REQUEST FOR INFORMATION

Supply of Section 26 and Section 29 Medicines
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Section A – Overview

Introduction

Purpose of this Request for Information (RFI)

TAS on behalf of District Health Boards ("DHBs") is requesting information regarding the supply and management of Section 26 and Section 29 medicines (the "services"). The information will inform TAS's decision as to whether to progress to a Registration of Interest ("ROI") or a Request for Proposal ("RFP") for the services. Respondents capable of providing the services, and other interested parties, are invited to respond to this RFI.

Background

What are Section 26 and Section 29 medications?

The Medicines Act 1981 permits an authorised prescriber to prescribe, administer or arrange for the administration of medicines for the treatment of a patient in his or her care. The medicine and its use may or may not be approved.

An approved medicine is a medicine which has been through a pre-market regulatory process in New Zealand and can be considered safe to prescribe, under the conditions set out in the Medicine Data Sheet. The prescriber must still consider both the benefits and risks of using the medicine before it is prescribed.

An unapproved medicine is a medicine for which consent, or provisional consent, has not been given by the Minister of Health for sale, distribution or marketing in New Zealand, that it has not been through the Medsafe regulatory process, approval has lapsed, the application was withdrawn or the product available is different in some way to the product that was approved. Unapproved medicines may still be prescribed to patients.

Section 26 ("s26") of the Medicines Act allows a pharmacist to manufacture, pack, label, sell and supply any medicine. In the instance of the s26 medicines listed on the Pharmaceutical Schedule these are manufactured by a third party for individual patients and are niche products and/or service a small market, where general manufacture of the product is not commercially viable.

Section 29 ("s29") of the Medicines Act allows for the sale or supply of unapproved medicines. The person or company who supplies the medicine must notify the Director-General of Health of the supply (via Medsafe) and record the name of the prescribing medical practitioner, the patient for whom the medicine was prescribed and the name and place of supply.

The Code of Health and Disability Services Consumers' Rights places obligations on the provider of services, including additional administrative requirements such as documenting patient’s details when prescribing/dispensing s29 medication. To cover the costs associated with the additional administrative work, wholesalers charge the pharmacy a per item fee as well as a percentage on top of the ex-manufacturer price.
Why are unregistered medications listed on the Pharmaceutical Schedule?

PHARMAC would prefer that all medicines listed in the Pharmaceutical Schedule were licensed for distribution in New Zealand. However, on occasion PHARMAC does need to list unregistered medicines. There are three main situations where PHARMAC currently encounters such a need:

1. Named Patient Pharmaceutical Assessment ("NPPA") requests for funding an unregistered or off-label medicine for an individual patient in exceptional circumstances.
2. There is a clearly established clinical need but no licensed products available in New Zealand.
3. Temporary listings to cover supply issues such as out-of-stock. These would be listed in the Pharmaceutical Schedule during the period that covers the stock outage.

What is the problem?

Community pharmacy identified that the current supply and management of subsidised s26/s29 medicines is an administrative burden and a cost burden to community pharmacy. The Community Pharmacy Services Governance Group (CPSGG) agrees that a long term solution for this issue should be found and supports this RFI.

DHBs pay a margin to community pharmacies under the Community Pharmacy Services Agreement ("CPSA"), which is a contribution towards pharmaceutical procurement and stockholding costs. It is calculated as a percentage of the schedule subsidy, being 4% for all medicines, except those with a subsidy of $150 or more, where it is 5%. DHBs and the sector have established a Pharmaceutical Margins Taskforce to address margin funding issues.

This RFI seeks to address the supply and management burden of subsidised s26/s29 medicines on pharmacy, imposed though the additional legislative and administrative requirements which result in extra supply chain costs being passed on to pharmacy.

What is the size of the problem?

Since 2012/2013 there has been an increase in the number of s26/s29 medicines listed on the Pharmaceutical Schedule, although the overall quantum of s26/s29 medications are low comparative to the total market. While volumes fluctuate there are approximately

- fifty s29 community medicines listed in the Pharmaceutical Schedule
- eight s26 medications listed on the Pharmaceutical Schedule
- $1.9 million worth of subsidised s26/s29 claimed in 2015 (excluding s29 as cost brand source)
- 45,000 initial items claimed in 2015 (excluding cost brand source claims).

What else should be considered?

While the focus of this RFI is concerned about subsidised s26/s29 medicines which are listed in the Pharmaceutical Schedule at cost ex manufacturer, we are also interested in the inclusion of

- cost brand source s26/s29 medicines
- exceptional circumstance/NPPA medicines
- s26/s29 medicines delivered to Medical Practitioners.
Respondents may also wish to consider the supply of non-subsidised s26/s29 medicines within their responses.

More information

Sapere undertook a think piece to identify if there are other industry/supply-chain/logistic models which could be considered as inputs into developing options for addressing the pharmaceutical margins issue currently facing the New Zealand health sector. The report has provided information on the issue of margins for the Pharmaceutical Margins Taskforce and the Community Pharmacy Governance Group to think through – it does not reflect any government policy or strategic direction at this time.


Deloitte was commissioned to undertake an Environmental Scan on Drug Margins. The Deloitte Report specifically informs the multi-party Pharmaceutical Margins Taskforce. The Deloitte Report was never intended to be a public document, yet due to the high level of interest is now being made publicly available.

1. Deloitte: Environmental Scan Regarding Drug Margins; Corporate Finance, January 2015 [http://centraltas.co.nz/assets/Publications/Pharmacy-Documents/Pharmaceutical-Margins/Deloitte+Scan+with+Cover+Note.pdf](http://centraltas.co.nz/assets/Publications/Pharmacy-Documents/Pharmaceutical-Margins/Deloitte+Scan+with+Cover+Note.pdf)
Description of Requirements

Overview

This RFI seeks to identify and assess the feasibility of a supply and management solution whereby DHBs contract with a provider for the provision of those services for subsidised s26/s29 medicines. The solution should deliver a quality improvement approach aligned to the NZ Triple Aim. The three Triple Aim objectives, and the key outcomes that we want to achieve for each objective, are:

*Improved quality, safety and experience of care*
- Ensure that the relationship between community pharmacist and consumer is maintained.
- No new or additional costs to consumer or pharmacy.

*Improved health and equity for all populations*
- Deliver a nationally consistent service enabling timely dispensing and/or delivery of the prescribed medicine to all New Zealanders.

*Best value for public health system resources*
- Reduce wastage of medicines where stockholding occurs.
- Simplify administration/compliance costs of these medicines across the supply chain.

The potential solution we wish to evaluate under this RFI could involve DHBs collectively contracting for wholesale/distribution services for subsidised s26/s29 medicines for all DHB hospital pharmacies and community pharmacies including cost brand source and exceptional circumstances medicines.

In assessing the feasibility of the possible solution for these medicines, DHBs would be interested in any information about the potential impact of implementing such a solution on the existing market and contracting arrangements for supply and management of all other medicines.

Statement of need

We are interested in receiving responses from
- credible providers who have the capability, experience and infrastructure to deliver on their proposed solution for subsidised s26/s29 medicines
- providers who have effective networks and strong relationships across the supply chain or can demonstrate how they will develop these
- solutions that meet the legislative requirements for the supply of subsidised s26/s29 medicines, including those listed as Source Brand Cost and Exceptional Circumstances.

All proposed solutions need to comply with relevant legislation/regulations and requirements of authorities, including:
- Medicines Act 1981
- Medsafe
- Medicines Control.

Appendix 1 provides additional information on relevant legislation and common practice.
Data management and integration

- Respondents should identify a proposed solution for data management and integration within existing systems and consider the implications of New Zealand ePrescription Service ("NZePS") and how they propose to link to NZePS in the short to medium term.
- Respondents should describe their capacity and capability to meet regulatory requirements for data management and integration now and into the future.

Network and infrastructure

- Respondents should describe their supply/distribution network, identifying standards they can meet such as timeframes from request to distribution.
- Respondents who intend to provide the solution as part of a collaborative effort that involves one or more other parties, or as part of a network of suppliers/distributors, should identify the third parties involved, how the collaboration or network would operate and which parties would be responsible for each aspect of the solution.
- Similarly, respondents who intend to outsource certain aspects of the provision of the solution to a third party should identify the third party and provide details as to how the outsourcing would work.

Financial model

Respondents should propose the financial model that will support efficient delivery of subsidised s26/s29 medicines and deliver best value for the health system, including reference to:

- Will pricing change based on scale?
- Is risk sharing model desired?
- What incentives are required?

If the answer to any of the above is yes, please provide details as to how that would be reflected in the proposed financial model.

If you consider that benefits and/or risks would arise from the exclusive provision of some or all of these services, please provide details.

Cost estimate

Respondents should provide an all-inclusive cost estimate. It should set out all costs associated with the proposed implementation and ongoing operation of the services. The estimate must be discretely priced, that is, the costs should be individually identified to allow for proper analysis.

Implementation considerations

Readiness to act

- Respondents should identify when they could implement their solution including but not limited to any staging required based on geographical location, product, or volume.
Let’s work together

- Tell us what else you know that is relevant to your proposed solution.
- Tell us what else you would need to know from us, to respond to an ROI or RFP (if TAS decides, following this RFI process, to issue an ROI or RFP for the services).
- Tell us what you think about the potential impact of implementing the solution on the existing market and contracting arrangements for supply and management of all other medicines.
Section B – Request for Information Process

RFI Process

Timetable

The anticipated timetable for this RFI process is as follows:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Release of RFI</td>
<td>23/03/2016</td>
</tr>
<tr>
<td>RFI questions close</td>
<td>4:00 pm on 19/04/2016</td>
</tr>
<tr>
<td>RFI closes</td>
<td>4:00 pm on 03/05/2016</td>
</tr>
<tr>
<td>Further discussion with respondents if necessary</td>
<td>12/05/2016</td>
</tr>
<tr>
<td>Evaluation of next steps commences</td>
<td>03/06/2016</td>
</tr>
</tbody>
</table>

Respondents are to note that this timetable is indicative only and may be subject to change at the sole discretion of TAS. All respondents will be notified of any change to the timetable by TAS’s authorised representative.

One option that TAS may progress following this RFI process is to issue a ROI or RFP in respect of the services. If an ROI or RFP is issued, that would likely happen after September 2016.

Communication

TAS will not communicate with any respondents about this RFI, except in the following circumstances:

- to answer questions about the RFI asked by respondents prior to the closing date for questions set out above
- to seek clarification of aspects of submitted responses.

All communication and/or correspondence between any respondent and TAS will be conducted in writing through the following authorised representative and in accordance with the terms set out in Sections B and C of this RFI:

Kendra Sanders  
TAS  
186 Willis Street, Level 3, PO Box 23075, Wellington 6140  
Email address: Kendra_Sanders@centraltas.co.nz

Respondents must not directly or indirectly approach any TAS or DHB staff, or any other person, to solicit information concerning any aspect of this RFI.

TAS will not be bound by any statement, written or verbal, made by any person other than the TAS authorised representative. The TAS authorised representative is the only person authorised to make representations or give explanations regarding this RFI.
TAS may change its authorised representative at any time. TAS will notify a change either by posting information on GETS or by email.

Preparing and submitting information

Respondents must respond by completing the response form set out in Appendix 2.

By submitting a response, each respondent accepts that it is bound by the terms and conditions contained in Sections B and C of this RFI.

Each respondent will

• examine the RFI and any documents referenced in the RFI
• consider all risks, contingencies and other circumstances relating to the services and include adequate provision in its response to manage such risks and contingencies
• document in its response all assumptions and qualifications made about the services
• ensure that any pricing estimates are in NZ$ and exclusive of GST
• if appropriate, obtain independent advice before submitting a response
• satisfy itself as to the correctness and sufficiency of its response, including its cost estimates.

Each respondent is responsible for ensuring that its response is received by TAS at the correct address on or before the deadline for the responses, which is 4:00 pm on 3 May 2016. Responses received after this time will be accepted only if TAS, at its sole discretion, decides to accept late responses.

RFI Questions

Respondents may submit written questions to clarify issues relating to the RFI. All questions must be submitted in writing to TAS's authorised representative by 4.00 pm on 19 April 2016. Questions received after this time will not be responded to, except as determined by TAS at its sole discretion.

TAS will endeavour to respond to questions in a timely manner. TAS may provide or withhold from any respondent, information in relation to any question. Information will usually only be withheld if it is deemed unnecessary, is commercially sensitive to a respondent, is inappropriate to supply at the time of the request, or cannot be released for legal reasons.

Questions and answers that TAS deems relevant to all respondents will be provided to all respondents. In doing so, TAS may summarise the respondent's question but will not name the respondent that asked the question. The question and answer may be posted on GETS and/or emailed to participating respondents.

In submitting a question, a respondent must clearly indicate any information related to the question that is commercially sensitive information. TAS will not publish such commercially sensitive information, but it may modify a submitted question to eliminate commercially sensitive information and publish this and the answer if TAS considers that it is of general significance to all respondents.

TAS may also give a respondent an opportunity to withdraw its question or to remove the commercially sensitive information from its question.
Next steps

Following consideration of the responses to this RFI, TAS may (without limitation)

- issue a ROI and/or RFP for whatever services TAS determines are required following this RFI process
- conclude the process without issuing an ROI or RFP.

Respondents who submit a response to this RFI will not be placed on any prequalified or registered respondents list for the purpose of any ROI or RFP process that TAS may conduct at a later stage.
Section C – RFI conditions

Rights reserved by TAS

TAS reserves the right to

- suspend or cancel (in whole or in part) this RFI
- re-advertise the RFI
- waive any irregularities or informalities in this RFI process
- vary this RFI at any time, including material variations
- accept late responses
- answer a question submitted after the deadline for questions
- accept or reject any non-compliant, non-conforming or alternative response
- issue an ROI or RFP in relation to the services, which could include descriptions of service requirements different to those set out in this RFI
- continue or conclude the process without issuing an ROI or RFP for the services
- enter into discussions with any one or more respondents relating to matters dealt with in this RFI, without disclosing this to, or doing the same with, any other respondent
- limit or extend the list of potential respondents beyond those who respond to this invitation
- seek clarification of any aspect of information provided in a response, and seek further information from any party without being required to request the same clarification or information from each respondent
- use information provided in the responses for the purposes of publishing an ROI or RFP.

No obligation to discuss

Nothing contained or implied in this RFI obliges TAS to discuss, justify or give reasons for any of its decisions or actions relating to this RFI or any response.

Ethics

Respondents must not attempt to influence or provide any form of personal inducement, reward or benefit to any representative of TAS or any DHB in relation to the RFI.

A respondent who attempts to do anything prohibited by Section B or Section C of this RFI may be disqualified from participating further in the RFI process (or a subsequent ROI or RFP process).

Anti-collusion

Respondents must not engage in collusive, deceptive or improper conduct in the preparation of their responses or other information submitted in any discussions with TAS. Such behaviour may result in the respondent being disqualified from participating further in the RFI process (or a subsequent ROI or RFP process). In submitting a response, the respondent warrants that its response has not been prepared in collusion with a competitor.
TAS reserves the right, at its discretion, to report suspected collusive or anti-competitive conduct by the respondents to the appropriate authority and to give that authority all relevant information including the concerned respondent’s response.

No liability

While TAS endeavours to supply correct information, it disclaims, to the extent allowed by law, any liability (in contract and in tort, including negligence) to any respondent or other person if they rely on any information provided by TAS in relation to this RFI, or for any direct or indirect damage, loss or cost incurred by any respondent or any other person in respect of the RFI process. Nothing contained or implied in the RFI, or RFI process, or any other communication by TAS to any respondent shall be construed as legal, financial or other advice.

Those submitting RFI responses will be deemed to have

- examined this RFI and all documents referenced (if any)
- considered all the risks, contingencies and other circumstances that may have an effect on their response
- satisfied themselves as to the correctness and sufficiency of their responses.

Information complete and accurate

All information provided by a respondent in a RFI response is warranted by the respondent to be complete and accurate in all material respects. The respondent also warrants to TAS that the provision of information to TAS, and the use of it by TAS for the analysis of RFI responses, will not breach any third party’s intellectual property rights.

Confidentiality

Confidential information means information that is

- contained in this RFI
- marked by either TAS or a respondent as ‘confidential’
- provided by TAS, a respondent or a third party in confidence.

Confidential information does not cover information that is in the public domain through no fault of either TAS or the respondent.

This RFI, and the information supplied by TAS (either itself or through its consultants or advisors) in connection with this RFI, is confidential information. You must not release or disclose any of the information to any other person (other than your employees or advisors) without the prior written consent of TAS.

TAS is not able to treat any part of your response as confidential unless you specifically request that it does. If you would like TAS to withhold any commercially sensitive, confidential proprietary, or personal information included in your response, please clearly state this in your response and identify the relevant sections of your response that you would like withheld.

Responses that TAS receives are subject to the Official Information Act 1982 (‘OIA’), the Privacy Act 1993, parliamentary and constitutional convention and any other obligations imposed by law. Any
request for information relevant to this RFI or a response will be considered in accordance with TAS’s obligations under the OIA. If TAS receives an OIA request that relates to a respondent’s confidential information, TAS will (to the extent reasonably possible) consult with the respondent and may ask the respondent to explain why the information is considered by the respondent to be confidential or commercially sensitive. TAS will not be in breach of its obligations if confidential information is disclosed by TAS to the appropriate authority because of suspected collusion or anti-competitive behaviour.

Costs of participating in the RFI process

Each respondent will meet its own costs associated with the preparation and presentation of its response and any discussions.

Intellectual property rights

For the purposes of this RFI, intellectual property rights means all intellectual property rights and interests, including copyright, trademarks, designs, patents, and other proprietary rights, recognised or protected by law.

The RFI and its contents remain the property of TAS. All intellectual property rights in the RFI remain the property of TAS or its licensors. TAS may request the immediate return or destruction of any or all RFI documents and any copies. Respondents must comply with any such request in a timely manner.

Each response to this RFI will, when delivered to TAS, become the property of TAS. Responses will not be returned to the respondents at the end of the RFI process.

Ownership of the intellectual property rights in responses remains the property of the respondent or its licensors. However, each respondent grants to TAS a non-exclusive, non-transferable, perpetual licence to retain, use, copy and disclose information contained in its response for any purpose related to this RFI process and potential ROI or RFP process or the services that TAS may conduct in relation to the matter dealt with in this RFI.

No binding legal relations

Neither the RFI, nor the RFI process, creates a process contract or any legal relationship between TAS and any respondent.

Governing law

This RFI is governed by the law of New Zealand, and the New Zealand courts have exclusive jurisdiction as to all matters relating to this RFI.
Appendix 1: Legislation and Common Practice

Sections 26 and 29 of the Medicines Act


26. Exemptions for pharmacists

(1) Notwithstanding section 17, but subject to subsections (2) and (3) and to the other provisions of this Act and to any regulations made under this Act, a pharmacist may manufacture, pack, label, sell, and supply any medicine.

(2) The authority conferred by subsection (1) shall extend only to the manufacture, packing, labelling, selling, or supplying of medicines,

(a) in the case of a pharmacist employed in a hospital, in the course of that pharmacist's employment as a pharmacist in that hospital:

(b) in any other case, by a pharmacist in a pharmacy.

(3) Subsection (1) shall not authorise

(a) the sale or supply of any medicine, except

   (i) pursuant to an order given or a request made by the person to whom the medicine is sold or supplied; or

   (ii) in the ordinary course of business with reference to the needs expressed by that person; or

(b) the sale or supply of a prescription medicine otherwise than pursuant to a prescription.

(4) Subject to subsection (2), nothing in section 20 or section 24 shall apply in respect of the sale or supply by a pharmacist of a medicine compounded by that pharmacist to suit the needs of a particular person.

Compare: 1960 No 97 ss11(1), (2)(c), 13(1)(a), (2), 14(1)(a)

29. Exemption for medicine required by medical practitioner

(1) Neither section 20 nor section 24 shall prevent—

(a) the supply by any person to any medical practitioner, on the medical practitioner's request, of any medicine required by that medical practitioner for the treatment of a particular patient currently under that medical practitioner's care; or

(b) the administration by any medical practitioner of any such medicine to any such patient.
(2) Every person who, for the purposes of subsection (1), sells or supplies to any practitioner any medicine that is a new medicine by virtue of paragraph (a) of the definition of the term new medicine in section 3(3) before the consent of the Minister to the distribution of that medicine has been notified in the Gazette shall, as soon as practicable after the end of every month in which he has so sold or supplied any such medicine, report that sale or supply to the Director-General in writing, naming the practitioner and patient, describing the medicine, and identifying the occasion when and the place where the medicine was so sold or supplied.

(3) Without limiting section 48, if any person fails to comply with subsection (2), the Minister may, in the manner prescribed in that section but without complying with subsection (2) of that section, prohibit that person from selling and supplying any new medicine to which subsection (2) applies before the consent of the Minister to the distribution of that medicine has been notified in the Gazette.

Compare: 1969 No 7 s16

Summary from Medsafe

Section 29 requirements for notification of sale or supply of unapproved medicines

Section 29 requires notification of sale or supply of unapproved medicines.

Section 29 of the Act permits the sale or supply to medical practitioners of medicines that have not been approved, and requires the "person" who sells or supplies the medicine to notify the Director-General of Health of that sale or supply in writing naming the medical practitioner and the patient, describing the medicine and the date and place of sale or supply, and the number of packs supplied.

No notification is required for an unapproved use of an approved medicine, nor is notification required if an authorised practitioner imports a medicine to treat his or her patient. However, if an unapproved medicine is sold or supplied to a medical practitioner, that sale or supply should be notified. If the supply is from one authorised prescriber to another, the supplying authorised prescriber is encouraged to notify the supply, but notification of supply is not mandatory in this case.

It should be noted that section 29 specifies only medical practitioners. This means that if other authorised prescribers wish to procure unapproved medicines their sources are limited to other authorised prescribers or to direct importation.

On occasions a pharmacist working in a pharmacy may be involved in the supply of an unapproved medicine as the medical practitioner’s agent. If the pharmacy has imported the medicine, it is the pharmacist’s responsibility to ensure that the details of supply are sent to Medsafe. If the medicine has been obtained from a distributor for an identified patient then that distributor should be given all information required to be held, according to section 29.

Anyone who imports an unapproved medicine for supply to a medical practitioner under Section 29 (other than a hospital or pharmacy) should ensure that they hold a licence to sell medicines by wholesale. They should also ensure that they hold the product specifications and certificates of analysis for each batch imported as required by Section 42.

Section 29 supply will be audited as part of the annual audit for a Wholesale licence.
Patient should be advised of the forwarding of information under section 29. Note that under the Health Information Privacy Code, Rule 3, the medical practitioner must advise the patient that information about supply of the medicine will be forwarded to Medsafe and recorded on a database as a requirement of the Medicines Act.

Section 29 Medicines: Pharmacy process

Section 29 medicines are unlicensed medicines that have not been assessed by Medsafe for quality, efficacy or safety and are not approved for use in New Zealand. Section 25 of the Medicines Act allows medical practitioners to prescribe unapproved medicines. Section 29 of the Medicine Act allows pharmacists to legally obtain and supply unapproved medicines to a patient only on receipt of a prescription from an authorised prescriber. When supplying Section 29 medicines pharmacists incur additional procurement and service costs.

A pharmacy can only initiate procurement of Section 29 medicines on a named-patient basis after they have received a prescription. This means that a pharmacy cannot order this medicine in advance or in larger quantities than immediately required to reduce costs, or to improve efficiency.

When ordering Section 29 medicines pharmacists must provide their wholesaler with the name of the prescriber and the patient so the wholesaler can supply this information to Medsafe. The few pharmacies that hold a wholesalers’ licence are able to import Section 29 medicines directly. When doing so the pharmacist must check the Certificate of Analysis (CoA) to ensure the specification of the product has been met, and it is the pharmacist’s responsibility to ensure that the details of the supply are sent to Medsafe.

Wholesalers typically charge a procurement fee on each order of Section 29 products to cover the necessary paperwork and reporting involved at their end. There is also an extra courier charge on each s29/s26 order and a higher wholesaler mark-up with no rebate or discounts. At current reimbursement rates, pharmacies are often paid less for these medicines than it costs to buy them into the pharmacy.

When a registered product has been replaced by a s29 medicine in the Pharmaceutical Schedule, or when a patient is unaware they have been prescribed an unlicensed medicine the pharmacists must check whether the prescriber is aware that their patient will be receiving an unlicensed medicine.

Pharmacists also have obligations under The Code of Health and Disability Services Consumers’ Rights, and The Health Information Privacy Code when supplying s29 medicines. Each time an s29 medicine is supplied the pharmacist must ensure the patient has been fully informed about their treatment, and has the appropriate information. Pharmacists are also required to advise patients that information about the supply of their s29 medicine will be forwarded to Medsafe and recorded on a database as a requirement of the Medicines Act on every dispensing.

The prescribing and availability of s29 medicines helps ensure New Zealanders receive necessary treatment. However, the extra work involved in the supply chain of these medicines is unsustainable, and must be addressed.
Appendix 2 – Response form for RFI: Supply of Section 26 and Section 29 Medicines

Please use the template below to respond to this RFI. You are welcome to supply information as appendices to this response sheet. If you choose to submit additional information as an appendix please note this in the relevant response box below.

Company information

<table>
<thead>
<tr>
<th>Full legal and trading name (if any) and address of the registered office in New Zealand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact name, along with job title and address, to whom all correspondence regarding this RFI should be directed</td>
</tr>
<tr>
<td>Telephone numbers to be used for verbal communication and e-mail address to be used for all electronic correspondence</td>
</tr>
<tr>
<td>Company website address</td>
</tr>
</tbody>
</table>

Requirements – Business Process

<table>
<thead>
<tr>
<th>Describe your capability, experience and infrastructure to deliver on your proposed solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confirm, by providing details, that you have effective networks and strong relationships across the supply chain, or describe how such networks would be developed.</td>
</tr>
</tbody>
</table>
Confirm, providing details, that your proposed solution meets legislative requirements

Requirements – Data management and integration

| Describe your solution for data management and integration within existing systems, considering the implications of New Zealand ePrescription Service (and how your solution will link to this in the short to medium term) |
| Describe and provide evidence of your capacity and capability to meet regulatory requirements for data management and integration now and into the future |

Requirements – Network and infrastructure

| Describe your supply/distribution network |
| Describe standards you can meet such as timeframes from request to distribution |
| If the solution will be provided as part of a collaboration/network, describe the third parties involved, how the collaboration/network would operate, and who would be responsible for each aspect of the solution |
| If you intend to outsource aspects of the provision of the solution to a third |
party, describe the third party and provide details as to how the outsourcing would work

Requirements – Financial Model

| Describe your financial model to support efficient delivery of subsidised s26/s29 medicines and deliver best value for the health system |
| Description if pricing will change based on scale, a risk sharing model is desired, or incentives are required, provide details |
| Describe any financial benefits and risks that you consider would arise from the exclusive provision of some/all of the services |

Requirements – Cost estimate

| Provide an all-inclusive cost estimate |

Requirements – Readiness to act

| Describe when you would be able to implement the solution, including any staging required based on geographical location, product, or volume |
Let’s work together

<table>
<thead>
<tr>
<th>Tell us what else you know that is relevant to your proposed solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tell us what else you would need to know from us, to respond to an ROI or RFP (if one is issued)</td>
</tr>
<tr>
<td>Tell us your views on the potential impact of implementing the solution on the existing market and contracting arrangements for supply and management of all other medicines</td>
</tr>
</tbody>
</table>