20 May 2019

Response to your Request for Official Information

I refer to your requests to the Ministry of Health (the Ministry) of 27 March 2019 under the Official Information Act 1982 (the Act) for:

"This is a request for information around registration of the drug OxyContin (oxycodone) by Medsafe, I believe around 2001, and the approval for funding by Pharmac, I believe in 2005, as well as subsequent reports about the medicine.

Please provide the following:

(1) Briefing papers on Oxycontin referred to during the registration process
(2) Any warnings about the drug raised by outside agencies or individuals or internal staff
(3) All email correspondence on the issue by Medsafe’s group director
(4) Submissions by the company licensed to sell the drug in NZ
(5) A summary of the final decision to register the drug

Relating to funding of the drug:

(6) Briefing papers that were considered by officials during this process
(7) any warning material from outside agencies or individuals or internal staff
(8) All email correspondence by Medsafe’s group director on this issue
(9) Submissions by the company licensed to sell the drug
(10) A summary of the final decision to fund the drug

Subsequent events

(11) All correspondence, including emails, reports, memos, letters, discussing concerns about the drug, including any calls for it to be withdrawn, from the time it was funded to today.

This should include any concerns about the way the drug was being marketed by its NZ licence holders"

On 17 April 2019, the Ministry provided you a document listing submissions and requested a refinement to part four of your request based on the submission list. You agreed to withdraw part four of the request.

On 23 April 2019, you again agreed to refine the scope of your request to limiting the request to information since 2014:
“This is a request for information around registration of the drug OxyContin (oxycodone) by Medsafe, since 2014, and the approval for funding by Pharmac, since 2014, as well as subsequent reports about the medicine.

Please provide the following:

(1) Briefing papers on Oxycontin referred to during the registration process
(2) Any warnings about the drug raised by outside agencies or individuals or internal staff
(3) All email correspondence on the issue by Medsafe's group director
(4) WITHDRAWN
(5) A summary of the final decision to register the drug

Relating to funding of the drug:

(6) Briefing papers that were considered by officials during this process
(7) Any warning material from outside agencies or individuals or internal staff
(8) All email correspondence by Medsafe’s group director on this issue
(9) Submissions by the company licensed to sell the drug
(10) A summary of the final decision to fund the drug

Subsequent events

(11) All correspondence, including emails, reports, memos, letters, discussing concerns about the drug, including any calls for it to be withdrawn, from the time it was funded to today.
   This should include any concerns about the way the drug was being marketed by its NZ licence holders.”

On 29 March you advised the Ministry that the same request had been made to both PHARMAC and the Health Quality and Safety Commission (HQSC). Accordingly, parts of the request where the Ministry believes the information is more likely to be held by PHARMAC or HQSC have not been transferred.

Response to your request

(1) Briefing papers on Oxycontin referred to during the registration process

This part of your request is refused pursuant to section 18(e) of the Act, as the document alleged to contain the information requested does not exist.

(2) Any warnings about the drug raised by outside agencies or individuals or internal staff

The Ministry has identified six documents within the scope of your request. A Centre for Adverse Reactions Monitoring (CARM) report with the identification number 115219 has been partially published on the Medsafe website via the link below. Accordingly, this document is refused under section 18(d) of the Act, as the information is already publicly available.

Please note that parts of the original full report have not been published pursuant to section 9(2)(a) of the Act, to protect privacy.

https://medsafe.govt.nz/profs/PUArticles/Sep2015/Oxycodone&Hyperalgesia.htm

Five pieces of correspondence related to the 169th Medicines Adverse Reactions Committee (MARC) meeting on 9 March 2017 are also within the scope of your request. Parts of these
documents have been withheld under section 9(2)(a) of the Act, to protect privacy. The minutes for this meeting are published at:

https://medsafe.govt.nz/profs/MARC/Minutes.asp

Medsafe actively monitors all public releases of information from other international medicine regulators. The below link may be of interest to you:


Other potential safety concerns (not necessarily warnings) have been raised in discussion with other international medicines regulators. However, these discussions are undertaken on the condition of an obligation of confidence, therefore details of the discussions are withheld under section 9(2)(ba)(i) of the Act, to protect information which is subject to an obligation of confidence, where the making available of the information would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should be continued to be supplied.

(3) **All email correspondence on the issue by Medsafe's group director**

Four emails have been identified that are within scope of your request. Parts of the emails have been withheld under section 9(2)(a) of the Act, to protect privacy.

(5) **A summary of the final decision to register the drug**

A “final recommendation” from the assessment report for the application for a new formulation of Oxycontin, which was approved in 2014, is within the scope of this request. The final recommendation is released to you in full. Please note that the Final Recommendation statement follows a standard format and, although not mentioned in this statement, the clinical safety and efficacy of the product was also assessed and found to be satisfactory according to international standards.

(6) **Briefing papers that were considered by officials during this process**

(7) **Any warning material from outside agencies or individuals or internal staff**

(8) **All email correspondence by Medsafe's group director on this issue**

(9) **Submissions by the company licensed to sell the drug**

(10) **A summary of the final decision to fund the drug**

(11) **All correspondence, including emails, reports, memos, letters, discussing concerns about the drug, including any calls for it to be withdrawn, from the time it was funded to today**

Parts six, seven, nine, ten and eleven of your request are refused under section 18(g) of the Act, as the information requested is not held by the Ministry. We believe the information requested is more likely to be held by PHARMAC or HQSC. However, as the same requests have already been made to both PHARMAC and HQSC we do not intend to transfer your request.

Part eight of your request is refused under section 18(e) of the Act, as the document alleged to contain the information requested does not exist or, despite reasonable efforts to locate it, cannot be found.
I trust that this information fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review any decisions that have been made in relation to this request.

Yours sincerely

[Signature]

Chris James
Group Manager
Medsafe
### Appendix 1: List of documents for release

<table>
<thead>
<tr>
<th>#</th>
<th>Date</th>
<th>Title</th>
<th>Decision on release</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2 September 2015</td>
<td>CARM report 115219</td>
<td>Refused under section 18(d) of the Act, as the document is already publicly available.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Parts withheld under section 9(2)(a) of the Act, to protect privacy.</td>
</tr>
<tr>
<td>2</td>
<td>12 April 2017</td>
<td>Letter: Updates to data sheets for opioid and benzodiazepine containing medicines – Teresa Taylor</td>
<td>Parts withheld under section 9(2)(a) of the Act, to protect privacy.</td>
</tr>
<tr>
<td>3</td>
<td>12 April 2017</td>
<td>Email: Recommendation from the Medicines Adverse Reactions Committee meeting - HQSC</td>
<td>Parts withheld under section 9(2)(a) of the Act, to protect privacy.</td>
</tr>
<tr>
<td>4</td>
<td>12 April 2017</td>
<td>Email: Recommendation from the Medicines Adverse Reactions Committee meeting - BPAC</td>
<td>Parts withheld under section 9(2)(a) of the Act, to protect privacy.</td>
</tr>
<tr>
<td>5</td>
<td>2 May 2017</td>
<td>Letter: Recommendations from the 169th Medicines Adverse Reactions Committee Meeting – Dr Kenneth Clark</td>
<td>Released in full.</td>
</tr>
<tr>
<td>6</td>
<td>2 May 2017</td>
<td>Letter: Recommendations from the 169th Medicines Adverse Reactions Committee Meeting – Helen Morgan-Banda</td>
<td>Released in full.</td>
</tr>
<tr>
<td>7</td>
<td>17 February 2014</td>
<td>Email: Oxydone</td>
<td>Released in full.</td>
</tr>
<tr>
<td>8</td>
<td>12 March 2014</td>
<td>Email: Oxycodone – Key lines</td>
<td>Released in full.</td>
</tr>
<tr>
<td>9</td>
<td>12 March 2014</td>
<td>Email: mundipharma questions</td>
<td>Parts withheld under section 9(2)(a) of the Act, to protect privacy.</td>
</tr>
<tr>
<td>10</td>
<td>14 July 2014</td>
<td>Email: Final draft response to LA Times on oxycodone – Stewart, do you want to decline an interview?</td>
<td>Parts withheld under section 9(2)(a) of the Act, to protect privacy.</td>
</tr>
<tr>
<td>11</td>
<td>17 April 2014</td>
<td>Final Recommendation – Oxycontin (New Formulation) – Registration</td>
<td>Released in full.</td>
</tr>
</tbody>
</table>
12 April 2017

Teresa Taylor
Head of Regulatory
Mundipharma NZ Ltd
ttaylor@pharmaco.co.nz

Dear Teresa

Updates to data sheets for opioid and benzodiazepine containing medicines

In March 2017 the Medicines Adverse Reactions Committee (MARC) reviewed the risks of serious side effects from the concomitant use of opioids, benzodiazepines and other central nervous system depressants. The minutes of the meeting will be published on the Medsafe website before the end of April (www.medsafe.govt.nz/profs/MARC/Minutes.asp).

The MARC review was prompted by research from the United States Food and Drug Administration (US FDA) which showed serious risks (including death) were associated with the combined use of opioids and benzodiazepines. The MARC considered that new information should be included in the data sheets of relevant products. The MARC recommended that similar wording to that proposed by the FDA should be used.

Mundipharma NZ Ltd are therefore kindly requested to update the data sheets with the following information:

Warnings and Precautions

Profound sedation, respiratory depression, coma, and death may result from the concomitant use of [TRADENAME] with benzodiazepines or other CNS depressants (e.g., non-benzodiazepine sedatives/hypnotics, anxiolytics, tranquilizers, muscle relaxants, general anaesthetics, medicines with antihistamine-sedating actions such as antipsychotics, other opioids, alcohol). Because of these risks, reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.

Observational studies have demonstrated that concomitant use of opioid analgesics and benzodiazepines increases the risk of medicine-related mortality compared to use of opioid analgesics alone. Because of similar pharmacological properties, it is reasonable to expect similar risk with the concomitant use of other CNS depressant drugs with opioid analgesics [see Section 4.5 Interactions with other medicines and other forms of interaction].
If the decision is made to prescribe a benzodiazepine or other CNS depressant concomitantly with an opioid analgesic, prescribe the lowest effective dosages and minimum durations of concomitant use. In patients already receiving an opioid analgesic, prescribe a lower initial dose of the benzodiazepine or other CNS depressant than indicated in the absence of an opioid, and titrate based on clinical response. If an opioid analgesic is initiated in a patient already taking a benzodiazepine or other CNS depressant, prescribe a lower initial dose of the opioid analgesic, and titrate based on clinical response. Follow patients closely for signs and symptoms of respiratory depression and sedation.

Advise both patients and caregivers about the risks of respiratory depression and sedation when [TRADENAME] is used with benzodiazepines or other CNS depressants (including alcohol and illicit drugs). Advise patients not to drive or operate heavy machinery until the effects of concomitant use of the benzodiazepine or other CNS depressant have been determined. Screen patients for risk of substance use disorders, including opioid abuse and misuse, and warn them of the risk for overdose and death associated with the use of additional CNS depressants including alcohol and illicit drugs [see Section 4.4 Warnings and Precautions].

**Interactions with other medicines and other forms of interaction**

<table>
<thead>
<tr>
<th>Benzodiazepines and other Central Nervous System (CNS) Depressants</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Impact</strong></td>
</tr>
<tr>
<td>Due to additive pharmacologic effect, the concomitant use of benzodiazepines or other CNS depressants including alcohol, increases the risk of respiratory depression, profound sedation, coma, and death.</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
</tr>
<tr>
<td>Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients closely for signs of respiratory depression and sedation [see Section 4.4 Warnings and Precautions].</td>
</tr>
<tr>
<td><strong>Examples</strong></td>
</tr>
<tr>
<td>Benzodiazepines and other sedatives/hypnotics, anxiolytics, tranquilizers, muscle relaxants, general anaesthetics, drugs with antihistamine-sedating actions such as antipsychotics, other opioids, alcohol.</td>
</tr>
</tbody>
</table>

As you are aware the outcome of Medsafe’s data sheet consultation has been published at [www.medsafe.govt.nz/consultations/OutcomeDatasheetFormat.asp](http://www.medsafe.govt.nz/consultations/OutcomeDatasheetFormat.asp). All data sheets provided with a CMN must now use the new data sheet format. If there is a published CMI please also update this in line with the data sheet changes. I would be grateful if you can please submit the appropriate CMN at your earliest opportunity and if you have any queries or comments, please do not hesitate to contact me.

Yours sincerely
Dear Iwona

I am writing to you on behalf of the Medicines Adverse Reactions Committee (MARC).

At the 169th meeting of the MARC held on 9 March 2017, the MARC discussed the risk of serious side effects including death from the concomitant use of opioids and benzodiazepines. The MARC also acknowledged HQSC’s work in this area.

The MARC recommended that a number of actions should be undertaken. I have listed the recommendations that relate to this topic below for your information:

- **Recommendation 5** - The Committee recommended Medsafe requests the sponsors of benzodiazepine and opioid products update the data sheets on the concomitant use of CNS depressants, including opioids and benzodiazepines.
- **Recommendation 6** - The Committee recommended Medsafe communicates the outcome of this discussion in a future edition of *Prescriber Update*.
- **Recommendation 7** - The Committee recommended the Medicines Classification Committee considers strengthening the classification of codeine when contained in cough and cold products and to revisit the classification of other opioids contained in cough and cold products.
- **Recommendation 8** - The Committee recommended Medsafe communicates with PHARMAC on restricting the funding of opioids and sedative hypnotics that can be obtained on each prescription.
- **Recommendation 9** - The Committee recommended Medsafe communicates with the Best Practice Advocacy Centre about an education programme on co-prescribing of opioids and sedative hypnotics and to draw their attention to the CDC recommendations for prescribing opioids for chronic pain outside of active cancer, palliative and end of life care.
- **Recommendation 10** - The Committee recommended Medsafe communicates with the Health Quality & Safety Commission to acknowledge their work in this area and to draw their attention to the Committee’s discussion on this topic as well as the CDC recommendations for prescribing opioids for chronic pain outside of active cancer, palliative and end of life care.
- **Recommendation 11** - The Committee recommended Medsafe communicates this discussion to DHB hospitals through the national Chief Medical Officers group, highlighting the Committee’s concerns that prescribing of opioids, benzodiazepines and other CNS depressants concomitantly are often initiated in hospitals and this may continue into primary care. Attention should be drawn to the CDC...
recommendations for prescribing opioids for chronic pain outside of active cancer, palliative and end of life care.

- Recommendation 12 - The Committee recommended communication with the Royal New Zealand College of General Practitioners to endorse an audit tool for general practitioners to check their opioid prescribing and co-prescribing practices.

Further information can be found in the minutes for this meeting which will be published on the Medsafe website shortly (www.medsafe.govt.nz/profs/MARC/Minutes.asp).

As mentioned, one of the recommendations was to contact HQSC to draw attention to a 2016 guideline for prescribing opioids for chronic pain that has been published by the United States Centers for Disease Control and Prevention (CDC). This guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care and end-of-life care (www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm). The MARC considered that this guideline may be of interest to you.

If you have any queries please don’t hesitate to contact me.

Kind regards

Chris

Chris James | Group Manager | Medsafe | Ministry of Health | (04) 819 6810 | 5(2)[a]
Hi Murray

I am writing to you on behalf of the Medicines Adverse Reactions Committee (MARC).

At the 169th meeting of the MARC held on 9 March 2017, the MARC discussed the risk of serious side effects including death from the concomitant use of opioids and benzodiazepines.

The MARC recommended that a number of actions should be undertaken. I have listed the recommendations that relate to this topic below for your information:

- **Recommendation 5** - The Committee recommended Medsafe requests the sponsors of benzodiazepine and opioid products update the data sheets on the concomitant use of CNS depressants, including opioids and benzodiazepines.

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- **Recommendation 11** - The Committee recommended Medsafe communicates this discussion to DHB hospitals through the national Chief Medical Officers group, highlighting the Committee's concerns that prescribing of opioids, benzodiazepines and other CNS depressants concomitantly are often initiated in hospitals and this may continue into primary care. Attention should be drawn to the CDC recommendations for prescribing opioids for chronic pain outside of active cancer, palliative and end
of life care.

- Recommendation 12 - The Committee recommended communication with the Royal New Zealand College of General Practitioners to endorse an audit tool for general practitioners to check their opioid prescribing and co-prescribing practices.

Further information can be found in the minutes for this meeting which will be published on the Medsafe website shortly (www.medsafe.govt.nz/profs/MARC/Minutes.asp).

One of the recommendations was to contact BPAC to request an education programme on avoiding co-prescribing of opioids and sedative hypnotics (including zopiclone). Alternatively the MARC considered that general practitioners could be referred to the United States Centers for Disease Control and Prevention guideline for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care and end-of-life care (www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm).

If you have any queries please don’t hesitate to contact the MARC secretariat Jo Prankerd at Jo_Prankerd@moh.govt.nz.

Kind regards

Chris

Chris James | Group Manager | Medsafe | Ministry of Health | (04) 819 6810 | 9(2)(a)
2 May 2017

Dr Kenneth Clark
Chair of the Chief Medical Officer Group

Ken.Clark@midcentraldhb.govt.nz

Cc: Dr Andrew Simpson, Acting Chief Medical Officer, Ministry of Health

Dear Dr Clark

Recommendations from the 169th Medicines Adverse Reactions Committee meeting

I am writing to you as chair of the Medicines Adverse Reactions Committee (MARC) on behalf of the Committee.

On 9 March 2017 the MARC reviewed the risks of harm associated with the concomitant use of opioids and benzodiazepines. This review was prompted by information released by the Food and Drug Administration in the United States (US). The US information showed there was an increased risk of death in patients taking this combination of medicines.

The MARC recommended that a number of actions should be undertaken (www.medsafe.govt.nz/profs/MARC/Minutes.asp).

The MARC also noted that prescribing of opioids in combination with benzodiazepines and other CNS depressants is often initiated in hospitals. Therefore the Committee wished to make you aware of this serious medicine safety concern and new guidelines issued by the United States Centers for Disease Control and Prevention (CDC). This 2016 guideline includes recommendations for prescribing opioids for chronic pain outside of active cancer, palliative and end of life care. The MARC considered it may be useful for this document to be communicated with DHB hospitals (www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm).

The Committee and I feel that the CMOs of the DHBs are best placed to influence the use of these medicines in secondary care to reduce the risk of harm to patients.
Further information can be found in the minutes of this meeting published on the Medsafe website (www.medsafe.govt.nz/profs/MARC/Minutes.asp). Additionally, for your information I have attached a copy of the paper that was discussed at the 169\textsuperscript{th} MARC meeting in March 2017.

If you have any queries, don't hesitate to contact me via the Medsafe secretariat for the MARC at MedsafeADRquery@moh.govt.nz.

Yours sincerely

[Signature]

Associate Professor David Reith
Chair
Medicines Adverse Reactions Committee
2 May 2017

Helen Morgan-Banda  
Chief Executive Officer  
The Royal New Zealand College of General Practitioners  
Level 4  
50 Customhouse Quay  
Wellington

rnzcmp@rnzcmp.org.nz

Dear Ms Morgan-Banda

Recommendations from the 169th Medicines Adverse Reactions Committee meeting

I am writing to you as chair of the Medicines Adverse Reactions Committee (MARC) following a review of the concurrent use of opioids and benzodiazepines.

On 9 March 2017 the MARC reviewed the risks of harm associated with the concomitant use of opioids and benzodiazepines. This review was triggered by new information published by the Food and Drug Administration in the United States. This new information showed that patients taking this combination of medicines were at increased risk of death.

The MARC considered that the serious risks associated with the combined use of opioids and benzodiazepines required that a number of actions should be taken in New Zealand. The MARC considered that general practitioners may find that many of their patients are initiated on this combination of medicines in hospital and would find additional support from the college in this area useful.

The Committee also considered that an audit tool for checking opioid prescribing produced and/or endorsed by the Royal New Zealand College of General Practitioners considers would be helpful.

Further information on this topic can be found in the minutes of this meeting published on the Medsafe website (www.medsafe.govt.nz/profs/MARC/Minutes.asp) and on the FDA website (www.fda.gov/Drugs/DrugSafety/ucm518473.htm). In addition, I have attached a copy of the paper that was discussed by the MARC at the 169th meeting in March.
If you have any queries, don't hesitate to contact me via the Medsafe secretariat for the MARC at MedsafeADRquery@moh.govt.nz.

Yours sincerely

[Signature]

Associate Professor David Reith
Chair
Medicines Adverse Reactions Committee
HI Chris

Thank you for the opportunity to comment on this.

It is difficult to set clear rules about look-a-like, sound-a-like (LASA) medicines because there is naturally a degree of opinion in the matter. By this I mean what is confusing to one person may be perfectly clear to another. During the new medicine assessment, PRB tries to be consistent, apply the legislation and guidelines, and overall retain pragmatism to ensure fairness to all applicants while ensuring medicines cannot be mixed up. The policy on naming (such as it is) is in the labelling guideline (part 5 of the NZRGM) although we also refer to international guidance such as issued by the MHRA and the WHO policy on non-proprietary names.

The naming of medicines is only loosely referred to in the Act and Regulations. It states that the label of a medicine must have the appropriate designation and a trade name (if any). However, medicines are not items of general commerce and it is important that the designation of the medicine is unique and the name is not misleading in terms of the intent or purpose of that medicine. When considering proprietary names (i.e. made up names that are not related to the active ingredient) it is relatively straight forward. However the same principles cannot apply to non-proprietary names which are comprised of the active ingredient and a company identifier. The situation is also complicated by generic companies developing proprietary names which are a derivation of the active ingredient plus a company identifier. In this case we need to also ensure the name fits with the WHO policy on trade names not infringing international policy on naming of active ingredients (INN). So in reality we have to consider each name on a case by case basis and there are no hard and fast rules.

Medsafe recognises that the name of a medicine must minimise the issues with LASA. It is important that the name of a medicine looks unique when spoken and written. Over the last 10 years it has become important that the medicines are not confused in electronic prescribing (using drop down boxes). Medsafe tends to pay most attention to the start of the medicine name because human nature is such that the start of the name is the most important (first 5 or 6 letters). It is also important that there is a substantial difference between genuine proprietary names so that there are not 2 medicines on the market whose name differs by one or two letters. Obviously this is less important when differentiating generic medicines which contain the same active, are the same dose form and are bioequivalent - which is why there are so many names that are the INN plus a company acronym.

With regard to "Oxydone BNM" we considered that this name was unique and unlikely to be confused with other medicines on the market with negative consequences. The name is derived from the active ingredient (oxycodone) plus a company identifier (BNM). The active ingredient appears below the trade name as does the mode of action, "controlled release" (see label linked). The innovator to Oxydone is OxyContin. We consider that the names are easily differentiated and both are distinguishable from the immediate release tablet "OxyNorm" by the statements "controlled release" and "modified release".

There are several medicines that start with "oxy" but there are none that look similar enough to "Oxydone" that would give cause for concern.

Considering the tail end of medicine names in terms of mitigating LASA is more difficult. We give consideration to names that start with the same three letters and end with the same four letters and we will look at how different the middle part is. However we do not insist on unique endings for names. We do not consider Oxydone and Biodone to be confusing. Biodone is an oral solution that contains
methadone supplied by Biomed. The active ingredients and dose form will be on the label so the designation of the medicine will be unique. There is also a Douglas methadone solution which is called Pallidone.

We consider that Bio and Oxy (and Palli) are sufficiently different when written and spoken that the names are acceptable. We would not consider that "done" should only be associated with methadone because we would regard "done" and "methadone" as having a strong association in the mind of the prescriber (refer to guidelines on umbrella branding). Given that there are many other actives that end in "done" we would not consider there was any greater confusion between Biodone and Oxydone than between Oxydone and methadone, risperidone or primidone when used as part of the trade name.

Hope this makes sense. Happy to discuss our polices in more detail prior to your meeting.

Regards

Sarah

<table>
<thead>
<tr>
<th>Date</th>
<th>Author</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/02/2013</td>
<td>Frances_Greer</td>
<td>Oxydone BNM NMA TT50-9155 - LABELs</td>
</tr>
</tbody>
</table>

Sarah Reader
Manager Product Regulation
Medsafe
Clinical Leadership, Protection and Regulation Business Unit
Ministry of Health
DDI: 048196836
Fax: 04 819 6806

http://www.moh.govt.nz
mailto:Sarah_Reader@moh.govt.nz

From: Chris James/MOH
To: Stewart Jessamine/MOH@MOH, Sarah Reader/MOH@MOH
Cc: 
Date: 14/02/2014 03:46 p.m.
Subject: Oxydone

Hi Stewart and Sarah

The HQSC EAG is still a little worked up about Oxydone issue (even though it is largely resolved now from my understanding) - so I need some help please.

I’ve got France having a look at a couple of things to confirm facts as we have a meeting in Auckland on Thursday next week (matrix, bioequivalence and consistency of data sheet with innovator).

What I wanted to know is what has been said to HQSC about this issue in previous meetings or correspondence (I want to be consistent and represent Medsafe’s position on this).
My recollection is that oxydone was considered during evaluation not to be a risk in terms of similar names (such as biodone) - can you please confirm Sarah and provide the criteria your evaluators use to assess medicine names.

I think the best approach is to go to the meeting and confirm our process and what was assessed to help educate the group about medicines regulation.

Thanks
Chris

Chris James
Manager
Clinical Risk Management
Medsafe
Ministry of Health

DDI: 04 819 6810
http://www.medsafe.govt.nz
mailto:Chris_James@moh.govt.nz
Thanks Peter.

Cheers,

Anna

(Acting for Jannel Carter)

Hi Anna and Bill,

Please see key lines for oxycodone. Interview is tomorrow with Dr Jessamine. Cheers Peter

Oxycodone has been assessed as fit for purpose as a powerful pain relief medicine for use in patients with severe pain in whom morphine is not tolerated or is not suitable. Oxycodone has similar side effects to morphine.

There has been a rapid increase in its use following its introduction, but recently prescriptions have declined following the promotion of best practice guidelines to GPs last year.

There is not any substantive evidence of concern of abuse of oxycodone, in comparison with other strong pain relief medicines from Police or other regulatory agencies.

There are appropriate controls in place including surveillance of dispensing information; investigation of unusual prescribing patterns; collecting and sharing with doctors and pharmacists information about known drug-seeking individuals; and restricting known drug users access to only one GP.
Hi Stewart

An application from Mundipharma for a new formulation of their oxycodone medicine, Oxycontin modified release tablets was received on 17 September 2012. The application is for full assessment and the company did not request priority review. Therefore the application is progressing in accordance with Medsafe’s standard time lines for new, prescription medicines (http://www.medsafe.govt.nz/regulatory/EvaluationTimeframesAndRegistrationSituation.asp).

For this specific application, the following steps have been completed.
The application was assessed and several issues and concerns raised.
The company was requested to respond to these issues and concerns on 28 March 2013.
A response was received on 7 October 2013 and was assessed. It was determined that the issues and concerns had not been satisfactorily resolved.
A second request to resolve the issues was sent to the company on 5 December 2013
A further response has been received from the company on 27 February and is awaiting assessment.

Regards

Sarah

Sarah Reader
Manager Product Regulation
Medsafe
Clinical Leadership, Protection and Regulation Business Unit
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http://www.moh.govt.nz
mailto:Sarah_Reader@moh.govt.nz

Stewart Jessamine  Sarah/Haley can you look at the statement bel... 12/03/2014 01:17:51 p.m.

From: Stewart Jessamine/MOH
To: Sarah Reader/MOH@MOH, Haley Ataera/MOH@MOH,
Date: 12/03/2014 01:17 p.m.
Subject: Fw: mundipharma question

Sarah/Haley can you look at the statement below with respect to the new formulation of mundipharmas oxycodone. What is the status of this application? It looks to me that we have had 2 RFIs (with company taking 6 months to get back to us on the first RFI) and we are getting close to the end of the process.
Hi Stewart

I've told Jehan we'll get something through to him later today on that MundiPharma question.

Can we say something along the lines of:

'MundiPharma lodged an application with Medsafe to ........ in September 2012.

The process has involved MedSafe going back to the applicant with a number of questions, and it is now in the final stages of being considered (?)

Erina O’Donohue
Senior Media Advisor
Ministry of Health
DDI: 04 496 2349
Mobile: 9(2)(a)
Tues-Fri, 9am - 5pm

http://www.health.govt.nz
mailto:erina_odonohue@moh.govt.nz
QUERY

Hello. My name is Scott Glover. I’m a reporter with the Los Angeles Times.

Here’s what I’d like to know:

Is OxyContin currently available in New Zealand? If so, which milligram strengths are available?

Does Mundipharma have an application pending for the reformulated version of the drug? If so, what is the status of that application? Which milligram strengths would be available in the reformulated version if/when that is approved?

If possible, I’d also like to speak with someone from your agency who is knowledgeable about the problem of opiate abuse and steps being taken to address it.

Thanks in advance for your help on this matter.

I can be reached via this email or on my cell phone:

Scott Glover, staff writer
Los Angeles Times

RESPONSE: To be attributed to Dr Stewart Jessamine, Group Manager, Medsafe (note that Medsafe is part of the Ministry and is the medicines and medical device regulator in New Zealand)

All medicines have benefits and risks, and these have to be considered for each patient. There is a legitimate role for opiates, including oxycodone, in the treatment and management of acute and chronic pain.

Recent data shows prescriptions for oxycodone have declined, suggesting that information being provided to prescribers (such as GPs) on the safe and effective use of opiates is having an effect.

There are appropriate controls in place for prescription medicines - including surveillance of dispensing information; investigation of unusual prescribing patterns; collecting and sharing with doctors and pharmacists information about known drug-seeking individuals; and restricting known drug users access to only one GP.
As well, PHARMAC - the New Zealand government agency which purchases drugs for use in the public health system - has provided additional information to health professionals to raise awareness of the appropriate use of oxycodone. This included articles being published in the Best Practice Journal, and the development of a resources kit for District Health Board hospitals.

Please see this link where you can search by oxycodone as the active ingredient to find the various formulations and their strengths, including those under the trade name of OxyContin.


Mundipharma had their reformulated product approved in May 2014.

You may find it of interest to see this information below regarding oxycodone, from the Best Practice Advocacy Centre. BPAC is an independent organisation that provides educational and continuing professional development programmes to medical practitioners and other health professional groups throughout New Zealand.


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Final Recommendation

All issues arising from this application and the supporting data relating to the composition, manufacture, quality control and stability of this product have now been resolved and the evaluation of this product is now complete.

The product can now be recommended for consent under section 20 of the Medicines Act 1981 for distribution in New Zealand for the following indication:

"The management of moderate to severe chronic pain unresponsive to non-narcotic analgesia."