Summary of responses to PHARMAC's consultation on: Improving access to medicines and devices in primary care

February 2016

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Introduction

This document provides a summary of the responses PHARMAC received to consultation on the current and potential future purchasing, funding and distribution arrangements for vaccines and some funded community medicines and devices.

PHARMAC received feedback from a range of stakeholders including suppliers, wholesalers, general practice and their professional bodies and advocates, pharmacy, Primary Health Organisations (PHOs), individual clinicians, stakeholder groups and other sector partners. Feedback was in the form of submissions and notes taken from meetings with various stakeholders.

The consultation requested feedback on the current model, and asked for feedback on a proposed model for both vaccines and other medicines and devices.

PHARMAC would like to thank all those who responded to this consultation and appreciates the time and consideration that respondents have given to providing feedback on the discussion document. We welcome any feedback on the process as we wish to continually improve our engagement with the sector.

High level summary of feedback

A large amount of feedback was received specifically on vaccines, with less emphasis on other medicines and devices. What became apparent when receiving feedback was the divergence between how the sector views funding and supply of vaccines and medicines and the assumptions underpinning the discussion document.

Six themes emerged from the questions asked (see Appendix 2 for list of questions). A high level summary of feedback under these themes is provided below. However, a detailed description of the feedback received is included in Appendix 1.

1. Problem definition

Respondents felt the problem definition outlined in the discussion document was unclear. There was a common view that the current vaccines model is fair, well established and meets the needs of providers and the National Immunisation Programme (NIP). Respondents suggested other ways to address issues around slippage of free stock and wastage.

In relation to other medicines and devices, respondents felt the proposed model would address some specific supply issues for general practice and that it may help with the streamlining of service funding. Others viewed the existing supply via prescription or Practitioner Supply Order (PSO) fulfilled the needs of general practice and could be expanded to accommodate other products if needed.

2. Vaccine supply and the differences relative to other medicines

Respondents saw the supply of vaccines as quite distinctly different relative to the supply of other medicines and devices and highlighted a number of features they felt worked well.

Under the current arrangements for vaccines, respondents felt the risk of stock outs is low. General practice does not have to pay for stock, allowing them to hold a good supply of vaccines regardless of size, location or type of practice. Government purchasing of vaccines ensures supply in the event of global stock shortages.

Respondents commented that the distribution model is efficient and gives PHARMAC visibility and control over stock levels and distribution; e.g. during disease outbreaks to coordinate distribution to areas most in need, or to run down stocks when products change to minimise waste.

Respondents noted a number of specialist functions around the distribution of vaccines that fundamentally differentiates them from other medicines. These include: batch tracking, packaging requirements, temperature monitoring and traceability with customers, and a zero tolerance for stock outs.

3. Costs

Costs across the health sector arose as a significant issue in feedback on the discussion document. Overall, feedback focused on the potentially negative cost impacts imposed by the suggested model, although this was mostly related to vaccines.

The financial impact on general practice was raised by most respondents in relation to vaccines and other medicines, these included:

- Implication on cashflow from purchasing stock
- Additional stock holding requirements (insurance, interest charges, space)
- Cost of unused or damaged stock
- Additional burden of compliance and administration costs (stock management, ordering, claiming, audit and labour costs)
- Transition costs

These costs were considered to have a greater impact on small or rural practices where volumes are low. Respondents noted that under the current model for vaccines and the PSO system there is no financial risk to general practice and few costs.

It was noted that suppliers and wholesalers would also face additional costs around stock management, transportation and risk, and that these costs would need to be reflected in the vaccine price or passed on to the provider.

In relation to stockholding costs for vaccines there was much discussion around who should be responsible for these costs, with no consensus. Respondents agreed that costs should not be passed on to patients.

4. Access and health outcomes

Many respondents considered that additional costs imposed by the proposed model would result in less stock being held in general practice leading to missed opportunities to vaccinate. This would affect small practices and high risk populations most due to the low demand for vaccines.

Respondents stated these impacts would adversely affect immunisation and coverage rates, increase inequity, and would have implications for general practice achieving their agreed immunisation targets.

There was some very positive feedback on the potential to improve patient outcomes by improving access to other medicines and devices. This feedback is captured below in the ‘Application of the proposed model’ theme.

5. Patient safety

Concerns around patient safety arose out of anticipated consequences resulting from a model where general practice would purchase their own stock. These concerns related to both vaccines and other medicines. There are three angles to this:

- the role of pharmacy both clinically and around the management of stock enhancing patient safety;
- the greater importance on cold chain quality standards and monitoring under the proposed model; and
- the financial incentives created potentially leading to inappropriate prescribing for financial gain and use of compromised stock to avoid losses.

In terms of improving patient safety, some felt placing a value on vaccine stock as it travels through the supply chain was likely to enhance cold chain compliance.

6. Application of the proposed model

There was support from a large number of respondents to develop a model that could help streamline supply and funding processes around medicines that require administration and oversight by a qualified health professional, such as a doctor or nurse.

Respondents noted implications for the development of community based models of care. These consisted of issues around how general practice access supplies of medicines and devices, as well as costs around the administration service that created access barriers for patients.

Issues highlighted were:

- Administration charges for patients and variation by practice and location driving inequity and access issues
- Not having stock on hand for immediate use
- Inconvenience for the patient in order to collect medicines for administration in general practice, particularly around acute conditions
- Having to make alternative supply arrangements for some medicines not available through community pharmacy
- Delays when pharmacy do not have stock on hand

Respondents raised a number of potential benefits from the proposed model around reducing cost for patients, convenience and timeliness of treatment. Products and treatments that would potentially benefit from the development of a new model included some injections and infusions as well as devices used for medicines administration.

Some respondents noted that improving the availability of medicines could lead to an increase in the number and types of providers, therefore opening up opportunities to better provide services in communities.

Despite the overall view around vaccines, some respondents noted that having one supply of vaccines (rather than the funded/non-funded split that exists under the current system) would make the process less complicated for vaccines also administered to non-funded patients; examples included travel vaccines, pertussis, and HPV vaccine.

Conclusion

The strength of feeling around the feedback we received in response to the proposed model has definitely made us aware of the sensitivities around vaccine supply and delivery to patients. We understand that any potential changes to vaccine supply processes would need significant and careful planning and coordination before any change could be considered.

Concerns around changes to vaccines dwarfed the positive sentiment towards improvements for other medicines and devices. This came about for two reasons: we did not define the problem with the current vaccines model with sufficient clarity; and we focused the discussion document on vaccines as the first step to developing a model that could be expanded to other medicines and devices in the future.

To be clear, the problem we see with the existing supply of vaccines relate to the supply of free stock throughout the supply chain and to providers. We consider the current system:

- does not create the right incentives around stock management and feel that all parties should be more accountable for stock under their control;
- reduces compliance with the Pharmaceutical Schedule due to the lack of control over use once free stock has been provided; and
- does not capture important information around use such as what was used, when it was used, who administered it, who the patient was.

In our view, these issues would also limit the expansion of the PSO to other medicines and devices.

While the characteristics of vaccines and other medicines and devices are different, we felt that the fundamentals of the purchase and claim model proposed in the discussion document would be flexible enough to fit any product. However, it is clear from feedback that many do not share this view, so while most people were not in support of changes to vaccines they were in favour of the model, or aspects of it, for other medicines and devices.

While this feedback will influence and shape our views, it will be balanced against what we see as the current issues around supply and access to vaccines and other medicines and devices; many of which were also reflected back to us in feedback from a range of respondents.

Next steps

We have decided to reconsider how we progress the development of a new model for vaccines. This means we will not be making any substantial changes to the supply and distribution of vaccines from July 2017 as proposed in the discussion document.

The first step is to develop a model for other medicines and devices. What emerged through feedback was considerable support for developing a model that addressed specific supply issues and which streamlined funding for the administration of medicines in general practice.

We’re looking to build on this support and work in partnership with the health sector to co-create and test a new model. To this end, we plan to seek an expression of interest (EOI) from qualified groups to partner with us and develop a model that could be adopted more widely.

We have already been approached by some groups interested in exploring opportunities to address specific issues around the supply of a few products and the potential to streamline funding processes. However, we would also like to develop and test any new model with a range

of providers and potentially across a number of products. We will be in touch with stakeholders with more information as the EOI is developed.

As the model develops, we may look at whether some components of such a model could be applied to vaccines.

We still believe some changes are required to the vaccines model to address our concerns around the management and accountability for stock, compliance with the Schedule and transparency of usage. We will continue to work towards this over the next few years.

Any changes to vaccines would need careful planning and coordination and further work is required around the problem definition. We will work closely with the sector to explore these issues further and identify improvements that can be made in a way that, where possible, addresses the concerns raised in feedback.

We'll be looking at making some small changes to vaccine contracts to give us the flexibility to test some ideas with a small group of vaccine providers should the opportunity arise. We anticipate this would have no impact on volumes or existing supply processes and we'll work with suppliers to make sure this is understood through the vaccines RFP process.

Disclaimer

PHARMAC has done its best to reflect and represent all views received as part of the feedback process. The purpose of this document is to report those views fairly and accurately and does not represent any view PHARMAC may have in agreement or disagreement with the points raised by respondents.

Appendix 1 – Summary of feedback by theme

Our discussion document contained two new proposed options for vaccines supply that are based around existing purchase and claim models: the first (option A) is similar to that used by general practice for influenza vaccine; the other (option B) being similar to how community pharmacy purchase and claim for medicines. For the purposes of simplicity, we refer to these collectively as the 'model' except where feedback relates specifically to one of the two.

1. Problem definition

We received a significant amount of feedback that the problem definition outlined in the discussion document was unclear. There was a common view across respondents that the current vaccines model is fair, well established and meets the needs of providers and the National Immunisation Programme (NIP). Some respondents noted the recent improvements and high immunisation rates as evidence of this.

In providing their feedback, some respondents highlighted that the nature of the immunisation programme made it fundamentally different from the provision of other medicines. In particular, it was seen as a critically important national public health intervention and its management requires an approach that is very different to pharmaceuticals. Vaccination, particularly of children, is not just for the individual but also for the community at large.

In contrast, respondents were divided in their agreement for the need to improve access to medicines and devices through general practice. Some respondents noted that the vaccines debate took away from the system being proposed for other products, which they saw as being helpful to addressing access issues. Respondents noted that as well as addressing access to medicines and devices, the model may help with the streamlining of service funding which is seen as a bigger barrier to access. Further discussion around current access issues and potential use for the proposed model is covered under the theme *'Application of the proposed model'* later in this document.

Those who did not perceive there to be existing problems to access to other medicines and devices were of the view that the existing supply via prescription or Practitioner Supply Order (PSO) fulfilled the needs of general practice. One respondent noted there were no disparities to accessing medicines in primary care. Others noted that if the problem was waste then PHARMAC needs to investigate and consider other ways to address this issue.

Some respondents also noted the lack of evidence around wastage and questioned whether there was justification for changing the model; respondents suggested that practices are very careful around managing stocks of vaccines already. A few respondents suggested that there was some delivery of vaccines to the non-funded population (not necessarily deliberate) and gave examples of vaccines that included DTap, PCV, HPV, and ADT. It was noted that reducing wastage and slippage would improve the efficiency of the NIP and was desirable for all parties. Rather than changing the system, improving the visibility of stock values, the application of metrics, tracking and monitoring with reporting back to general practice on their wastage and slippage may raise it as an issue that gets more focus.

Some responses suggested that there is no need to move vaccines to a different model in order to expand access to specific pharmaceutical products in general practice. One respondent felt that the theoretical benefit for a small number of products does not justify changing the national immunisation programme. A number of respondents suggested that if the problem is direct

access to medicines and devices then the PSO mechanism could be expanded to accommodate this. The point was made that there were already many medicines and devices being supplied this way, especially in rural areas. One respondent also suggested the PSO mechanism could accommodate the supply of vaccines to general practice in a more efficient way as it would reduce the number of low volume orders from distributors.

One respondent noted that the barriers to accessing treatments in the community are not technical ones but are more about improving communication and collaboration between health professionals.

2. Vaccine supply and the differences relative to other medicines

This section deals with feedback on the vaccines supply mechanism. It also covers feedback we received around the proposed and existing supply mechanisms for other medicines and devices. Respondents saw the supply of vaccines as quite distinctly different relative to the supply of other medicines and devices. It is clear that any potential changes to vaccine supply would need careful planning and coordination to address the complexities and sensitivities highlighted by the responses we received.

The vaccines supply mechanism

There was a large amount of feedback, specifically in relation to vaccines, highlighting features of the supply mechanism that people felt currently worked well. Respondents also highlighted the need to consider the potential impacts on the many individual components and processes that make up the vaccine supply chain.

Many respondents noted that general practice hold a good supply of vaccines regardless of size, location or type of general practice. It was noted under this discussion (and elsewhere under the cost theme later in this document) that this is because general practice did not have to pay for stock.

Some respondents questioned whether changing to the new system would remove the Government owned stockpile. Respondents considered that having a Government owned and managed stockpile, along with a firm commitment to purchase, minimises the risk of disruption to supply in the event of global stock shortages and allows for effective and efficient distribution of stock during disease outbreaks.

It was noted vaccines have long lead times to manufacture and, globally, manufacturing capacity is deemed insufficient to meet increasing demand. This would also have implications for suppliers and PHARMAC around changes to stockpile management and any stock building processes that may be needed as a consequence of changing the current model.

The existing model, with one nominated wholesaler and a single Government vaccine store in which purchasing, distribution and administration is centralised, reduces duplication and is considered by many as the most efficient model. One respondent noted that volumes have doubled and costs associated with distribution have increased but the funding for the distribution service had reduced per transaction. They also noted the existing system has features that yield advantages due to the large amount of experience and intellectual property built up over 15 years.

Some respondents noted the existing model gives PHARMAC full visibility and maximum control over stock quantities and allows PHARMAC to regulate the distribution if needed, in a

coordinated fashion. Respondents thought the current management by PHARMAC of vaccine stock complements the existing system, particularly so during changes to the NIP or product changes by running down existing supplies before switching to minimise waste.

Some respondents highlighted that the current model offers suppliers certainty around annual volumes due to the 3 yearly sole supply contract cycle, followed up with quarterly updating by PHARMAC of a rolling 24 month forecast for vaccine orders. The volume based indications are supplemented by purchase orders provided 6 months in advance and the presence of a Government owned stock buffer.

Respondents noted a number of specialist functions around the distribution of vaccines that would need to be factored into any new model and would ultimately be reflected in vaccine prices and distribution costs. Specific examples included batch tracking, packaging requirements, temperature monitoring and traceability with customers and a zero tolerance for stock outs. These features fundamentally differentiate vaccines distribution from other medicines.

One respondent noted that changing storage and transportation models possibly puts more risk on an already fragile cold chain supply for vaccines in New Zealand.

Even though respondents strongly preferred the current model over the options presented, there were differing views on which option would be preferable. Those that preferred Option A suggested this would be simpler for general practice as it was similar to the influenza vaccine model that people understand. Some respondents also considered it favourable as there would not be a mismatch between funding and the cost of vaccines.

However, some respondents felt Option B was better than A for vaccine distribution to general practice. Having vaccines purchased by wholesalers and on-sold to general practice, as in Option B, provided one point of ordering and set of quality standards for all vaccines, regardless of supplier. It would also ensure stock was close to the practice to enable faster delivery, would be less risk to the cold chain, would enable buffer stock to be held at different points in the distribution chain and would not require extensive procurement arrangements between suppliers and distributors. Conversely, some respondents suggested that if more wholesalers were involved in the distribution of vaccines, this would increase the number of shipments and create additional costs and risks through the supply chain and lead to significantly higher prices for vaccines.

Supply of other medicines and devices

Some respondents noted that the proposed concept could help address a range of issues around medicine and device supply to general practice. Respondents suggested that resolving supply issues would make the development of community based services easier and assist with primary/secondary integration.

Other respondents, however, felt that the existing mechanisms are already sufficient and that supply through pharmacy is associated with established claiming and medicines management processes including daily orders from wholesalers, management of expiry, and disposal of medicines. Some respondents suggested that rather than developing new supply mechanisms it would be more beneficial to fix the issues that prevent special authority products to be supplied under PSO.

In the discussion document we also asked a question about the existing PSO mechanism. Many respondents stated the PSO mechanism is well established, easy to use and could be extended to other medicines and devices. In contrast, other respondents noted that the need for the PSO

mechanism has reduced overtime and is now mainly relevant for rural areas. Moreover it was suggested that as an open access mechanism it creates additional problems of waste and can be used as a back door method of obtaining prescription without a co-payment. A group of respondents suggested one remedy to this would be for the PSO to include individual patient information.

Consumer representatives involved in the feedback process were generally supportive of the work, seeing it as potentially improving the efficiency of the pharmaceutical supply chain and making it easier for some patients to access medicines. They felt possible savings generated by improvements in the distribution model could be reinvested into the delivery of services for disadvantaged populations.

3. Costs

Costs across the health sector arose as a significant issue in feedback on the discussion document. Overall, feedback focused on the potentially negative cost impacts imposed by our suggested mechanism although this was mostly related to vaccines.

Irrespective of the respondent's place in the supply chain, the overall financial impact on general practice was considered an overriding issue. There was much feeling that the suggested changes in the discussion document were just passing cost through to general practice. These costs were not limited to the additional stock holding requirements but placed additional burden of compliance, transition, administration (in the form of ordering, claiming, audit and management costs), insurance and increased nursing workforce hours. Some respondents commented that general practice would need to be funded for any additional costs resulting from a change to the model.

Where stockholding costs should fall in the supply chain provided for a variety of differing views amongst respondents. Some felt that suppliers should take some responsibility for stockholding costs because they are the beneficiaries of vaccine procurement. In contrast, some respondents had the view that as immunisation is a public health measure, stockholding costs should sit at the highest administration level, that being Government. Other respondents reasoned that stockholding costs should be incurred by parties in the supply chain that are best resourced to fund vaccines and manage the financial risk; these included District Health Boards via hospital pharmacies, pharmacies, vaccination clinics and larger practices. Finally, some respondents felt general practice should take more financial responsibility for the management of vaccine stock. No respondents felt these costs should be passed on to patients.

Many respondents noted that the time delay between purchase and reimbursement would create additional stockholding costs and cashflow issues for providers, particularly those with a poor credit history and as such are required to pay upfront for supply or new providers with already large overdrafts from establishments. One respondent noted the possibility that extended payment terms could be offered by wholesalers to mitigate this risk. Some respondents noted that influenza vaccine is different to other vaccines in that the purchase price is relatively small and there is fast turnover of stock. As a result, practices may receive reimbursement for the vaccine before they have to pay for it. In addition there is a large unsubsidised market for influenza that allows general practice to offset the stock holding risk.

A number of respondents provided detail on the level of stockholding in general practice; this ranged from 2 – 4 weeks of stock on hand. Some respondents also estimated how much stock

an average sized general practice would carry at any one point in time if they were required to purchase vaccines. These estimates ranged between $10,000 and $15,000.

Many respondents raised concerns that the low demand for some products would increase the financial risk of providers being left with unused stock. It was noted that this would have a greater impact on small or rural practices where volumes are low. For example, the Hib vaccine and the DTaP-IPV vaccine are used on the schedule only once so may be held for reasonably long periods of time in small practices or practices who have low numbers of under 5 year olds.

In a non-vaccine related issue, the relatively short shelf life of other products that do or could go through providers e.g. iron carboxymaltose, zoledronic acid, and enoxiparin, were highlighted as stock cost risks to providers. The risk of being caught with short-dated stock potentially means general practice would be more reluctant to be involved in the service provision of these products. In the eyes of at least one respondent, a reasonable allowance for some wastage should be made by PHARMAC. Factors outside the control of the practice, such as the child vomiting once vaccine has been prepared, syringe failure, or misadministration, could sit with the practice as an unrecoverable cost.

Similar to other medicines, some respondents felt immunisations could become a specialist service only being provided by some practices that can manage the stockholding and administration costs. For example, travel and adult vaccinations not covered by the Schedule tend to be referred by smaller practices to larger commercial vaccinators.

There are links between the cost theme and the theme of supply mechanisms where it relates to the present performance of PSOs. Respondents noted that under the current PSO system there is no financial risk to general practice, compliance costs are virtually non-existent, there are no upfront purchasing costs and low storage costs. In other words, there is not a large stockholding cost burden on general practice.

Additionally, respondents raised further issues associated with increased stockholding costs which included immunisation providers not carrying sufficient stock or only carrying enough stock for their enrolled populations, or their willingness to participate in vaccination programmes in the future. The requirement for providers to more carefully manage cashflow may result in some inconvenience for patients and or have an adverse impact on vaccination rates.

Respondents were offered two proposed pricing models for vaccines and asked to state a preference. Many respondents stated that neither option would be preferred to the status quo for the reasons stated above. Both proposed pricing models were identified by respondents as having additional risks and costs to providers. As well, both were seen as more complex than present arrangements, and therefore thought to have further financial impact, again with small providers being seen to be at a greater disadvantage.

There was the feeling among respondents that both models would lead to more frequent transactions, more administration and that the greater use of rebates would result in higher purchase prices leading to providers facing higher costs than currently exist in the system. These tie in with the access and health outcomes theme (discussed below) in terms of potentially impacting on national targets for immunisation rates.

In a similar vein to the issues raised around additional costs to providers; suppliers and wholesalers also face additional costs that would need to be reflected in the vaccine price or passed on to the provider. These were considered to include:

- extra holding costs for the safety stockpile,
- additional wholesaler and distributor holding costs,
- storage and auditing at regional warehouses,
- cost of picking and packing at national store and regional warehouses,
- cost of temperature loggers,
- forecasting,
- the cost of more robust packaging and temperature monitoring in distribution, and
- any costs associated with more frequent ordering as general practice seek to reduce stockholding costs and risk.

A number of respondents raised the wider system costs associated with developing and implementing the systems and processes, negotiation and monitoring, stock transition, the change management required and ongoing maintenance of systems with periodic adjustments to the claiming arrangements. A number of respondents also noted that a number of fridges are old and too small, therefore imposing costs on the sector in terms of fridge and data logger investment.

Some respondents highlighted that the fees charged to patients for some services reflect the risk carried by the practice. There was some concern that under the proposed model, the Government's tight control on funding coupled with restrictions on what costs can be passed on to patients would limit individual practices' ability to recoup costs in excess of what they are funded for. One respondent noted the tendency for reimbursement schemes not to keep pace with the cost of doing business.

4. Access and Health Outcomes

Responses under this theme reflected similar attitudes documented in other themes towards the split between vaccines and other medicines and devices. Most respondents indicated that patient access to vaccines is currently adequate and cited rising immunisation rates as evidence of this. One respondent also noted that New Zealand has seen significant improvements in coverage and timeliness. They noted that with the increase in coverage measured at 8 months of age, we are also closing the ethnicity gaps and consequently the greatest gains in associated disease prevention are now being seen in Māori and Pacific children.

Conversely, feedback suggested that there still seem to be barriers to treatment with other medicines and devices and therefore achievement of objectives around 'care closer to home'. We discuss this in more detail under the theme 'Application of the proposed model' below.

Nearly all of the feedback suggested negative impacts to access and health outcomes related to vaccines. Many respondents considered that additional costs imposed by the proposed model would create a number of perverse incentives around timely access to vaccines and the consequent health outcomes. There was concern that this may result in less stock being held in general practice. It was felt this would lead to stock not being available to patients in a timely manner including concerns that providers might miss opportunities to vaccinate. The risk of a stock out was considered greatest for small practices and for high risk populations due to the low demand for vaccines. There was suggestion that some general practice providers would stop providing immunisation services altogether. Respondents stated this would adversely impact on immunisation and coverage rates, increase inequity, and would have implications for general practice achieving their agreed immunisation targets.

Another respondent commented on vaccines not being available to patients if the practice was on stop supply with its wholesaler due to payment issues.

One respondent made performance comparisons of the proposed options to the Australian system where the experience suggests that stock levels are kept low and that there are times when patients are unable to access vaccines during their appointment with implications for return visits and potential missed opportunities to vaccinate. In a similar manner, temporary stockouts mean patients get turned away and there is some awareness that these missed opportunities mean that at a practice level higher immunisation targets may not be reached. Additionally, some New Zealand research was cited that showed that children with a high percentage of missed vaccination opportunities are up to 9 times more likely to have an incomplete immunisation history.

Some respondents thought the options presented indicated an intention to increase the number and types of vaccination providers, opening up opportunities to provide alternate service to communities. To achieve high immunisation rates within the community requires knowledge of who has and who hasn't been immunised; this information is available in practices and PHOs through patient registration. Other providers may not have access to this information with associated risks to the National Immunisation Register based on inaccurate data and issues with identifying the primary provider and follow up of late vaccinations.

Some respondents outlined that under the current system the vaccine and the practice visit are free to the patient and expressed concern that any new costs may be passed on to patients.

One respondent noted that there may be a risk of patients falling through the cracks during a transition period between the current system and the implementation of any new one and thus not receiving the appropriate vaccinations.

The lack of a guaranteed Government stockpile described under the supply theme (discussed earlier in this document) could increase the chance of stock outages with consequences for patient access and health outcomes.

For the reasons discussed under the cost theme, respondents felt that rural patients are not disadvantaged under the current PSO model but would be under the proposed model. Conversely some respondents thought that the proposed model would be a positive change for rural communities given that some patients are 2-3 hours away from the closest hospital.

There was some very positive feedback on the potential to improve patient outcomes by improving access to other medicines and devices. This feedback is captured below in the 'Application of the proposed model' theme.

5. Patient Safety

Concerns under the patient safety theme arose out of anticipated consequences as a result of changing from the existing model to a model where general practice would purchase their own stock. These safety concerns applied to both vaccines and other medicines. There are three angles to this; pharmacy expertise around clinical checks and managing medicines, the implications for cold chain management, and the changes to cost structures creating new incentives for stock management.

Some respondents felt that the present arrangements and a good clinical relationship between pharmacy and general practice adds a second set of eyes into the prescribing and dispensing of medicines. It was considered that direct access would remove some of the checks that presently exist but that the presence of clinical pharmacists in general practice would go some way to mitigating this concern.

Respondents also identified that the current role of pharmacy already involves much in the way of medicines management in order to ensure that stock is stored and supplied within regulations and best practice. Respondents noted that pharmacies also currently manage the expiry and disposal of medicines. Some respondents highlighted the need for careful management around vaccine expiry dates and concern was also raised about what would happen in the event of a recall if more sites hold stock of medicines.

Respondents felt that quality standards plus cold chain monitoring and audit would become more important under the proposed model to ensure patient safety. Respondents also highlighted that the current supply chain has a number of checks in place around the transfer of vaccines stock between different entities. Increasing the complexity and diversity of the distribution channel could impact the integrity of the cold chain and the ability of practice staff to evaluate vaccine quality.

Conversely, a number of respondents felt that there would be no change associated with cold chain accreditation, monitoring and audit processes. It was further noted that placing a value on vaccine stock as it travels through the supply chain was likely to enhance cold chain compliance but there is a need for better systems to be in place to manage any failures in the cold chain.

Another factor raised by respondents was around incentives and patient safety. Some respondents felt that there may also be a risk of inappropriate prescribing when the prescriber also benefits financially from the dispensing. Additionally, effective and efficient resource allocation may be jeopardised if practices are overburdened with extra expectations and costs around dispensing, potentially undermining patient safety. Some respondents also expressed concern that under some circumstances products may be compromised through mishandling and that the cost incentive would be strong enough to still use the product rather than incur the cost of waste.

6. Application of the proposed model

As we've outlined above, the majority of respondents were not in favour of changing the vaccines model. Despite the overall view that vaccines and medicines are different in terms of funding and supply, some feedback suggested there are vaccines which could potentially fit the proposed model. There was also considerable support from a large number of respondents to develop a model that could help streamline supply and funding processes around medicines that require administration and oversight by a qualified health professional, such as a doctor or nurse.

Respondents noted that issues around how general practice access supply of medicines and devices, as well as costs around the administration service that created barriers to access for patients, had implications for the development of community based models of care.

A number of respondents highlighted issues to accessing some medicines and devices needed to treat patients in general practice. These included not having stock on hand for immediate use, multiple contact points for the patient in order to collect and be treated for acute conditions, and having to make alternative supply arrangements for some medicines not available through

community pharmacy. One respondent from a rural practice highlighted their frustration with having to make arrangements to get some medicines and what this meant for delays in treatment.

Some respondents noted that in relation to access, the biggest issues were around funding of the administration service. Respondents noted that while the medicine was funded, the administration service was not meaning these charges were passed on to patients. What patients had to pay also varied significantly by practice or location? An example was given that while Jadelle is funded the means of insertion are not. In urban areas women can attend family planning clinics at no cost, whereas general practice in rural areas has to pass on the cost to patients. In this sense, some respondents felt that patient charges are driving inequity and access issues. One respondent considered that any new model needs to be consistent across the country.

Respondents raised a number of potential benefits from the proposed model. Costs could be lower for patients and the treatment more timely. Others noted that if the practice had stock available, it would be more convenient for the patients and potentially less confusing about what the patient needs to do, e.g. collect script, store medicines appropriately, make another appointment and return to the practice for administration. However, one respondent suggested having stock on hand would not improve the timeliness of some treatments as there are other steps in the process, such as lab tests, that introduce delays. This respondent also noted that some treatments are planned for a follow-up visit anyway, examples given were iron and zoledronic acid infusions and most joint injections.

One respondent noted that a number of models that would address issues around service funding and supply already exist in some areas. The Primary Options for Acute Care (POAC) model in Auckland was given as an example that could be rolled out on a national scale. However, other respondents operating a similar model suggested improvements could be made to streamline supply and the funding of administration services.

Respondents highlighted a number of products and treatments that would potentially benefit from the development of a new model for general practice. These included:

Injections and Infusions such as:

- IV antibiotics e.g. cefazolin for cellulitis
- IV fluids for rehydration
- Enoxaparin for venous thromboembolism
- Iron carboxymaltose
- Triamcinolone acetonide (intra-articular injection)
- Adenosine
- Oncology infusions/injectable chemotherapy agents available in primary care requiring health professional administration and oversight
- Depot injections for management of mental health conditions in stable patients
- Zoledronic acid
- Testosterone injections
- Insulin

Devices such as:

- Intra Uterine Contraceptive Devices

- Urinary catheter products
- Stoma care products
- Incontinence products
- Wound care products
- Orthopaedic products e.g. moon boots, splints for non ACC orthopaedic care
- IV administration products e.g. cannula, diluent, giving sets for administering IV infusions
- Materials used for contraception device insertion e.g. local anaesthetic, scalpel, dressing packs
- Glucometers

Pharmaceuticals currently available via PSO such as:

- Oral antibiotics
- Analgesics
- Anti inflammatories
- Antihistamines
- Naloxone
- Adrenaline
- Atropine
- Hydroxocobalamin
- Medroxyprogesterone acetate

Some respondents noted that a change in supply could increase the number and types of providers opening up opportunities to better provide services in communities due the availability of medicines. An example that was given would be an occupational health nurse delivering a vaccine programme to isolated areas. At the moment an occupational health nurse needs to have a relationship with a doctor to obtain a supply of adrenaline for emergency use; this is a real anomaly as adrenaline is a legal requirement of offsite vaccinating.

Despite the overall view that vaccines and medicines are different in terms of funding and supply, some feedback suggested there are vaccines which could potentially fit the purchasing model similar to influenza vaccine as providers are familiar with the process. There are also vaccines which may on occasions be administered to non-funded patients; examples included travel vaccines, pertussis for grandparents or healthcare workers, and HPV vaccine. One respondent noted that with the current pertussis outbreaks it is beneficial to the whole community to have as many people vaccinated for pertussis as possible and having one supply would make the process less complicated.

One respondent also noted the model being proposed may open up possibilities for non-general practice health providers to access vaccines such as Well Child Tamariki Ora providers and lead maternity carers who offer clinic services. It was noted this may be possible under the existing arrangements.

Miscellaneous other feedback

We also received from some respondents, feedback which related to other parts of the health system, or, that we felt was not within the scope of our discussion document. However we think it is still appropriate to document this in order to highlight the full range of feedback we received.

In relation to vaccines, some respondents raised the following potential improvements that could be made to the current system:

- Smaller providers should be able to access smaller amounts of influenza vaccine at the beginning of the season.

- The immunisation benefit would be able to be claimed by more than general practice e.g. outreach immunisation services.

- It would be beneficial to have private market vaccines more readily available – these are currently ordered in as needed causing delays and increased costs from small orders.

- One respondent felt that all vaccinators, regardless of profession, should be funded for providing subsidised vaccinations to eligible patients. Pharmacists who have undertaken appropriate training are able to deliver vaccinations for influenza, herpes zoster, meningococcal disease and tetanus/pertussis and diphtheria.

- Some suggested additions or changes to the Immunisation Schedule including:
    - Shingles vaccine which has a strong consumer demand but is not funded
    - Chicken pox for vulnerable people
    - Boostrix instead of ADT for boosters to try and eliminate pertussis
    - Free influenza vaccine for all Māori, Pacific Island and quintile 5 people
    - Meningitis vaccine
    - Hepatitis A vaccine for those with hep B or C

- Better way of capturing flu vaccinations given elsewhere to eligible population e.g. in the workplace, pharmacy, and having one claiming process for influenza.

- One respondent would like to see medicines and devices tagged to a patient/client as a necessary foundation for the sharing and recording of reliable information in any future electronic record.

- Some respondents felt that refrigerators in general practice should be monitored and alarmed (possibly to IMAC).

- The need for more stability data from the vaccine suppliers. This should be a requirement for the purchasing agreement. No vaccine should be purchased without comprehensive stability data. The respondent gave the example that this year's quadravalent flu vaccine gave very little stability data and providers were required to contact the manufacturers for every breach.

Other feedback in relation to vaccines:

- Some respondents felt the immunisation benefit did not reflect the cost of delivery at the practice. One respondent noted that research has shown that immunisation is not regarded as an income stream by most general practices, and in fact results in additional costs to providers, especially when working with patients who are not convinced of the merits of immunisation.

- A few respondents commented that the current vaccine ordering and distribution system works extremely well for outreach immunisation services. There was some feeling that change in the model will be detrimental to these services because of increased cost and risk shifting. It was noted that immunisation outreach providers are bulk funded for

service delivery and do not claim immunisation subsidy benefit. We note these comments for future reference which will be useful for considering their specific supply needs should a change of model be developed in the future.

- One respondent raised the need to assess the impacts on IT systems, processes and contracts such as the PHO agreement and outreach service provider agreements. This also included consideration of who would be responsible for the implementation and education of providers.

- One respondent requested that when choosing a future system, consideration is given to the collection of data so there is a means for identifying how many people have been vaccinated with each vaccine for analysis and monitoring purposes.

In relation to other medicines:

- One respondent noted that any model that shifts the delivery of high cost medicines away from wholesalers may have flow on implications as there may not be a corresponding reduction in their costs.

- PSO's are difficult for pharmacy to manage where the PSO pack size for a medicine varies from the pack size listed by PHARMAC, this should be aligned.

- Private hospital access to PSO seems an unnecessary cost.

Appendix 2 – Summary of questions asked in the discussion document

Supply of medicines and devices

1. What are your thoughts about our approach to improving access to medicines and devices in general practice?
2. What medicines and devices would general practice benefit from having direct access to?
3. What works well with the existing PSO mechanism and what medicines and devices are suited to being supplied to general practice by pharmacy?
4. What do you see as the patient-level impacts of such a change?

Vaccines

5. Of the two options described earlier, Option A – Price to provider or Option B – Price ex-manufacturer, which one would be preferable and why?
6. What are the good features of the existing Immunisation Benefit claims process?
7. What improvements would you like to see in the future?
8. To what extent do you think stockholding costs covered under the current arrangements?
9. What additional costs would be created under a 'purchase and claim' model?
10. To what extent should stockholding costs be borne by patients, providers, funders, or suppliers?
11. Are there any arrangements that providers, funders or suppliers could put in place to help mitigate stockholding costs to providers? For example, bulk purchasing by Primary Health Organisations (PHOs) on behalf of their members, or funding for stockholding costs.
12. What one-off transition costs do you foresee in moving to a 'purchase and claim' model?
13. What stock issues do you foresee in transitioning to a 'purchase and claim' model?
14. What other processes or supply arrangements do we need to understand so they can be factored into any future development?
15. Would there be any implications for managing cold chain accreditation, monitoring and audit under the proposed system?