Response to TGA scheduling delegate's interim decision and invitation for further comment for the ACMS, October 2015

[redacted]

12 October 2015

The National Drug Research Institute's (NDRI) mission is to conduct and disseminate high quality research that contributes to the primary prevention of harmful drug use and the reduction of drug-related harm in Australia. Since its inception in 1986, NDRI has become one of the largest centres of drug research and public health expertise in Australia. It is a designated World Health Organization (WHO) Collaborating Centre for Alcohol and Drug Abuse.

NDRI has an extensive track record of completing and disseminating research on Take Home Naloxone (THN). Lenton has conducted research and evidence based advocacy for wider availability of naloxone for some 15 years and has co-authored publications on this topic in academic, trade and mass media publications. He is currently a Chief Investigator on evaluations of THN programs in the ACT, NSW and WA.

Consistent with our earlier submission NDRI, along with many organisations working towards reducing drug-related harm in the community, welcomes the Therapeutic Goods Administration (TGA) delegate's interim decision is to down-schedule single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone to Schedule 3.

We note that the delegate pointed to the accumulating international evidence in support of the effectiveness of naloxone when used by laypersons to treat opioid overdose in the community setting. Specifically we were pleased to see the evaluation of the ACT ENAACT program cited in his deliberations. This is one of a number of similar trials being conducted in Australia which are due to published in 2016, and are producing remarkably similar outcomes in terms of effectiveness and lack of serious adverse effects.

Key Points:

At this point we wish to emphasise the following which we believe are issues important to address in moving towards rescheduling in February 2016:

1. **Needles.** We acknowledge the delegate's instruction regarding OTC naloxone would be supplied labelled with full and clear instructions for use, understandable by consumers.

Needles will also need to be included, typically 1x 23 gauge needle suitable for intramuscular (IM) injection per minijet®. For any existing stock, adding the needles at the pharmacy retail point may be appropriate at the short term and ideally there should be no additional cost to the consumer for this. However, into the future needles, and potentially a safe disposal container, should be included within the minijet packaging is not as part of the minijet® unit itself.

2. **Instruction materials.** The delegate has noted that new instructional materials suited for the lay-consumer will need to be developed. As noted in our previous submission those persons and government and drug consumer organisations involved in the existing take home naloxone (THN) programs in Australia will be an important resource in developing these materials. In this regard it is important to note that the OTC naloxone is likely to be accessed by a less knowledgeable and injection-savvy group (e.g. parents, other family members, non-drug using peers) than those experienced users of injectable drugs who have comprised the bulk of the participants in existing THN programs. In addition, it is likely that as the OTC naloxone program develops pain patients and others on prescribed opioid analgesics will be another potential customer group who would benefit from access to OTC. This will include the elderly and their carers. These groups will need to be considered in the development of instructional materials and there are likely to be international examples of suitable materials for reference.
3. **Training of pharmacy staff** will be important. It is likely that many pharmacies which are involved in the sale of injecting equipment and the dispensing and dosing of opioid substitution therapy are likely to be early suppliers of OTC naloxone. We understand that the Pharmaceutical Council of Australia is appropriately already starting to develop staff training modules to address OTC naloxone sale. Approaches are currently being made to them from some stakeholders involved in the existing THN programs in Australia to offer support in that endeavour.
4. **Some OTC naloxone customers will require or seek further training** in overdose prevention and management and naloxone administration. Pharmacists should also be trained to refer these customers for further training. It will be important that mechanisms for further training be developed including online and face-to-face delivery modes.
5. **Working group.** Whilst it is not crucial that all the above issues are addressed before the recommended implementation of 1 February 2016, and it is important that this date is not delayed, there is considerable work to be done. It would be ideal if there was a co-ordinated approach to this to ensure that consumer friendly instruction materials, online and face to face training for consumers and training of pharmacy staff complement each other. One possible way forward would be to convene a working group of key stakeholders with a finite time line and a goal of developing materials and supportive training to facilitate the availability of OTC naloxone. Potential stakeholders could include:
    - The Australian Pharmaceutical Council
    - The Pharmacy Guild of Australia
    - UCB, the suppliers of the naloxone minijet® and potentially other pharmaceutical companies involved in naloxone supply.

- The Australian Injecting & Illicit Drug Users League (AIVL) is the national organisation representing people who use/have used illicit drugs and is the peak body for the state and territory peer-based drug user organisations.
- Members of the Naloxone National Reference Group (NNRG), auspiced by the Centre for Research Excellence into Injecting Drug Use, CREIDU. The NNRG includes services, communities and researchers directly involved in the implementation of the existing THN programs in Australia.
- Other stakeholders who could facilitate the aim of the working group.

6. **Cost to consumer.** We support the delegate's recommendation for dual listing which means that the drug can still be provided with government subsidy if a prescription is produced. The cost of naloxone is currently listed (exclusive of dispensing fee) as A$16.90 per 400 µg/mL [redacted]. However, under the Pharmaceutical Benefits Scheme, consumers can get up to five minijets® for A$37.70, or A$6.10 on concession with a Health Care Card. While the dual listing means those accessing naloxone on prescription under Schedule 4 will still be able to access it at a discount, it is important that the retail price per unit across the counter is kept as low as possible as price will be a significant barrier to access especially for those opioid consumers who are financially disadvantaged. We wonder whether it might also be possible for those with a Health Care to access the OTC naloxone at a subsidised price. Alternatively, we note the existing provisions for continued dispensing (https://www.psa.org.au/download/guidelines/medication-management/continued-dispensing-scenarios.pdf) for Statins and the oral contraceptive device where the consumer who has presented at the pharmacist for continued dispensing of these prescription medicines is only required to pays their usual PBS/RPBS co-payment for this supply. OTC naloxone could be subject to a similar mechanism, at least allowing that patients with a previous prescription for naloxone could obtain OTC naloxone at the PBS subsidy rate.
7. **Intranasal naloxone.** Rescheduling of the pre-filled injectable naloxone preparations should not be an obstacle to newer intranasal preparations of naloxone being similarly scheduled as they become available.

Barwon Health

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Response to TGA scheduling delegate's interim decision and invitation for further comment for the ACMS, October 2015

[redacted]

Barwon Health's Drugs and Alcohol Service (DAS) treatment team provides clinical non-residential withdrawal and counselling services and injecting drug users support services for people living in the Barwon region. Under the clinical leadership of the Addiction Psychiatrist, DAS clinicians provide a range of time limited, integrated clinical and therapeutic interventions for people aged 26 years and their families above who have moderate to severe substance use disorders and co-morbid mild to moderate high prevalence mental health disorders (e.g., depression, anxiety, trauma related and personality disorders). Private GPs located on site at DAS also provide opioid replacement therapies for people with opioid dependence. Up to 700 individuals per year access this bust pharmacotherapy clinic.

DAS incorporates the provision of Naloxone as an integral part of its service delivery. We have been offering this service since December 2014.

The Therapeutic Goods Administration (TGA) delegate's interim decision is to down-schedule single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone to Schedule 3, while maintaining listing Schedule 4.

We note that the interim decision reflects the current international evidence around the safety of the drug, its effectiveness in treating opioid overdose and its low abuse liability. We also note that the interim decision notes efforts underway in Australia to make the drug more available through take-home programs. Here, results of the evaluation of the Expanding Naloxone Availability in the ACT were specifically referenced by the TGA Delegate. The final report for that evaluation found that at least 57 successful reversals with program-issued naloxone had taken place among 200 program participants, without any serious adverse events. To this we would add that many more people have been trained in similar programs across the country, with similarly positive effects. In this context we support the delegate's requirements that the labelling and packaging of Schedule 3 naloxone be made suitable for consumer use.

Although the delegate's recommendation is welcome, it is important to ensure that the benefits of rescheduling can be maximised. Cost is a barrier to accessing medications in some of the key populations for take-home naloxone; we therefore urge monitoring of naloxone cost and consideration of alternative, possibly cheaper, formulations if they were to become available. We note that the Pharmaceutical Benefits Advisory Committee recently recommended that naloxone remain listed on the Pharmaceutical Benefits Scheme. We support this decision and suggest that any change of Scheduling by the TGA should not alter this listing on the PBS, and would support mechanisms that could see subsidies provided to those on low incomes who obtain the drug over the counter (such as through continued dispensing). We would also suggest that there be a recommendation to include appropriate needles in the current pre-filled syringe packaging to ensure that people who purchase the drug are able to administer it without needing to obtain any additional equipment. Finally, we would also urge the ACMS to consider devices that allow for the intranasal administration of the drug to reduce the risks of blood borne virus transmission.

[redacted]

APSAD

Advisory Committee on Medicines Scheduling
Therapeutic Goods Administration
By email to Medicines.Scheduling@tga.gov.au

14 October 2015

Submission on the delegate's interim decision regarding the down scheduling of naloxone, October 2015

The Australasian Professional Society on Alcohol and other Drugs (APSAD) expresses its thanks to the Advisory Committee for providing an opportunity to respond to the delegate's interim decision regarding the re-scheduling of naloxone from a Schedule 4 medicine to a Schedule 3 medicine.

APSAD is Australia's leading multidisciplinary organisation for professionals involved in the alcohol and other drug field.

APSAD is dedicated to promoting improved standards in clinical practice for medical practitioners and other health professionals who deal with alcohol and other drug-related problems in the course of their work. It also provides a network of alcohol and other drug professionals in Australia, New Zealand and the Asia Pacific. The Society is also involved in promoting population health, particularly as it relates to preventive interventions concerning alcohol, tobacco, pharmaceutical products and illicit drugs.

Through its internationally recognised scientific journal, the *Drug and Alcohol Review*, and its annual Scientific Conference, APSAD provides a forum for the latest research on the nature, prevention and treatment of physical, psychological and social problems related to the use of psychoactive substances.

APSAD currently has over 380 members across Australia and around the world. The Society has particularly strong links with New Zealand and the Asia Pacific region.

Our members represent a wide range of professional disciplines including; administrators, educators, counsellors, general practitioners, nurses, physicians, psychologists, medical researchers, pharmacists, policy advisors, psychiatrists, social/behavioural researchers, and public health experts.

The interim decision to down schedule naloxone

APSAD's specific interest in this topic reflects the fact that many of our members treat people who are dependent on opioids, and others play a key role in the area of the prevention and management of opioid overdose. As such, we have had an ongoing interest in the expansion of naloxone availability in Australia.

The Therapeutic Goods Administration website clearly documents the evidence supporting the interim decision on down scheduling naloxone and has advised that they have received no objections to this. For this reason, we will not present again the evidence in support of making naloxone more readily available to potential overdose witnesses and others by means of the down-scheduling, as to do so would not add anything to the information already well synthesised in the interim decision.

We point out, however, that some of our members were active in the development and subsequent evaluation of the Expanding Naloxone Availability ACT (ENAACT) program. As was noted in the interim decision, a central finding of the evaluation of the program is that lay community members who are potential overdose witnesses can be readily trained to use naloxone to reverse opioid overdoses and are willing and able to do so within their families and communities. During the course of the evaluation, 57 reversals took place using program-

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provided naloxone, a pleasing result which has led other jurisdictions to act to make naloxone more readily available. The evaluation report also supported the down-scheduling of naloxone to Schedule 3, reflecting the need to have naloxone widely available to potential overdose witnesses.

As a consequence, APSAD fully supports the interim decision and looks forward to it being confirmed, and the new provisions coming into effect on 1 February 2016.

As was pointed out in some of the submissions provided to the Therapeutic Goods Administration during the previous phase of consultation, expanded access to naloxone includes both the physical availability of the drug as a pharmacist only medicine, and its cost as well. APSAD considers it crucial that the cost of naloxone to consumers, once it becomes a Schedule 3 medicine, be no higher than it is now under Schedule 4. We will be monitoring the situation to see what implications the decision may have for the cost to consumers, especially to potential overdose witnesses who are relatively disadvantaged financially. Developments in naloxone delivery devices and routes of administration need to be closely monitored as well.

Yours faithfully,

CREIDU

Centre for Research Excellence into Injecting Drug Use

Response to TGA scheduling delegate's interim decision and invitation for further comment for the ACMS, October 2015

[redacted]

The Centre for Research Excellence into Injecting Drug Use (CREIDU) is funded by the National Health and Medical Research Council to improve the health of people who inject drugs through research that generates new evidence and informs public health policy and practice. CREIDU brings together experts in injecting drug use from across Australia working in research, policy and practice. CREIDU wishes to make this submission on behalf of our members and key stakeholders.

CREIDU also auspices the Naloxone National Reference Group, a working group which include services and communities directly involved in the implementation of the 'take home naloxone' programs described below. CREIDU supports increasing the availability of naloxone in Australia to assist in reversing opioid overdoses which occur in the community.

The Therapeutic Goods Administration (TGA) delegate's interim decision is to down-schedule single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone to Schedule 3, while maintaining listing on Schedule 4.

In line with our earlier submission, we support the delegate's interim decision and look forward to naloxone being available as a Schedule 3 drug from February 2016.

We note that the interim decision reflects the current international evidence around the safety of the drug, its effectiveness in treating opioid overdose and its low abuse liability. We also note that the interim decision notes efforts underway in Australia to make the drug more available through take-home programs. Here, results of the evaluation of the Expanding Naloxone Availability in the ACT were specifically referenced by the TGA Delegate. The final report for that evaluation found that at least 57 successful reversals with program-issued naloxone had taken place among 200 program participants, without any serious adverse events. To this we would add that many more people have been trained in similar programs across the country, with similarly positive effects. In this context we support the delegate's requirements that the labelling and packaging of Schedule 3 naloxone be made suitable for consumer use.

Although the delegate's recommendation is welcome, it is important to ensure that the benefits of rescheduling can be maximised. Cost is a barrier to accessing medications in some of the key populations for take-home naloxone; we therefore urge monitoring of naloxone cost and consideration of alternative, possibly cheaper, formulations if they were to become available. We note that the Pharmaceutical Benefits Advisory Committee recently recommended that naloxone remain listed on the Pharmaceutical Benefits Scheme. We support this decision and suggest that any change of Scheduling by the TGA should not alter this listing on the PBS, and would support mechanisms that could see subsidies provided to those on low incomes who obtain the drug over the counter (such as through continued dispensing). We would also suggest that there be a recommendation to include appropriate needles in the current pre-filled syringe packaging to ensure that people who purchase the drug are able to administer it without needing to obtain any additional equipment. We would also support initiatives to allow naloxone provision to at-risk people by suitably-trained professionals other than pharmacists. Finally, we would also urge the ACMS to consider devices that allow for the intranasal administration of the drug to reduce the risks of blood borne virus transmission. during the use of the drug.

ATODA
Alcohol Tobacco & Other Drug Association ACT

Medicines.scheduling@tga.gov.au

ATODA's response to the Schedule delegate's interim decision for amending the Poisons Standard to have naloxone, when used for the treatment of opioid overdose, included in Schedule 3

To the Advisory Committee on Medicines Scheduling,

We note that the delegate of the Secretary of the Department of Health has given notice of their interim decision for amending the Poisons Standard to have naloxone, when used for the treatment of opioid overdose, included in Schedule 3.

The Alcohol Tobacco and Other Drug Association ACT (ATODA) is the peak body representing the non-government and government alcohol, tobacco and other drug (ATOD) sector in the Australian Capital Territory (ACT). ATODA seeks to promote health through the prevention and reduction of the harms associated with ATOD.

ATODA has been actively involved in developing and supporting Australia's first overdose management program that provides naloxone on prescription to potential overdose victims in the ACT. As referenced in the *Reasons for the scheduling delegate's interim decision and invitation for further comment for the ACMS, October 2015,* we note that the outcomes of this program conducted in the ACT support the view that easier availability of naloxone is likely to decrease the proportion of opioid overdoses resulting in death.

The delegate has clearly documented the evidence supporting this interim decision and has advised that they have received no objections to the re-scheduling.

We fully support the interim decision and look forward to it being confirmed, and the new provisions coming into effect on 1 February 2016.

As was pointed out in the submission provided to TGA during the previous phase of consultation, expanded access to naloxone includes both the physical availability of the drug as a pharmacist only medicine, and its cost as well. We will be monitoring the situation to see what implications the decision may have for the cost to consumers, especially to potential overdose witnesses who are relatively disadvantaged financially.

Additionally, Schedule 3 medications still have limited capacity for dispensing (i.e. by doctors and pharmacists). This can create unnecessary barriers to the effective rolling out of take home naloxone programs around the country and we urge the TGA to note this and suggest jurisdictions look at their own regulations in order to improve the situation to have the greatest potential to reduce opioid overdose related deaths.

Yours sincerely,

[redacted]

15 October 2015

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Sydney Medically Supervised Injecting Centre response to TGA scheduling delegate's interim decision on prepacked single use syringes of naloxone.

[redacted]

The Sydney Medically Supervised Injecting Centre welcomes the TGA delegate's interim decision to 'down schedule' the currently available single use mini jets containing 400mcg of naloxone hydrochloride to Schedule 3, with the recommendation for dual listing as Schedule 4. Given numbers of accidental opiate overdose deaths continue to increase in Australia, measures to improve the availability of this safe and effective overdose treatment are needed. There are a number of particular issues which need to be addressed to ensure success rolling out and uptake of naloxone distribution programs across Australia.

PRICE

Keeping price to a minimum will be essential. The people most affected by accidental opiate overdose in this country are a marginalised and stigmatised group on low incomes. Dual listing would allow a subsidised price, including a capped price for health care card holders. Sydney MSIC would urge the TGA to note that cost to consumers is key and thus encourage relevant drug companies to keep the over the counter cost low.

DISPENSING

The intent of improving access is clearly to improve access to this life saving medication. While the 'down scheduling' of naloxone is welcome, it is noted that the actual dispensing of the medication is still limited to a doctor or pharmacist.

In additional to doctor and pharmacy dispensing, there are many relevant services that could roll out naloxone training among their staff and participants/clients – such as Needle Syringe Programs, Opiate Substitution Treatment Services, other Alcohol and Other Drug services, hostels and other low threshold services where overdose may occur. Clearly these would be ideal settings for a scale up of naloxone distribution, and barriers to providing trained clients with naloxone itself need to be minimised.

After discussion with both the TGA and NSW Pharmaceutical Services, it appears there is no mechanism to allow authorised prescribers to delegate their authority to dispense. As far as we understand it in NSW in order for dispensing of naloxone to occur via anyone other than

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authorised prescribers then an exemption would have to be sought from NSW Health. Division 4, Clause 18, of the relevant NSW legislation deals with the dispensing of Schedule 3 medications. In part 5 there is an exemption for adrenalin use in anaphylactic emergencies. Advice from NSW Pharmaceutical Services is that with appropriate authority such an exemption could be possible for naloxone. The similarities are obvious – both medications can be administered in an emergency situation by a non-health professional with appropriate training in order to save a life. It is noted that naloxone is a far safer drug with no abuse potential and no significant dangers associated with its use.

We would strongly urge the TGA to acknowledge this situation and recommend health authorities review their own jurisdictional regulations in order to maximise the actual availability of naloxone and broaden dispensing capacity. Widespread availability is necessary to have any population impact on overdose deaths.

TRAINING

There will clearly need to be training available for pharmacists, but also for other agencies. Some customers attending for over the counter naloxone may need additional training in addition to what can be offered by a pharmacist and so pharmacies should have access to a list of local organisations where additional training is conducted. Many organisations already have training materials/instructions/packages available and should be involved in this process. As is noted in the delegate's interim decision, clear written instructions must be available with the product, and must be understandable to consumers.

NEEDLE TIPS

The currently available single use mini jet of naloxone does not include a needle tip in order for the drug to actually be administered. Currently all take home naloxone programs include this additional equipment (typically a 23 gauge needle) free of charge in the box itself. It is essential that whenever and however naloxone is provided it needs to be with all necessary equipment to allow administration in an emergency to occur.

OTHER PRODUCTS

In Australia currently there is only one product available as a single use pre packed mini jet of 400mcg naloxone – however were other products to become available we would urge that they be similarly scheduled. Additionally, while intranasal naloxone is not currently licensed for use in Australia, it is expected that this will change in the future. Any products for a single use pre packed intranasal dose of naloxone should be similarly approached.

Thursday October 15th, 2015

RE: TGA interim decision on Naloxone re-scheduling

To Whom It May Concern,

I note that the delegate of the Secretary of the Department of Health has given notice of their interim decisions for amending the Poisons Standard to have naloxone, when used for the treatment of opioid overdose, included in Schedule 3.

I am a university based researcher at the ANU. My research includes assessment of the effectiveness and value of take-home naloxone for non-medical lay people in Australia.

The delegate has clearly documented the evidence supporting this interim decision and has advised that they have received no objections to the re-scheduling. I fully support the interim decision and look forward to it being confirmed.

As was pointed out in some of the submissions provided to TGA during the previous phase of consultation, expanded access to naloxone includes both the physical availability of the drug as a pharmacist only medicine, as well as cost of the drug. Barriers that may exist for those accessing naloxone in a pharmacy setting include social as well as economic issues. Many of the key populations for whom naloxone should be accessible include citizens who are marginalised because of their drug use and/or those who are low income. Consideration of accessibility is essential; this includes educating pharmacists and other medical professionals on the benefits of naloxone for people who use opioids as well as maintaining a reasonable price point.

In addition, the expanded access to naloxone that will arise from the re-scheduling should encourage medical professionals to prescribe and recommend naloxone to all consumers using opioids; both licit and illicit. Education should be provided for both consumers and providers on the benefits of easy access to naloxone for all those using opioid drugs.

In summary, I support the re-scheduling amendment. However I also reiterate the importance of focussed education for medical professionals around the importance of naloxone for people who use opioids and the need to provide this drug without barriers or stigma. Furthermore, that naloxone should remain co-listed on the PBS.

The sector will be monitoring the situation to see what implications this decision has for the accessibility of naloxone.

Kind regards,

[redacted]
[redacted]

The Pharmacy Guild of Australia

Interim decision & reasons for decisions by delegates of the secretary to the Department of Health

Comments by the Pharmacy Guild of Australia to the proposed amendments referred by the delegate for scheduling advice

Naloxone

October 2015

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INTERIM DECISION 1.2 – NALOXONE – NEW SCHEDULE 3 ENTRY

Interim Decision: (The delegate's interim decision is that a new Schedule 3 entry for naloxone when used for the treatment of opioid overdose be created).

Overview

As stated in our pre-meeting submission, the Guild supports creating a new Schedule 3 entry for naloxone. Creating a new Schedule 3 entry will remove barriers to access and ameliorate legal issues regarding supplying a Schedule 4 medicine to another person, which is prohibited in certain jurisdictions.

Nevertheless the Guild believes the supply of naloxone needs to be accompanied with information that outlines key steps for consumers to take in the event of an opioid overdose either on the product label or as a pack insert. These inserts would complement the professional advice given by the pharmacist at the point of supply.

The Guild is concerned that without such information, consumers will access these products without having a sound understanding regarding the limitations of naloxone as well as how and when to administer it, particularly in an emergency situation when the product will be used.

The Guild is committed to working with all stakeholders regarding the development and dissemination of such information through community pharmacy.

Additionally, while not specifically a scheduling matter, the Guild advocates that naloxone should remain listed on the PBS to enable affordable access to patients as well as facilitate data collection on product usage. This may also assist in in referral and access to services to treat drug dependence.

Pfizer Australia
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07 October 2015

Medicines Scheduling Secretariat
Office of Medicines Authorisation (MDP 122)
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Dear Sir/Madam,

Re: Interim Decision to Amend Part 4 of the Poisons Standard
(New entry in Schedule 2 for esomeprazole)

Pfizer Australia (Pfizer) is pleased to note the Delegate's interim decision to create a new entry in Schedule 2 for esomeprazole in oral preparations containing 20 mg or less per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 7 days' supply.

In making their recommendation, the Delegate has highlighted a number of key factors:

- Esomeprazole is a safe and effective first line treatment for consumers with frequent symptoms of gastro-oesophageal reflux disease.
- Heartburn and other symptoms of gastro-oesophageal reflux disease are common.
- Esomeprazole has very low toxicity with short-term use.
- The proposed Schedule 2 pack size (seven days' supply), labelling (including RASML warning statements) and provision of Consumer medicine information will help ensure appropriate use of esomeprazole as a Schedule 2 medicine.
- The current RASML label warnings for all OTC PPIs would apply to esomeprazole in Schedule 2 or Schedule 3.
- Esomeprazole may be more effective in the treatment of gastro-oesophageal reflux disease than ranitidine which is currently available as an unscheduled medicine (seven days' supply) and as a Schedule 2 medicine (14 days' supply).

Pfizer is in agreement with each of the above reasons for the recommendation and supports the broadest appropriate level of access to, and optimal availability of, safe and effective medicines.

Pfizer appreciates the due consideration given by the Delegate and the ACMS in recommending inclusion of esomeprazole in Schedule 2, and for the opportunity to respond to this interim decision.

Yours faithfully,