 1960s and 1970s before being withdrawn.

In terms of the New Zealand context, Medsafe will utilise archival material to ascertain the extent of use in this country, if any.

Medsafe has a memorandum of understanding with the Medicines & Healthcare products Regulatory Agency (MHRA) in the United Kingdom and will receive any relevant information from its review as it becomes available.

ENDs
Regards
Charlotte Gendall

Sent from my iPhone

On 20/03/2017, at 7:24 AM, [redacted] wrote:

This page all section 9(2)(a)

Hi Ministry team,

Can you please confirm this report that Primodos was sold in NZ until the Ministry asked Schering to withdraw it from July 1975?

Can you please provide details of any cases of birth defects arising from this drug in NZ?

We are keen to update this story as soon as possible on our website.

Thanks very much,

[redacted] Education Reporter, New Zealand Herald, 2 Graham St, Private Box 92 198, Victoria St West, Auckland 1010
ddi [redacted]

From: [redacted]
Sent: Monday, 20 March 2017 7:03 a.m.
To: [redacted]
Subject: FW: New Zealand / Primidos story - document below

Here you go – ZB bulletin, document and translation

From: [redacted]
Sent: Monday, 20 March 2017 6:59 a.m.
To: [redacted]
Subject: FW: New Zealand / Primidos story - document below

ZB story, plus email for us to expand

From: [redacted]
Sent: Monday, 20 March 2017 6:53 a.m.
To: [redacted]
Subject: FW: New Zealand / Primidos story - document below

Newstalk ZB has obtained evidence suggesting the drug Primodos - a pregnancy test pill linked to birth defects - was once sold in New Zealand.

The pill was manufactured by German company Schering, who continue to deny any wrong doing.

Section 9(2)(a) reports

Damning evidence in the UK suggests Primidos - given to more than a million British women in the 1960s and 70s - may have caused thousands of severe birth defects and life-threatening abnormalities.

A document given to Newstalk ZB suggests The New Zealand Ministry of Health asked drug company Schering to immediately stop selling and exporting the drug to New Zealand in 1975.

The ban took immediate effect on the ninth of July that year.

German translation of the document from Section 9(2)(a)

The document asks to immediately stop selling and exporting Primodos to New Zealand. The New Zealand Ministry of Health is said to have forced Schering to

withdraw the preparation. The stop took immediate effect on july 9, 1975.

From: [redacted]
Sent: Monday, 20 March 2017 6:19 a.m.
To: [redacted]
Cc: [redacted]
Subject: Re: New Zealand

Dear [redacted]

We have the decision by Schering pharma division from 9 July 1975 (in german Original) to withdraw PRIMODOS (dragees - 2x10 mg) from the market in New Zealand with immediate effect.

Under the table it says:

"Remark: we have been forced by the New Zealand

health authorities to withdraw the preparation"

Best regards

[redacted]

File 13217 p. 89

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This page all section 9(2)(a)

Sent by: Chris James/MOH
20/03/2017 08:20 a.m.

To: Rowan Pollock/MOH@moh,
cc:
bcc:

Subject: Fwd: Questions re: Primodos

FYI also with link to telegraph article.
Chris

Begin forwarded message:

From: "Stewart Jessamine" [redacted]
Date: 19 March 2017 at 7:40:28 PM NZDT
To: "Charlotte Gendall" [redacted]
Cc: "Chris James" [redacted], "Peter Abernethy" < [redacted]
Subject: Re: Questions re: Primodos

Thanks chris
This product is old enough that you may need to gobs know to old copies of New Ethicals and or the postcard data on Medsafe listed in the 60s.

Sent from my iPhone

On 19/03/2017, at 4:22 PM, Charlotte Gendall [redacted] wrote:

Hi Chris -thanks for that.

My own quick search hasn't produced anything substantive but did show up this as an interesting sidebar ... http://collections.tepapa.govt.nz/object/1340667

[redacted] seems to have had some knowledge .... in any case, perhaps a very tentative draft response today could be:

DRAFT RESPONSE - please attribute to a spokesperson

Medsafe understands that this product was used in the UK in the 1960s and 1970s before being withdrawn. In terms of the New Zealand context, Medsafe will utilise archival material to ascertain the extent of use in this country, if any.

Medsafe has a memorandum of understanding with the Medicines & Healthcare products Regulatory Agency (MHRA) in the United Kingdom and will receive any relevant

information from its review as it becomes available.

ENDS

Essentially, I can tell him we'll get back to him tomorrow.

Charlotte Gendall
Senior Media Advisor
Ministry of Health
DDI: Section 9(2)(a)
MOB:

http://www.health.govt.nz

Chris James---19/03/2017 03:46:53 p.m.---From: Chris James/MOH To: Charlotte Gendall/MOH@moh,

From: Chris James/MOH
To: Charlotte Gendall/MOH@moh,
Cc: Stewart Jessamine/MOH@moh, Peter Abernethy/MOH@moh
Date: 19/03/2017 03:46 p.m.
Subject: Re: Questions re: Primodos

Hi Charlotte

As per the article this product was used in U.K in the 60s before being withdrawn in 1975. This largely predates regulation of medicines and certainly not regulation as we see today.

In terms of nz context I don't have that information to hand and we may need to search through our archives to ascertain extent of use in nz if any.

I will need to get our team to take a look at this and given the historical nature of the issue i would have thought tomorrow would be ok? Need access to paper archive files potentially. We have an mou with mhra in U.K so may be able to get info on their review as it becomes available.

Chris

On 19/03/2017, at 3:14 PM, Charlotte Gendall Section 9(2)(a)

> wrote:

Sorry to bother you guys again on a weekend - do we have any background on Primodos? Even just if it's ever been prescribed here?

This has come via min office ..

Thanks muchly

Charlotte

Sent from my iPhone

Begin forwarded message:

From: [redacted]
Date: 19 March 2017 at 2:58:33 PM NZDT
To: "media@moh.govt.nz" <media@moh.govt.nz>
Subject: Questions re: Primodos

Hi there,

I am interested in whether is any fallout in NZ from findings in the UK about the pregnancy test Primodor:
http://www.telegraph.co.uk/news/2017/03/18/new-evidence-claims-against-pregnancy-test-drugs-linked-birth/
http://www.dailymail.co.uk/health/article-4327024/New-thalidomide-scandal-1960s-pregnancy-test-pill.html

Has the ministry had any advice on this?

Was the drug prescribed in NZ?

And if so, how prevalent was it and will there be any follow up investigation here?

Regards,

[redacted]
Political Reporter
The New Zealand Herald
Parliamentary Press Gallery
[redacted]

This page all section 9(2)(a)

Sent by: Chris James/MOH
20/03/2017 08:35 a.m.

To: Rowan Pollock/MOH@moh,
cc:
bcc:

Subject: Fwd: Primodos

FYI

Begin forwarded message:

From: "Kathy Daly" [redacted]
Date: 20 March 2017 at 8:31:23 AM NZDT
To: "Evelina Pereira" [redacted]
Cc: "Therec" [redacted], "Chris James" [redacted]
Subject: Primodos

Hi Evelina,
We have a media query about Primodos, sold in NZ in the 60's and 70's we think
So there should be information on the old cards that were in the metal filing cabinet in the [redacted] and there should be a [redacted] closed file.
Please will you access both the card filing system and the [redacted] file? If it could be done today under urgency that would be great.
Thanks
Kathy

Kathy Daly
Team Leader (Product Safety)
Compliance Management
Medsafe
Clinical Leadership, Protection & Regulation
Ministry of Health
DDI: [redacted]

http://www.medsafe.govt.nz

mailto[redacted]

Fw: fyi - 1230 pm draft statement primodos
Charlotte Gendall to: Lily Chan 30/01/2018 10:20 a.m.

From: Charlotte Gendall/MOH
To: "Angela Kenealy" [redacted]
Cc: Media Team
Date: 20/03/2017 12:28 p.m.
Subject: fyi - 1230 pm draft statement primodos

Hi Angela - FYI I've worked with Stewart J and Chris J to provide the following statement. Chris is handling the immediate investigation so this is attributed to him. However if an interview is required at any point, it would be Stewart. We'll continue to update you. Charlotte

DRAFT STATEMENT - please attribute to Chris James, Manager Medsafe

Any indications that a medicine may have caused serious adverse effects are treated extremely seriously by both the Ministry of Health and Medsafe.

As the current reports relate to a period more than 50 years ago, the Ministry is urgently working through its archival files to establish the specifics of use for Primodos in this country, if any.

We have established that in May 1975 the then Department of Health issued a clinical services letter advising that it was withdrawing systemic hormonal testing preparations for pregnancy testing from the New Zealand market.

We are continuing to seek further information relating specifically to Primodos.

We're also searching for any files which may be held by the Centre for Adverse Reactions Monitoring (CARM) in Dunedin

http://www.medsafe.govt.nz/profs/PUarticles/ADRreport.htm

CARM has been operating since 1965 so if adverse reports relating to a product such as Primodos had been received, we would expect them to be held there.

We'll provide updated additional information as soon as it's available and would advise any members of the public who may have specific concerns about Primodos to contact Healthline - 0800 611 116 - or email the Ministry on info@health.govt.nz .

We've also contacted the company involved.

As we've said in a previous statement, Medsafe has a memorandum of understanding with the Medicines & Healthcare products Regulatory Agency (MHRA) in the United Kingdom and will receive any relevant information from its review as it becomes available.

ENDs

Charlotte Gendall
Senior Media Advisor
Ministry of Health
DDI: Section 9(2)(a)
MOB:

http://www.health.govt.nz

Fw: Primodos oral - updated info
Charlotte Gendall to: Lily Chan 30/01/2018 10:23 a.m.

----- Forwarded by Charlotte Gendall/MOH on 30/01/2018 10:22 a.m. -----

From: Charlotte Gendall/MOH
To: "Angela Kenealy" [redacted]
Cc: Peter Abernethy/MOH@MOH
Date: 20/03/2017 04:04 p.m.
Subject: Fw: Primodos oral - updated info

Hi .. as discussed, here's an update of bullet points relating to the Primodos.

I've talked to CJ and am about to draft a new statement , reflecting the below.

We'd also intend to put up a statement on the Ministry / Medsafe websites for the purposes of consumer facing info.

Charlotte Gendall
Senior Media Advisor
Ministry of Health
DDI: [redacted]
MOB: [redacted]

http://www.health.govt.nz

----- Forwarded by Charlotte Gendall/MOH on 20/03/2017 04:04 p.m. -----

From: Chris James/MOH
To: Charlotte Gendall/MOH@MOH,
Cc: Stewart Jessamine/MOH@MOH
Date: 20/03/2017 03:52 p.m.
Subject: Primodos oral

Hi all

I have an update from what we have been able to get from archives so far:

- Primodos first appeared in New Ethicals in 1966 - suggesting it was available and prescribed in NZ from that time.
- There is no information on how many patients were prescribed this product. Medsafe has contacted Bayer to obtain information if it is available.
- Minutes from the Drug Assessment Advisory Committee in 1975 recommended that Primodos should be withdrawn from the market in New Zealand. This was due to "reports received from overseas that birth defects have occurred when hormonal pregnancy tests have been taken in early pregnancy".
- The NZ Department of Health withdrew Primodos from the market and removed stock from pharmcies in June 1975.
- CARM has not received any reports of foetal malformations associated with the use of Primodos.

- CARM has received one report that described an adverse reaction in an adult only.

That is all I have so far. Yet to hear from Bayer.

Some general info:

Primodos was a hormone based preparation containing norethisterone and ethinylestradiol.

Chris

Chris James | Group Manager | Medsafe | Ministry of Health | Section 9(2)(a)

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

Fw: Primodos oral - updated info
Charlotte Gendall to: Lily Chan 30/01/2018 10:24 a.m.

----- Forwarded by Charlotte Gendall/MOH on 30/01/2018 10:24 a.m. -----

From: Charlotte Gendall/MOH
To: Angela Kenealy [redacted],
Cc: "Jonathan Franklin" Section 9(2)(a) Michael Johnson [redacted]
Date: 20/03/2017 04:20 p.m.
Subject: RE: Primodos oral - updated info

Hi there .. I am just redrafting a new statement to go on both websites, and to media. It will encourage anyone with concerns to contact helpline or email Ministry.

We'll continue to update info as necessary etc etc

I don't believe that at this point either STewart or CHris feel that a further formal " investigation " is warranted but they will continue to go through any relevant archival material and will also be in touch with UK authorities, and the company

I'll be in touch shortly with that statement.

Charlotte Gendall
Senior Media Advisor
Ministry of Health
DDI: [redacted]
MOB: Section 9(2)(a)

http://www.health.govt.nz

Angela Kenealy Hey - thank you for those points. What happens... 20/03/2017 04:14:22 p.m.

From: Angela Kenealy [redacted]
To:
Cc: Section 9(2)(a) "Jonathan Franklin" [redacted], Michael Johnson
Date: 20/03/2017 04:14 p.m.
Subject: RE: Primodos oral - updated info

Hey – thank you for those points. What happens next? Do people with concerns need to call helpline? Is there anything we need to investigate??

Angela Kenealy | Press Secretary | Office of the Hon Dr Jonathan Coleman
Parliament Buildings |Wellington |Ph: Section 9(2)(a) | mobile: Section 9(2)(a)

From: [redacted] Section 9(2)(a)
Sent: Monday, 20 March 2017 4:05 p.m.
To: Angela Kenealy [redacted] Section 9(2)(a)
Cc: [redacted]
Subject: Fw: Primodos oral - updated info
Importance: High

Hi .. as discussed, here's an update of bullet points relating to the Primodos.

I've talked to CJ and am about to draft a new statement , reflecting the below.

We'd also intend to put up a statement on the Ministry / Medsafe websites for the purposes of consumer facing info.

Charlotte Gendall
Senior Media Advisor
Ministry of Health
DDI: [redacted] Section 9(2)(a)
MOB: [redacted]

http://www.health.govt.nz

----- Forwarded by Charlotte Gendall/MOH on 20/03/2017 04:04 p.m. -----

From: Chris James/MOH
To: Charlotte Gendall/MOH@MOH,
Cc: Stewart Jessamine/MOH@MOH
Date: 20/03/2017 03:52 p.m.
Subject: Primodos oral

Hi all

I have an update from what we have been able to get from archives so far:

- Primodos first appeared in New Ethicals in 1966 - suggesting it was available and prescribed in NZ from that time.
- There is no information on how many patients were prescribed this product. Medsafe has contacted Bayer to obtain information if it is available.
- Minutes from the Drug Assessment Advisory Committee in 1975 recommended that Primodos should be withdrawn from the market in New Zealand. This was due to "reports received from overseas that birth defects have occurred when hormonal pregnancy tests have been taken in early pregnancy".
- The NZ Department of Health withdrew Primodos from the market and removed stock from pharmcies in June 1975.

- CARM has not received any reports of foetal malformations associated with the use of Primodos.
- CARM has received one report that described an adverse reaction in an adult only.

That is all I have so far. Yet to hear from Bayer.

Some general info:

Primodos was a hormone based preparation containing norethisterone and ethinylestradiol.

Chris

Chris James | Group Manager | Medsafe | Ministry of Health | Section 9(2)(a)

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

Fw: fyi - primodos - afternoon statement
Charlotte Gendall to: Lily Chan 30/01/2018 10:28 a.m.

----- Forwarded by Charlotte Gendall/MOH on 30/01/2018 10:28 a.m. -----

From: Charlotte Gendall/MOH
To: "Angela Kenealy" [redacted]
Cc: Section 9(2)(a) [redacted]
Date: 20/03/2017 04:45 p.m.
Subject: fyi - primodos - afternoon statement

FYI - we'll plan to put this out to media shortly and also on website/s. Charlotte

DRAFT STATEMENT - please attribute to Chris James, Manager Medsafe

As we said earlier today, any indications that a medicine may have caused serious adverse effects are treated extremely seriously by both the Ministry of Health and Medsafe.

As the current reports relate to a period more than 50 years ago, the Ministry has been urgently working through its archival files to establish the specifics of use for Primodos in this country.

Today, we have established that

- Primodos first appeared in New Ethicals in 1966 - suggesting it was available and prescribed in New Zealand from that time.
- In May 1975 the then Department of Health issued a clinical services letter advising that it was withdrawing systemic hormonal testing preparations for pregnancy testing from the New Zealand market. It did not specifically identify Primodos
- There is no information on how many patients were prescribed this product. Medsafe has contacted Bayer to obtain information if it is available.
- Minutes from the Drug Assessment Advisory Committee in 1975 recommended that Primodos should be withdrawn from the market in New Zealand. This was due to "reports received from overseas that birth defects have occurred when hormonal pregnancy tests have been taken in early pregnancy".
- The NZ Department of Health withdrew Primodos from the market and removed stock from pharmcies in June 1975.

We have also searched for any files which may be held by the Centre for Adverse Reactions Monitoring (CARM) in Dunedin

http://www.medsafe.govt.nz/profs/PUarticles/ADRreport.htm

CARM has been operating since 1965 so if adverse reports relating to a product such as Primodos had been received, we would expect them to have been held there.

- CARM has not received any reports of foetal malformations associated with the use of Primodos.

- CARM has received one report that described an adverse reaction in an adult only.

We'll continue to provide updated additional information as soon as it's available and would advise any members of the public who may have specific concerns about Primodos to contact Healthline - 0800 611 116 - or email the Ministry on info@health.govt.nz .

We've also contacted the company involved, Bayer.

As we've said in a previous statement, Medsafe has a memorandum of understanding with the Medicines & Healthcare products Regulatory Agency (MHRA) in the United Kingdom and will receive any relevant information from its review as it becomes available.

BACKGROUND INFORMATION

Primodos was a hormone based preparation containing norethisterone and ethinylestradiol.

ENDS

Charlotte Gendall
Senior Media Advisor
Ministry of Health
DDI:
MOB: Section 9(2)(a)

http://www.health.govt.nz

Sent by: [redacted]

To: [redacted]
cc:
bcc:

20/03/2017 04:53 p.m. Subject: RE: Media query (Primodos)

Hi Chris
Thank you for this update. I really appreciate the heads-up [redacted]
Regards
Janelle

Janelle Ashton | Manager Information Systems | New Zealand Pharmacovigilance Centre [https://nzphvc.otago.ac.nz]
NZPhvC, PO Box 913, Dunedin 9054, New Zealand | DDI: [redacted]

From: [redacted]
Sent: Monday, 20 March 2017 4:51 p.m.
To: Janelle Ashton
Cc: [redacted]
Subject: RE: Media query (Primodos)

Hi Janelle

We are providing media with an update very soon. We are also expecting to have something on our website shortly. This will state info as CARM has provided - ie no reports of foetal malformations associated with Primodos. One report of an ADR in an adult.

Appreciated your help with this today.

Chris

Chris James | Group Manager | Medsafe | Ministry of Health | [redacted]

From: Janelle Ashton [redacted]
To: [redacted]
Cc: [redacted]
Date: 20/03/2017 03:31 p.m.
Subject: RE: Media query (Primodos)

This page all section 9(2)(a)

Hi Rowan
For your information, I am fielding media enquiries here :
The first was The NZ Herald
Then Radio New Zealand.
My response is " Medsafe handle all media enquiries you need to phone Rowan Pollock on [redacted]

Radio NZ then asked if CARM had provided all information requested by Medsafe to Medsafe.
My response "Yes"
Janelle

Janelle Ashton | Manager Information Systems | New Zealand Pharmacovigilance Centre [https://nzphvc.otago.ac.nz]
NZPhvC, PO Box 913, Dunedin 9054, New Zealand | DDI: [redacted]

From: [redacted]
Sent: Monday, 20 March 2017 2:31 p.m.
To: Janelle Ashton
Subject: RE: Media query (Primodos)

Thanks for your response, Janelle, much appreciated.

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

From: Janelle Ashton [redacted]
To: [redacted]
Cc: Michael Tatley [redacted] Ruth Savage [redacted]
Date: 20/03/2017 02:28 p.m.
Subject: RE: Media query (Primodos)

Hi Rowan
Further to our telephone discussion, I have now checked the original cases for any identification of Primodos and there is one case.
It is report 004018
Patient : 42y Female [redacted]
Primodos administration [redacted]
Reaction onset [redacted] Hemiplegia
Reporter Comment: "Primodos given for [redacted]

This page all section 9(2)(a)

[redacted]

Other information : [redacted]
Regards
Janelle

Janelle Ashton | Manager Information Systems | New Zealand Pharmacovigilance Centre [https://nzphvc.otago.ac.nz]
NZPhvC, PO Box 913, Dunedin 9054, New Zealand | DDI [redacted]

From: [redacted]
Sent: Monday, 20 March 2017 8:51 a.m.
To: Janelle Ashton
Cc: Michael Tatley; Ruth Savage; [redacted]
Subject: Media query (Primodos)

Hi Janelle

I understand Michael is away at the moment and therefore I am hoping you could help.

We have had a media query about the use of a product called Primodos (contains norethisterone and ethinyloestradiol) used in the 1960s and 1970s as a hormone-based pregnancy test.

Have their been any adverse reactions reported with this product? This specifically relates to birth defects, but any information would be helpful.

Happy to discuss further.

Thank you
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

This page all section 9(2)(a)

Fw: Urgent check needed on these Primodos lines for the Caucus run - needed by 9:30am
Charlotte Gendall to: Lily Chan 30/01/2018 10:29 a.m.

----- Forwarded by Charlotte Gendall/MOH on 30/01/2018 10:29 a.m. -----

From: Charlotte Gendall/MOH
To: Angela Kenealy [redacted]
Cc: Chris James/MOH@MOH, Stewart Jessamine/MOH@MOH
Date: 21/03/2017 09:29 a.m.
Subject: Re: Urgent check needed on these Primodos lines for the Caucus run - needed by 9:30am

Hi Angela - Chris has checked these lines and they're fine. Re the adult patient, we should be cautious in what's said about dates etc which could lead to any identification but the essence is:

The adverse adult report was a reaction [redacted] taking the product.
It was not related to [redacted]
There's no indication from the records that the person was [redacted]

Charlotte Gendall
Senior Media Advisor
Ministry of Health
DDI: [redacted]
MOB: [redacted]

http://www.health.govt.nz

Angela Kenealy Talking points: Primodos Issue: the use of Prim... 21/03/2017 08:58:18 a.m.

From: Angela Kenealy [redacted]
To: "media@moh.govt.nz" <media@moh.govt.nz>,
Date: 21/03/2017 08:58 a.m.
Subject: Urgent check needed on these Primodos lines for the Caucus run - needed by 9:30am

Talking points: Primodos

Issue: the use of Primodos (a systemic hormonal testing preparations for pregnancy testing) which new research has now linked to birth defects

Lines:
Any indications that a medicine may have caused serious adverse effects are treated extremely seriously by both the Ministry of Health and Medsafe.

Investigations continue, the Ministry of Health is urgently going through the relevant archives,

working with UK agencies and the drug manufacture.

I encourage any members of the public with specific concerns about Primodos to contact Healthline, 0800 611 116.

Labour's David Clark has called for registry to be established: This would duplicate the system already in place, which has been operating since 1965. It's also putting the cart before the horse as in the first instance we need to establish the extent of the issue.

Additional information:
Primodos was a hormone based preparation containing norethisterone and ethinylestradiol.

Primodos was available in New Zealand from 1966 through to May 1975 when the then Department of Health issued a clinical services letter advising that it was withdrawing systemic hormonal testing preparations for pregnancy testing from the New Zealand market. It did not specifically identify Primodos.

As the current reports relate to a period more than 50 years ago, the Ministry has been urgently working through its archival files to establish the specifics of use for Primodos in this country.

There is no information on how many patients were prescribed this product. Medsafe has contacted Bayer to obtain information if it is available.

Minutes from the Drug Assessment Advisory Committee in 1975 recommended that Primodos should be withdrawn from the market in New Zealand. This was due to "reports received from overseas that birth defects have occurred when hormonal pregnancy tests have been taken in early pregnancy".

The NZ Department of Health withdrew Primodos from the market and removed stock from pharmcies in June 1975.

The Ministry of Health has also searched for any files which may be held by the Centre for Adverse Reactions Monitoring (CARM) in Dunedin.

CARM has been operating since 1965 so if adverse reports relating to a product such as Primodos had been received, it should be held there.

CARM has not received any reports of foetal malformations associated with the use of Primodos. CARM has received one report that described an adverse reaction in an adult only.

Medsafe has a memorandum of understanding with the Medicines & Healthcare products Regulatory Agency (MHRA) in the United Kingdom and will receive any relevant information from its review as it becomes available.

Angela Kenealy | Press Secretary | Office of the Hon Dr Jonathan Coleman
Minister of Health, Minister for Sport and Recreation
Parliament Buildings | Wellington | Ph: Section 9(2)(a) | mobile: Section 9(2)(a)
facebook.com/jonathan.coleman.56 twitter.com/jcolemanmp www.beehive.govt.nz

Fw: FYI update primodos
Charlotte Gendall to: Lily Chan 30/01/2018 10:50 a.m.

----- Forwarded by Charlotte Gendall/MOH on 30/01/2018 10:50 a.m. -----

From: Charlotte Gendall/MOH
To: "Angela K" Section 9(2)(a)
Date: 21/03/2017 01:13 p.m.
Subject: FYI update primodos

Hi Angela FYI - we've had a few queries on primodos again today but not as many as yesterday. I've updated w Chris and Stewart today , and can also point the journos towards Bayer for its statement, when I send the email out.

Charlotte

DRAFT STATEMENT - attribute to Chris James, General Manager Medsafe

Medsafe and the Ministry of Health will continue to monitor and investigate the historic availability of the medicine Primodos in New Zealand.

As we said yesterday, any indications that a medicine may have caused serious adverse effects are treated extremely seriously.

We can provide the following updates:

· Medsafe has been in discussion with the manufacturer Bayer.
· At this time, Bayer is not able to provide any indication of the volume of doses of Primodos distributed in New Zealand. However the company has committed to providing whatever usage data it can, if and when it becomes available. Bayer will also provide other information relating to the Medicines & Healthcare products Regulatory Agency (MHRA) review currently underway in the United Kingdom.
· Medsafe has now completed its search of any files which may be held by the Centre for Adverse Reactions Monitoring (CARM) in Dunedin. CARM has been operating since 1965 so if adverse reports relating to a product such as Primodos had been received, we would expect them to have been held there. As we noted on Monday:
· CARM has not received any reports of foetal malformations associated with the use of Primodos.
· CARM has received one report that described an adverse reaction in an adult only.

Medsafe has a memorandum of understanding with the Medicines & Healthcare products Regulatory Agency (MHRA) in the United Kingdom. We have also contacted them to discuss

the current concerns. The MHRA have undertaken to update Medsafe as their review continues.

Any members of the public who may have specific questions about Primodos should discuss their concerns with their GP. They can also contact Healthline - 0800 611 116 - or email the Ministry on info@health.govt.nz.

We'll provide any updated additional information as it becomes available.

Background Information

· Primodos was a hormone based preparation containing norethisterone and ethinylestradiol.
· Primodos first appeared in the New Ethicals publication in 1966 - suggesting it was available and prescribed in New Zealand from that time.
· In May 1975 the then Department of Health issued a clinical services letter advising that it was withdrawing systemic hormonal testing preparations for pregnancy testing from the New Zealand market. It did not specifically identify Primodos
· Minutes from the Drug Assessment Advisory Committee in 1975 recommended that Primodos should be withdrawn from the market in New Zealand. This was due to "reports received from overseas that birth defects have occurred when hormonal pregnancy tests have been taken in early pregnancy".
· The NZ Department of Health withdrew Primodos from the market and removed stock from pharmacies in June 1975.

ENDS

Sent from my iPhone

This page all section 9(2)(a)

Fw: FYI - Sarah catherall primodos
Charlotte Gendall to: Lily Chan 30/01/2018 10:31 a.m.

From: Charlotte Gendall/MOH
To: "Angela Kenealy" [redacted]
Date: 24/03/2017 01:53 p.m.
Subject: FYI - [redacted] primodos

Hi Angela - FYI the Dom Post reporter [redacted] has approached us as follows. It's a mix of her own interest and media. So far, I've supplied her with previous statements and publicly available material however she also asked a specific qu about rates on stillbirths and miscarriages, I'm attaching the table I plan to send her, along with explanatory lines urging caution with the date.

Can you give me a heads up on the latest info about the drug, Primodol and how widely it was distributed?
[redacted], [redacted] born stillborn at [redacted].
[redacted] born in [redacted]
How would I go about finding out if [redacted] given this drug?
Would there be any records still existing?
Her GP [redacted]
How do I find out how widely it was distributed, and whether to any pregnant women in [redacted]
This is both personal interest of course, and also a potential story, hence why I am going through the media desk.
I would also love to get some rates on stillbirths and miscarriages from 1968 to 1978 - year by year.

Charlotte Gendall
Senior Media Advisor
Ministry of Health
DDI: [redacted]
MOB: [redacted]

http://www.health.govt.nz

From: Charlotte Gendall/MOH
To: [redacted]
Date: 23/03/2017 02:50 p.m.
Subject: Re: attention Charlotte Gendall

Hi Sarah - I'll give you a call shortly but just wanted to get you all the info I currently have.

1. Medsafe statement:

http://www.health.govt.nz/news-media/news-items/statement-primodos

2. Additional comment from Medsafe:

RESPONSE
To date, there have been a small number of contacts with Medsafe, the Ministry and Healthline.

As of Tuesday afternoon, Healthline had received three calls related to Primodos but none were directly from women who may have been prescribed the product. The callers were either asking about the possible effects of the product, or inquiring about advice being given to women.

Medsafe has had a similarly small number of direct contacts, including two from women who were prescribed the product during the time it was available in this country.

When an initial contact is made, any calls or emails are acknowledged. More details can be sent to the Ministry and, with the caller's permission, may be referred to the Centre for Adverse Reactions Monitoring if a report of a possible adverse reaction is required.

We won't be in a position to reveal any further detail on individual contacts in order to protect personal and medical details of people who may have been prescribed the product.

Medsafe is still awaiting information from Bayer about what data is available on how many people may have used the product in this country. The company has committed to providing whatever usage data it can, if and when it becomes available.

3. Contact with Bayer .. this is what I understand is their media position, although you would need to confirm it with them.

Bayer denies that Primodos was responsible for causing any deformities in children.
UK litigation in respect of Primodos, against Schering (which is now owned by Bayer), ended in 1982 when the claimants' legal team, with the approval of the court, decided to discontinue the litigation on the grounds that there was no realistic possibility of showing that Primodos caused the congenital abnormalities alleged.
Since the discontinuation of legal action in the UK in 1982, no new scientific knowledge has been produced which would call into question the validity of the previous assessment of there being no link between use of Primodos and the occurrence of congenital abnormalities.
Based on the facts and on the law, Bayer does not accept that Primodos was responsible for causing congenital abnormalities.

Best regards,

Section 9(2)(a)
Head of Law, Patents and Compliance ANZ _____

Bayer: Science For A Better Life

Bayer Australia Limited
Country Platform ANZ
Law, Patents and Compliance
875 Pacific Highway
2073 Pymble, Australia

This page all section 9(2)(a)

Tel: [redacted]
Fax: [redacted]
Mobile: [redacted]
E-mail: [redacted]

4. How do I find out how widely it was distributed, and whether to any pregnant women in [redacted] that's one for Bayer , they have undertaken to get the data back to us but nothing as yet so it wouldn't hurt to ask them direct.

5. **data on still births**

InfDthTypes.xls

* we are happy to provide the data attached for your interest but please note that the rate of stillbirths and miscarriages **cannot be directly linked to the use of primodos**

* the Ministry publishes the number of fetal deaths (also known as still births) annually in the Fetal and Infant Death publication. The attached spreadsheet shows the number and rate of the various death types covered by this publication back from 1942-2013 **however** we would not recommend using these figures for direct comparisons over time. For instance, New Zealand's definition of "still birth" changed in September 1995 when changes to the Births Deaths and Marriages Act came into effect. This changed NZ's definition from late fetal deaths (28 weeks gestation or more) to fetal deaths (20 weeks gestation, or 400g birthweight). This means that current rates can't be directly compared to historic rates.

6. We don't hold any **direct patient records** here. How frustrating that the GP [redacted] However we've had a think and apparently hospitals retain records, and they should still be available - so [redacted] definitely worth a try.

Will call you this arvo.

Charlotte Gendall
Senior Media Advisor
Ministry of Health
DDI: [redacted]
MOB: [redacted]

http://www.health.govt.nz

[redacted] Hi Charlotte I left a message on your phone today 22/03/2017 04:44:54 p.m.

From: [redacted]
To: media@moh.govt.nz,
Date: 22/03/2017 04:44 p.m.
Subject: attention Charlotte Gendall

Hi Charlotte
I left a message on your phone today.
Can you give me a heads up on the latest info about the drug, Primodol and how widely it was

distributed?
[redacted],
stillborn at [redacted]
[redacted] born in [redacted]
How would I go about finding out if [redacted] given this drug?
Would there be any records still existing?
Her GP [redacted]
How do I find out how widely it was distributed, and whether to any pregnant women in [redacted]
This is both personal interest of course, and also a potential story, hence why I am going through the media desk.
Any info you can send me would be most helpful.
Kind regards [redacted]
--

[redacted]

Senior writer, Life and style

The Dominion Post - A division of Fairfax Media New Zealand Ltd

[redacted]

Level 7, Telecom Central, 42-52 Willis St, New Zealand

PO Box 3740, Wellington 6140

Fw: fyi - general update - primodos - friday
Charlotte Gendall to: Lily Chan 30/01/2018 10:35 a.m.

----- Forwarded by Charlotte Gendall/MOH on 30/01/2018 10:35 a.m. -----

From: Charlotte Gendall/MOH
To: "Angela Kenealy" [redacted]
Cc: Peter Abernethy/MOH@MOH
Date: 24/03/2017 03:37 p.m.
Subject: fyi - general update - primodos - friday

HI Angela - I've had a couple of general inquiries about Primodos today so have prepared this as an update for interested media. Let me know what you think. Charlotte

DRAFT STATEMENT

Medsafe, the Ministry of Health and Healthline continue to report a small number of contacts about Primodos.

As of Friday afternoon (24 March), Healthline had received a total of six calls related to Primodos, with a variety of inquiries ranging from availability and use in New Zealand to information on potential effects.

Medsafe has had a similarly small number of direct contacts, including some from women who may have been prescribed the product during the time it was available in this country. The number of direct contacts from women who may have been prescribed the product is currently less than 10.

When an initial contact is made, any calls or emails are acknowledged. More details can be sent to the Ministry and, with the caller's permission, may be referred to the Centre for Adverse Reactions Monitoring if a report of a possible adverse reaction is required.

We won't be in a position to reveal any further detail on individual contacts in order to protect personal and medical details.

The Ministry of Health has been in contact with Bayer, the company that now owns the company that manufactured Primodos. Bayer has been asked to provide information such as how many patients received Primodos in New Zealand. We are still awaiting information from Bayer but they have undertaken to provide it as soon as it becomes available.

ENDS

Charlotte Gendall
Senior Media Advisor
Ministry of Health
DDI: [redacted]
MOB: [redacted]

http://www.health.govt.nz

Sent by: Rowan Pollock/MOH

30/03/2017 03:18 p.m.

To: Peter Abernethy/MOH@MOH,
cc: Chris James/MOH@MOH,
bcc:

Subject: Fw: Primodos Update

Hi Peter

Responses to the questions are below:

- Bayer are unable to provide sales data. It is understood that by 1975 the sales of Primodos in New Zealand were low.
- According to archived records, Primodos was first listed in New Ethicals in January 1966. The New Ethicals publication lists medicine monographs and these monographs include available brands of medicines.
- It is noted in archived records that Primodos was withdrawn from the retail pharmacy level from 9 June 1975. Similar action was taken by the Australian authorities in 1976.
- Therefore, based on the information available Primodos was used between 1966 and 1975.
- CARM have received six reports following the initial media query.

Please note that none of the six reports to CARM have provided much detail (eg, some are not sure if it was Primodos that they took).

Let me know if you have any further questions.

Thank you
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | Section 9(2)(a)

----- Forwarded by Rowan Pollock/MOH on 30/03/2017 02:49 p.m. -----

From: Chris James/MOH
To: Rowan Pollock/MOH@moh,
Date: 30/03/2017 02:42 p.m.
Subject: Fwd: Primodos Update

FYI

Begin forwarded message:

From: "Kathy Daly" Section 9(2)(a)
Date: 30 March 2017 at 2:35:47 PM NZDT
To: "Chris James"
Cc: "Peter Abernethy" Section 9(2)(a)

Subject: Fw: Primodos Update

Hi Chris,
This isn't me.
Thanks
Kathy

----- Forwarded by Kathy Daly/MOH on 30/03/2017 02:35 p.m. -----

From: Peter Abernethy/MOH
To: Kathy Daly/MOH@MOH,
Date: 30/03/2017 02:29 p.m.
Subject: Fw: Primodos Update

Hi Kathy, are these answerable at the moment? Regards

Peter Abernethy
Media Relations Manager
Ministry of Health
DDI: Section 9(2)(a)
Mobile: [redacted]
For urgent media responses please copy: media@moh.govt.nz

http://www.health.govt.nz
mailto: Section 9(2)(a)

----- Forwarded by Peter Abernethy/MOH on 30/03/2017 02:29 p.m. -----

From: Section 9(2)(a)
To: Contact <media@moh.govt.nz>,
Date: 30/03/2017 01:59 p.m.
Subject: Primodos Update

Hi Media Team!

Can I please check in how you are tracking on your investigation into the use of Primodos in New Zealand?

ie
- The volume of doses distributed in New Zealand.

- Whether it was used solely between 1966 and 1975?
- An update on whether MoH/Medsafe/CARM has received any new reports of potential foetal malformations associated with the use of Primodos.
- If so, how many cases is the Ministry of Health investigating.

I'm looking at a potential follow up story tomorrow, ideally if I could get an update by 11am tomorrow it would be useful?

Many thanks,

[redacted] | Health Correspondent | Newshub | MEDIAWORKS | DDI [redacted]

Sent by: Chris James/MOH
30/03/2017 05:05 p.m.

To: Peter Abernethy/MOH@MOH,
cc: Rowan Pollock/MOH@MOH,
bcc:

Subject: Re: Fw: Primodos Update

Looks fine thanks. I imagine they will come back for more detail on the 6 of which we don't have much

Chris

Chris James | Group Manager | Medsafe | Ministry of Health | Section 9(2)(a)

Peter Abernethy Hi Rowan and Chris, I've tinkered. Is... 30/03/2017 04:38:46 p.m.

From: Peter Abernethy/MOH
To: Rowan Pollock/MOH@MOH,
Cc: Chris James/MOH@MOH
Date: 30/03/2017 04:38 p.m.
Subject: Re: Fw: Primodos Update

Hi Rowan and Chris, I've tinkered. Is this ok?

A total of six instances where Primodos may have been used have been reported to the Centre for Adverse Reactions Monitoring based in Dunedin. Unfortunately because of the length of time now elapsed the reports have little confirmed detail - including whether Primodos was actually taken.

Based on information from Bayer, the company which distributed Primodos, the medicine was available in New Zealand from 1966 to 9 June 1975 when it was withdrawn from pharmacies. Similar action was taken by the Australian authorities in 1976. Unfortunately Bayer is unable to provide sales data but the company believes that by 1975 sales of Primodos were low.

Peter Abernethy
Media Relations Manager
Ministry of Health
DDI: Section 9(2)(a)
Mobile: [redacted]
For urgent media responses please copy: media@moh.govt.nz

http://www.health.govt.nz
mailto: Section 9(2)(a)

Rowan Pollock Hi Peter Responses to the questions a... 30/03/2017 03:18:44 p.m.

From: Rowan Pollock/MOH
To: Peter Abernethy/MOH@MOH,
Cc: Chris James/MOH@MOH
Date: 30/03/2017 03:18 p.m.
Subject: Fw: Primodos Update

Hi Peter

Responses to the questions are below:

- Bayer are unable to provide sales data. It is understood that by 1975 the sales of Primodos in New Zealand were low.
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- Therefore, based on the information available Primodos was used between 1966 and 1975.
- CARM have received six reports following the initial media query.

Please note that none of the six reports to CARM have provided much detail (eg, some are not sure if it was Primodos that they took).

Let me know if you have any further questions.

Thank you
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | Section 9(2)(a)

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From: Chris James/MOH
To: Rowan Pollock/MOH@moh,
Date: 30/03/2017 02:42 p.m.
Subject: Fwd: Primodos Update

FYI

Begin forwarded message:

From: "Kathy Daly" Section 9(2)(a)
Date: 30 March 2017 at 2:35:47 PM NZDT
To: "Chris James" Section 9(2)(a)
Cc: "Peter Abernethy"
Subject: Fw: Primodos Update

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This isn't me.
Thanks
Kathy

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To: Kathy Daly/MOH@MOH,
Date: 30/03/2017 02:29 p.m.
Subject: Fw: Primodos Update

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Peter Abernethy
Media Relations Manager
Ministry of Health
DDI: Section 9(2)(a)
Mobile: [redacted]
For urgent media responses please copy: media@moh.govt.nz

http://www.health.govt.nz
mailto: Section 9(2)(a)

----- Forwarded by Peter Abernethy/MOH on 30/03/2017 02:29 p.m. -----

From: Section 9(2)(a)
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Date: 30/03/2017 01:59 p.m.
Subject: Primodos Update

Hi Media Team!

Can I please check in how you are tracking on your investigation into the use of Primodos in New Zealand?

ie
- The volume of doses distributed in New Zealand.
- Whether it was used solely between 1966 and 1975?
- An update on whether MoH/Medsafe/CARM has received any new reports of potential foetal malformations associated with the use of Primodos.

- If so, how many cases is the Ministry of Health investigating.

I'm looking at a potential follow up story tomorrow, ideally if I could get an update by 11am tomorrow it would be useful?

Many thanks,

[redacted] | Health Correspondent | Newshub | MEDIAWORKS | DDI [redacted]

Fw: FYI herald primodos
Charlotte Gendall to: Lily Chan 30/01/2018 10:51 a.m.

----- Forwarded by Charlotte Gendall/MOH on 30/01/2018 10:50 a.m. -----

From: Charlotte Gendall/MOH
To: "Angela K" Section 9(2)(a)
Cc: Peter Abernethy/MOH@moh
Date: 30/03/2017 08:12 p.m.
Subject: FYI herald primodos

Hi Angela FYI the Herald 9(2)(a) filed a very late series of qus on Primodos. The team has pulled this together at short noti ce.. Charlotte

DRAFT RESPONSE

The Ministry of Health and Medsafe have encouraged women who may have experience of being prescribed hormone-based pregnancy testing products such as Primodos to report their concerns.

Individual cases can not be commented on but if appropriate, they are referred to the Centre for Adverse Reactions Monitoring based in Dunedin (CARM) for reporting of possible adverse events.

Both the Ministry and Medsafe regard any possible adverse events extremely seriously.

To date, a total of six instances where Primodos may have been used have been reported to CARM. Unfortunately because of the length of time now elapsed the reports have little confirmed detail - including whether Primodos was actually taken.

Based on information from Bayer, the company which distributed Primodos, the medicine was available in New Zealand from 1966 to 9 June 1975 when it was withdrawn from pharmacies.

Similar action was taken by the Australian authorities in 1976. Unfortunately Bayer is unable to provide sales data but the company believes that by 1975 sales of Primodos were low.

Medsafe has established that general practices and pharmacies were alerted via a clinical newsletter issued by the Department of Health in 1975. Pharmacies were also notified via the company's recall of the product.

Medsafe continues to seek information relating to the use of this product in New Zealand.

Medsafe will be closely following the review by the working group in the U.K. and will make

available all information it has on use in New Zealand if this is helpful.

ENDS

From: [redacted]
Date: 30 March 2017 at 6:00:09 PM NZDT
To: "media@moh.govt.nz" <media@moh.govt.nz>, [redacted]
Subject: Primodos

Hi guys,

I know it's late but I have just spoken to a woman who was prescribed a hormone-based pregnancy testing drug [redacted] and now believes it caused her son to born with tracheostenosis. She has been in contact with Medsafe and CARM. Her name is [redacted]

She is concerned she was prescribed the drug by [redacted] after the department of health ordered it to be pulled from the market. She wants answers as to why and how it was still available and being prescribed.

What measures did the Department of Health go to to make sure those sorts of drugs were no longer being used? Was it followed up with the manufacturers? Did they check pharmacies? How were doctors and pharmacies notified of the need to stop selling/prescribing the drugs?

What is Medsafe doing now to investigate how she was able to get the drug so long after it had been pulled? What are they doing to investigate whether it was the drug which caused the problem?

Please could you let me know when you will be able to provide a response? We would like something as soon as possible.

Thanks

[redacted]
HEALTH REPORTER
NEW ZEALAND HERALD

Sent from my iPhone

This page all section 9(2)(a)

Fw: FYI - friday update - primodos
Charlotte Gendall to: Lily Chan 30/01/2018 10:49 a.m.

----- Forwarded by Charlotte Gendall/MOH on 30/01/2018 10:49 a.m. -----

From: Charlotte Gendall/MOH
To: "Angela Kenealy" [redacted]
Cc: Peter Abernethy/MOH@MOH
Date: 31/03/2017 10:53 a.m.
Subject: FYI - friday update - primodos

Hi Angela - FYI - we've received the following queries from Newstalk ZB and Herald. Here's the additional information we're able to provide today. [redacted] questions are a little more detailed but Chris James is offsite so I can't check some of those queries directly with him right now. Charlotte

NEWSTALK - [redacted]
Just wondering whether the Ministry of Health will be carrying out an investigation into Primodos given [redacted] has come forward, saying she thinks she was given the drug in [redacted]
She wants to know what the Government did to ensure the drug was pulled following the directive to do so in 1975.
She also wants an expert working group set up by the Government so they can look into it to find out what exactly happened
She wants them to talk to people who've been affected by it and people who took it.
Is the Ministry consider doing any of these things?

HERALD - [redacted]
Can you tell me if Medsafe or the Ministry are aware of other brands of hormonal pregnancy testing drugs being used and sold in New Zealand in the 60s and 70s? Did the recall notice issued extend to all drugs of the type or was it only specific brands?
Can you comment on how someone would have been prescribed and given [redacted] a hormonal pregnancy testing drug in [redacted] (after the recall)?
Does the Ministry of Health believe notifying GPs and pharmacies through a newsletter was sufficient to make sure the use of the drugs ended?
Now that six women have approached Medsafe and lodged a report with CARM, what happens? Will Medsafe or CARM continue to investigate those instances?

DRAFT
Medsafe will continue to monitor and assess any reports received by it and / or CARM.

Any decision on additional levels of investigation such as formally establishing a working group would be a matter for future consideration.

It's important to acknowledge that the international information surrounding Primodos which recently came to light is currently being formally reviewed by a working group in the United Kingdom.

Medsafe and the Ministry of Health will be following that review closely to learn what implications there might be for women who may have received the product in this country.

Through its memorandum of understanding with the Medicines & Healthcare products Regulatory Agency (MHRA), Medsafe can receive information directly from the UK regulator. Medsafe is also happy to make available to the working group any and all information from New Zealand which may be useful.

ENDS

Charlotte Gendall
Senior Media Advisor
Ministry of Health
DDI: Section 9(2)(a)
MOB:

http://www.health.govt.nz

Sent by: Charlotte Gendall/MOH

11/04/2017 11:36 a.m.

To: Rowan Pollock/MOH@MOH,
cc:
bcc:

Subject: Re: Primodos Update

Hi Rowan .. thanks for that. I think that we could take down what's already up there, and replace it with the attached - I've meshed it together with the existing info, previous media responses, and your dot points.

It wont date so quickly.

What do you think?

Primodos Update 11 April (Gendall).docx

Charlotte Gendall
Senior Media Advisor
Ministry of Health
DDI: Section 9(2)(a)
MOB:

http://www.health.govt.nz

Rowan Pollock Hi Charlotte I've added a couple of dot... 11/04/2017 10:39:42 a.m.

From: Rowan Pollock/MOH
To: Charlotte Gendall/MOH@MOH,
Date: 11/04/2017 10:39 a.m.
Subject: Primodos Update

Hi Charlotte

I've added a couple of dot points for consideration.

[attachment "Primodos Update.docx" deleted by Charlotte Gendall/MOH]

Thanks
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | Section 9(2)(a)

Primodos

The Ministry of Health and Medsafe are aware of public interest around the product Primodos and any other systemic hormonal testing programmes previously available in New Zealand.

Any indications that a medicine may have caused serious adverse effects are treated extremely seriously by both the Ministry of Health and Medsafe.

As recent international reports have related to a period dating back up to five decades ago, the Ministry has been working through its archival files to establish the specifics of use for these products in New Zealand.

We have established that

- Primodos first appeared in New Ethicals in 1966 - suggesting it was available and prescribed in New Zealand from that time.
- Minutes from the Drug Assessment Advisory Committee in 1975 recommended that Primodos should be withdrawn from the market in New Zealand. This was due to "reports received from overseas that birth defects have occurred when hormonal pregnancy tests have been taken in early pregnancy".
- In May 1975 the then Department of Health issued a clinical services letter advising that it was withdrawing systemic hormonal testing preparations for pregnancy testing from the New Zealand market. It did not specifically identify Primodos
- The NZ Department of Health withdrew Primodos from the market and removed stock from pharmacies in June 1975.
- There is no information on how many patients were prescribed this product. Medsafe has contacted Bayer to obtain information if it is available however the company has advised it unable to do so at this time.
- Amenorone Forte was another hormone based pregnancy testing preparation available in New Zealand. It first became available in 1968 and was withdrawn at the same time as Primodos, in June 1975.
- ~~In 1976, CARM received one report of foetal malformation possibly associated with the use of Amenorone Forte, however no product name was identified.~~
- The average monthly sales of Amenorone Forte in New Zealand during 1974 was 252 units.
- ~~Communication on the withdrawal of these products from the New Zealand market is available here~~

Commented [RP1]: Got a letter from Bayer; would need to talk to them first if going to publish

Commented [RP2]: This is based on the minutes from the Drug Assessment Advisory Committee

Commented [RP3]: The medicine strengths in the report don't quite match up with the strengths in Amenorone Forte, but this may have been a transcription error

Commented [RP4]: From records – probably need to check with Sanofi Aventis (company that took over Roussel) that this can be published

Commented [RP5]: Link to relevant information from records [this more relates to the OIA, but could include in future]

During this process, we have been encouraging women who may have experience of being prescribed hormone-based pregnancy testing products such as Primodos to report their concerns and we have also been working closely with the Centre for Adverse Reactions Monitoring (CARM) in Dunedin.

http://www.medsafe.govt.nz/profs/PUarticles/ADRreport.htm

Any concerns can be reported directly to the Ministry, and can also be referred to CARM for reporting of possible adverse events.

Additionally, it's important to acknowledge that the international information surrounding Primodos is currently being formally reviewed by a working group in the United Kingdom.

Medsafe and the Ministry of Health will be following that review closely to learn what implications there might be for women who may have received the product in this country.

Through its memorandum of understanding with the Medicines & Healthcare products Regulatory Agency (MHRA), Medsafe can receive information directly from the UK regulator.

Medsafe is also happy to make available to the working group any and all information from New Zealand which may be useful.

We'll continue to provide updated additional information as it becomes available and would advise any members of the public who may have specific concerns about Primodos to contact Healthline - 0800 611 116 - or email the Ministry on info@health.govt.nz

Sent by: Charlotte Gendall/MOH

08/05/2017 02:16 p.m.

To: Rowan Pollock/MOH@MOH, Chris James/MOH@MOH,
cc: Peter Abernethy/MOH@MOH,
bcc:

Subject: Fw: Hormonal pregnancy tests

Hi Rowan and Chris - I think that looks good. My thoughts are to simply update the following link by removing the existing text, and inserting the new content (with a note that we have provided additional material).

I dont think we need the historic documents but the letter to Medsafe might be a useful attachment.

http://www.health.govt.nz/news-media/news-items/statement-primodos

I can work with the webteam to get a draft ready for you to look at? I will talk to them about it when you are happy..

Charlotte Gendall
Senior Media Advisor
Ministry of Health
DDI: Section 9(2)(a)
MOB

http://www.health.govt.nz

----- Forwarded by Charlotte Gendall/MOH on 08/05/2017 02:10 p.m. -----

From: Rowan Pollock/MOH
To: Charlotte Gendall/MOH@MOH,
Date: 03/05/2017 11:57 a.m.
Subject: Hormonal pregnancy tests

Hi Charlotte

Just wanting to follow up on the Primodos (and Amenorone Forte) media statement. You made some suggestions to update the media statement (which I have attached) prior to Easter and I wanted to discuss about any further steps from here.

For your info, we were asked under the OIA to provide the Amenorone Forte records and are considering adding this to the website (but would appreciate your thoughts on this too). Could also add the Primodos records and letter from Bayer (they are alright with this, just have to redact personal information). I've attached this information so you can have a look at it. The Primodos records have not been redacted as yet.

I'd be keen to get your thoughts on this when you have some time.

Primodos Update 11 April (Gendall).docx Letter to Medsafe_Redacted.pdf

Many thanks
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | Section 9(2)(a)

Sent by: Ana Blake-Kelly/MOH

09/05/2017 11:54 a.m.

To: Charlotte Gendall/MOH@MOH,
cc: WebTeam/MOH@MOH, Rowan Pollock/MOH@MOH, Chris James/MOH@MOH,
bcc:
Subject: Re: Fw: Hormonal pregnancy tests - updating for monday / tuesday ? in PREVIEW

Hi
Here's the link in Preview:

<https://preview.health.govt.nz/news-media/news-items/statement-hormonal-testing-preparations>

Username: [redacted]
Password: Section 9(2)(a)

Cheers
Ana

Charlotte Gendall Hi Ana and web team - thanks for yo... 09/05/2017 09:55:04 a.m.

From: Charlotte Gendall/MOH
To: WebTeam/MOH@MOH, Ana Blake-Kelly/MOH@MOH,
Cc: Rowan Pollock/MOH@MOH, Chris James/MOH@MOH
Date: 09/05/2017 09:55 a.m.
Subject: Re: Fw: Hormonal pregnancy tests - updating for monday / tuesday ?

Hi Ana and web team - thanks for your help on this.

Here's a revised draft of the new statement we'd like to put up.

[attachment "Statement - HTPs.docx" deleted by Ana Blake-Kelly/MOH]

* note - we **wont** publish the Bayer letter I sent through previously

Hope this works, can you please copy Rowan Chris and I when the draft is reading.

Thank you.

Charlotte Gendall
Senior Media Advisor
Ministry of Health
DDI: Section 9(2)(a)
MOB: [redacted]

http://www.health.govt.nz

WebTeam Hi Charlotte I'm just checking whether... 08/05/2017 05:01:31 p.m.

From: WebTeam/MOH
To: Charlotte Gendall/MOH@MOH,
Cc: WebTeam/MOH@MOH
Date: 08/05/2017 05:01 p.m.
Subject: Fw: Hormonal pregnancy tests - updating for monday / tuesday ?
Sent by: Ana Blake-Kelly

Hi Charlotte

I'm just checking whether the updates are to the copy that appears as the News Article dated 20 March. < http://www.health.govt.nz/news-media/news-items/statement-primodos>

The copy in the draft attached appears to be to different copy compared to the article on the website. It's only showing one set of track changes.

I also need to check with one of the others about what MoH usually do in this situation when a news article is updated. I don't think we change the original published date, but the date at the bottom of the page usually gets updated.

Talk Tuesday if that's ok.

Cheers
Ana

----- Forwarded by Ana Blake-Kelly/MOH on 08/05/2017 04:56 p.m. -----

From: Charlotte Gendall/MOH
To: WebTeam/MOH@MOH,
Date: 08/05/2017 02:35 p.m.
Subject: Fw: Hormonal pregnancy tests - updating for monday / tuesday ?

Hi WebTeam - Ive had an approach from Medsafe to provide some updated information in the Primodos space. My thoughts are to simply update the following link by removing the existing text, and inserting the new content (with a note somewhere on the page that we have provided additional material).

The letter to medsafe is also available to possibly use as a downloadable attachment if you thought it was appropriate.

http://www.health.govt.nz/news-media/news-items/statement-primodos

Let me know what you think ..

Charlotte

[attachment "Primodos Update 11 April (Gendall).docx" deleted by Charlotte Gendall/MOH] [attachment "Letter to Medsafe_Redacted.pdf" deleted by Charlotte Gendall/MOH]

Sent by: Rowan Pollock/MOH

09/05/2017 04:40 p.m.

To: Amanda Taylor/MOH@MOH,
cc:
bcc:

Subject: Website publishing

Hi Amanda

There is also a media release (update to Primodos statement) in the website editor tray, that needs to go up on the Medsafe website. It has already been added to the Ministry of Health website.
It just needs to be added on the Media Releases for 2017 section (on the Publications, Recent Media Releases page) and the link on the front page removed.
I've sent the word document with the text to Becci.

Many thanks
Rowan

Rowan Pollock | Manager | Clinical Risk Management | Medsafe | Ministry of Health | Section 9(2)(a)

Fw: FYI - nz doctor - primodos
Charlotte Gendall to: Lily Chan 30/01/2018 10:50 a.m.

----- Forwarded by Charlotte Gendall/MOH on 30/01/2018 10:50 a.m. -----

From: Charlotte Gendall/MOH
To: "Angela Kenealy" [redacted], "Shannon Stewart"
Date: 27/07/2017 04:07 p.m.
Subject: FYI - nz doctor - primodos

Hi Angela and Shannon - FYI a follow up query for NZD on Primodos. Cheers Charlotte

[redacted] **NZ Doctor Primodos**
Please can I request an update on any information relevant to New Zealand about Primodos? We last heard from Medsafe about this in March, with Chris James saying the ministry was urgently working through its archives to establish the specifics of Primodos use in New Zealand – what were the findings of this search?
Mr James also said there was a memorandum of understanding with the UK's Medicines and healthcare Products Regulatory Agency who were doing a review into adverse effects during pregnancy. Have there been any outcomes of that review which have been shared with the Ministry?
If you can come back to me about this on Monday, that would be great.
Response:
Senior Media Advisor Charlotte Gendall

DRAFT RESPONSE
Since the initial reports emerged earlier this year, the Ministry of Health and Medsafe have consistently encouraged women who may have experience of being prescribed hormone-based pregnancy testing products such as Primodos to report their concerns.

As appropriate, individual cases have been referred to the Centre for Adverse Reactions Monitoring based in Dunedin (CARM) for reporting of possible adverse events.

Both the Ministry and Medsafe regard any possible adverse events extremely seriously.

To date, a total of 10 instances where Primodos may have been used have been reported to CARM. Unfortunately because of the length of time now elapsed the reports have little confirmed detail - including whether Primodos was actually taken.

Based on information from Bayer, the company which distributed Primodos, the medicine was available in New Zealand from 1966 to 9 June 1975 when it was withdrawn from pharmacies.

Similar action was taken by the Australian authorities in 1976. Unfortunately Bayer is unable to provide sales data but the company believes that by 1975 sales of Primodos were low.

Medsafe has established that general practices and pharmacies were alerted via a clinical newsletter issued by the Department of Health in 1975. Pharmacies were also notified via the

company's recall of the product.

Medsafe continues to seek information relating to the use of this product in New Zealand.

Medsafe continues to closely follow the review by the working group in the U.K. and will make available all information it has on use in New Zealand if this is helpful.

ENDS

Charlotte Gendall
Senior Media Advisor
Ministry of Health
DDI: Section 9(2)(a)
MOB:

http://www.health.govt.nz

Sent by: Chris James/MOH
06/10/2017 01:00 p.m.

To: Jo Prankerd/MOH@MOH,
cc:
bcc:

Subject: Re: Proposed changes to MOH Statement on Hormonal Testing Preparations

Hi Jo

Wording looks fine.

Chris

Chris James | Group Manager | Medsafe | Ministry of Health | Section 9(2)(a)

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Jo Prankerd Hi Chris I spoke with Susan yesterday... 06/10/2017 11:51:35 a.m.

From: Jo Prankerd/MOH
To: Chris James/MOH@MOH,
Date: 06/10/2017 11:51 a.m.
Subject: Proposed changes to MOH Statement on Hormonal Testing Preparations

Hi Chris

I spoke with Susan yesterday about amending the wording on the MOH and Medsafe websites regarding hormonal testing preparations because in the last OIA to Section 9(2)(a) we said we would review the current wording, specifically bullet point 4.

This is the current wording (http://www.health.govt.nz/news-media/news-items/statement-hormonal-testing-preparations):

We have established that:

- Primodos first appeared in New Ethicals in 1966 – suggesting it was available and prescribed in New Zealand from that time.
- Minutes from the Drug Assessment Advisory Committee in 1975 recommended that Primodos should be withdrawn from the market in New Zealand. This was due to "reports received from overseas that birth defects have occurred when hormonal pregnancy tests have been taken in early pregnancy".
- In May 1975 the then Department of Health issued a clinical services letter advising that it was withdrawing systemic hormonal testing preparations for pregnancy testing from the New Zealand market. It did not specifically identify Primodos.
- *The NZ Department of Health withdrew Primodos from the market and removed stock from pharmacies in June 1975.*
- There is no information on how many patients were prescribed this product. Medsafe has contacted Bayer to obtain information if it is available however the company has advised it unable to do so at this time.
- Amenorone Forte was another hormone based pregnancy testing preparation available in New Zealand. It first became available in 1968 and was withdrawn at the same time as Primodos, in June

1975.

We thought bullet point 4 could be expanded to:

- The NZ Department of Health withdrew Primodos from the market in June 1975.
- A recall letter was sent by the Pharmaceutical Manufacturers' Association to wholesalers, retail chemists, public and private hospitals according to the Department of Health's recall code of the time.
- The recall was the responsibility of the drug companies marketing the preparations.

Are you ok with this wording? When you get the chance please let me know if you'd like to make any changes and then I'll talk to Charlotte in Comms about getting it updated on the MOH website.

Thank you!

Jo

Jo Prankerd | Senior Advisor Pharmacovigilance | Clinical Risk Management | Medsafe | Ministry of Health | Section 9(2)(a)

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