Review of Pharmacy Remuneration and Regulation
#092_ANON-58KW-N5A6-9

Pharmacy Remuneration and Regulation Review 2017




Dear Members of the Review Panel,

Re: Pharmacy Remuneration and Regulation Review 2017

Thank you for the opportunity to provide further input into the review of pharmacy remuneration and regulation.

The Icon Group (Icon) is both a purchaser of pharmacy services and provider of pharmacy services, through its own Icon Cancer Care day hospitals.

Icon is also the owner of Slade Health, one of Australia's largest TGA licensed sterile compounding businesses. It provides management services to the owners of Epic and Slade Pharmacies, two of Australia's leading hospital pharmacy businesses.

Through these multiple touch points with pharmacy services, and guided by our key principles of delivering exceptional patient care and increased access to cancer care, we have approached the Interim report with a view to providing a response focused on those areas of the review that are directly related to our core areas of expertise, namely chemotherapy compounding and hospital pharmacy services and their role in the delivery of high quality care to patients.

We remain available for further discussions at any time.

Yours sincerely,

Mark Middleton
Group CEO - Icon

David Slade
Founder and CEO - Slade Health
Director – Icon
Proprietor – Slade Pharmacy

Andrew Reid
CEO – Pharmacy Services

10.3 CHEMOTHERAPY COMPOUNDING - PAYMENTS

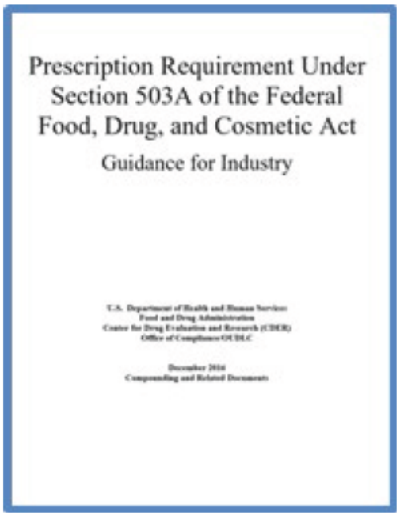
The rationale for differential payments for compounding of chemotherapy preparations is not substantiated on the basis of patient risks or health outcomes for medicines that must meet an appropriate level of quality, whether prepared at a Therapeutic Goods Administration (TGA) licensed or non-TGA-licensed facility.

Icon strongly disagrees with the above statement and suggests that there is substantial independent and qualified documentary evidence that:

1. Demonstrates that medications compounded in a licensed (e.g. TGA) facility are significantly safer (i.e. impart less patient risk) than those medications produced in a non-licensed facility, and
2. Proves there is definable additional compliance/regulatory costs (on every dose) associated with the maintenance of that (TGA) license – Refer Table 5.

In relation to patient safety; any move away from the independent and external manufacturing review processes currently undertaken by the Federal Governments' own regulation body (i.e. the TGA) introduces increased patient risk. This increased risk could, directly, lead to the injury or death of Australian patients – as has been witnessed in overseas situations, such as the USA, where non-GMP licensed pharmacies, were, until recently, allowed to 'manufacture' medicines for widespread distribution.

It is critical to draw a distinction between risk and incidents, the two are not the same. That chemotherapy compounding occurs in a pharmacy setting and that pharmacy hasn't had a known incident does not support a conclusion that the pharmacy is compounding at the same safety and assurance levels as a TGA licensed facility. Working at heights without the required safety equipment and not having a fall does not mean you aren't operating at a higher risk than if those protections were in place.


Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

Table 1: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf

In the above referenced report, the USA Food and Drug Administration (USFDA) makes the following observations in relation to medicines produced in non-licensed pharmacies:

> *In 2012, contaminated injectable drug products that a compounding pharmacy shipped to patients and health care practitioners across the country caused a fungal meningitis outbreak that resulted in more than 60 deaths and 750 cases of infection. This was the most serious of a long history of outbreaks associated with contaminated compounded drugs. Since the 2012 fungal meningitis outbreak, FDA has investigated numerous other outbreaks and other serious adverse events, including deaths, associated with compounded drugs that were contaminated or otherwise compounded improperly. For example, patients have been hospitalized after receiving compounded non-sterile drugs that were hundreds or even thousands of times their labelled strength.*
>
> *FDA has also identified many pharmacies that compounded drug products under insanitary conditions whereby the drug products may have been contaminated with filth or rendered injurious to health, and that shipped, sometimes in large amounts, the compounded drug products made under these conditions to patients and health care providers across the country.*

This strong language (e.g. "Filth or rendered injurious to health"), from an independent regulatory oversight organization (such as the USFDA), should deliver significant concern to any group proposing a move away from licensed and government funded compounding in Australia. Such a decision would undoubtedly increase patient risk and this is a view also supported by many of the industry customers (a verifiably independent group of Key Opinion Leaders (KOL's)).

Icon has undertaken significant customer/KOL consultation with public and private hospital Directors of Pharmacy to gauge industry feedback to the Interim Reviews' comments. This feedback strongly supports Icon's view that there is a tangible difference in quality of medication compounded by licensed TGA compounding facilities.

In summary – the feedback was:

- In terms of sourcing preference:
  - TGA is preferred 1st,
  - In-house (hospital) compounding is the 2nd choice,
  - Outsourcing to a non-TGA compounder is the least likely option (and is an option that is not permissible/approved for most customers, due to safety concerns)
- The differences between TGA licensed manufacturing versus non-licensed manufacturing were that TGA licensed medications are:
  - Of higher quality and safety – customers are confident GMP/sterility is met and that the production process is externally monitored. Also the accountability is there.
  - Validity/Stability much longer than other in-house/non-TGA.
  - Extended stability on compounded products – leading to reduced stock obsolescence and reduction in cost to government from otherwise having to pay for a medicine that cannot be administered to a patient.
- The main safety concern is potential microbial contamination.

If the panel wish to discuss this feedback directly with our customers, we can provide contact details on request.

In relation to differential costs and payments, the higher quality medicines produced by a licensed compounder are of that higher quality because of the compliance systems that have been implemented as part of an embedded manufacturing framework. Maintenance of these support systems is a pre-requisite to retaining the TGA license, and they come at a cost. The TGA guidelines (Table 2 below) provide detail into the additional safety/compliance steps required to maintain the TGA license and why licensed compounding costs significantly more than non-licensed compounding.

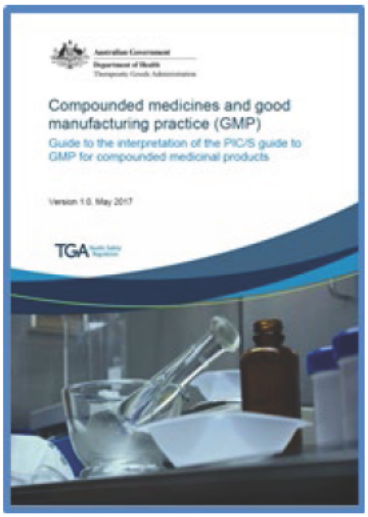


Table 2: https://www.tga.gov.au/sites/default/files/compounded-medicines-and-good-manufacturing-practice-gmp.pdf

A few examples of where these regulations manifest into expenditure are:

- **Risk Management:** TGA cGMP guidelines directs that formal risk assessment studies be undertaken by suitably qualified staff (and external experts) whenever any changes to production processes, equipment, personnel or systems are proposed. Non-licensed pharmacies have no requirement for formal risk assessment procedures.
- **Microbiology:** TGA licensed facilities are required to undertake significant, continuous and costly microbiological monitoring of their facilities. These programs involve Capital Expenditure outlay, consumable outlay and huge investment of time (usually 3-4 dedicated QA professionals within each facility - a cost of >$300,000/year). Non-licensed pharmacies have no such requirement (and consequently, often little understanding of microbial contamination of product)
- **Shelf life stability:** TGA licensed facilities are required to justify stability claims via scientific methods (such as external, independent, laboratory testing). These methods are costly to validate and complete - stability programs at most TGA licensed companies cost >$100,000/year.

A more detailed summary of the additional steps and specific costs incurred in the maintenance of a TGA compounding license are shown in Table 5 to this document.

10.3 CHEMOTHERAPY COMPOUNDING STANDARDS

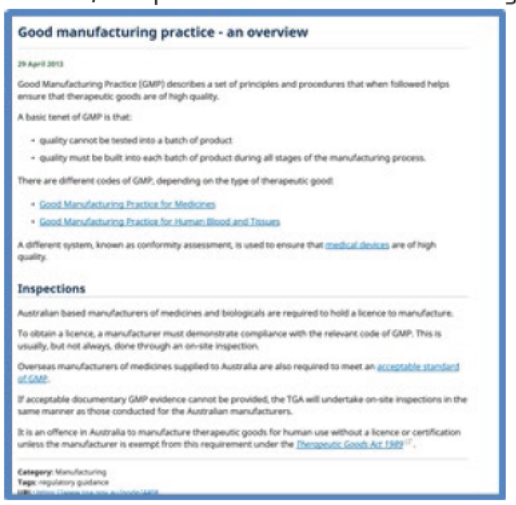
The current standards for the compounding of chemotherapy medicines in community pharmacy and other facilities appear to be overly complex. The oversight currently includes legislation, codes and guidelines. The overlap and inconsistency of these across Australia do not provide clear rules or guidance for compounders.

con strongly disagrees with the above statement and suggests that there is clear, unambiguous guidance for sterile medicinal compounders via:

1. Current Good Manufacturing Practice (i.e. cGMP); and
2. The PIC/s and TGA implementation of cGMP.

The only acceptable minimum standard for the manufacture of sterile medicines for wide-spread distribution, as recognised by the TGA, FDA and other international regulatory bodies, is cGMP. No other acceptable standard exists. No other standard is required to be developed.

The PIC/s implementation of cGMP is the gold standard – accepted globally.



Good manufacturing practice - an overview

29 April 2013

Good Manufacturing Practice (GMP) describes a set of principles and procedures that when followed helps ensure that therapeutic goods are of high quality.

A basic tenet of GMP is that:

- quality cannot be tested into a batch of product
- quality must be built into each batch of product during all stages of the manufacturing process.

There are different codes of GMP, depending on the type of therapeutic good:

- Good Manufacturing Practice for Medicines
- Good Manufacturing Practice for Human Blood and Tissues

A different system, known as conformity assessment, is used to ensure that medical devices are of high quality.

Inspections

Australian based manufacturers of medicines and biologicals are required to hold a licence to manufacture.

To obtain a licence, a manufacturer must demonstrate compliance with the relevant code of GMP. This is usually, but not always, done through an on-site inspection.

Overseas manufacturers of medicines supplied to Australia are also required to meet an acceptable standard of GMP.

If acceptable documentary GMP evidence cannot be provided, the TGA will undertake on-site inspections in the same manner as those conducted for the Australian manufacturers.

It is an offence in Australia to manufacture therapeutic goods for human use without a licence or certification unless the manufacturer is exempt from this requirement under the Therapeutic Goods Act 1989.

Category: Manufacturing
Tags: regulatory guidance

Table 3: https://www.tga.gov.au/good-manufacturing-practice-overview

Welcome to the PIC/S website!

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) is a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. It is open to any Authority having a comparable GMP inspection system. PIC/S presently comprises 49 Participating Authorities coming from all over the world (Europe, Africa, America, Asia and Australasia).

PIC/S aims at harmonising inspection procedures worldwide by developing common standards in the field of GMP and by providing training opportunities to inspectors. It also aims at facilitating co-operation and networking between competent authorities, regional and international organisations, thus increasing mutual confidence. This is reflected in PIC/S' mission which is ***to lead the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products.***

This is to be achieved by developing and promoting harmonised GMP standards and guidance documents; training competent authorities, in particular inspectors; assessing (and reassessing) inspectorates and facilitating the co-operation and networking for competent authorities and international organisations.

The current website provides information on

- PIC/S in general (see "About")
- Members (the "PIC/S Participating Authorities")
- Publications (Guides, guidance documents, etc.)
- Events (forthcoming events organised by PIC/S)
- Activities of PIC/S (training, harmonisation of GMDP, compliance, etc.)
- Accession to PIC/S
- PIA Academy - the PIC/S Inspectorates' Academy

For persons, who are unfamiliar with PIC/S, we strongly recommend that they first read the PIC/S information brochure (see below "Related documents", which provides a short, general overview on PIC/S.

For general enquiries, which are not addressed in the Frequently Asked Questions, you are welcome to contact the PIC/S Secretariat.

Table 4: https://www.picscheme.org/en/about

Predominantly, all medications sold in Australia, either over the counter, or via prescription, must comply with cGMP/TGA regulations. Medications, to be listed and subsidised on the Pharmaceutical Benefits Scheme, must first be approved by the TGA. It therefore seems illogical for any plan or consideration to move away from this this gold standard for one segment of the market - the sterile compounding sector – which in fact carries the highest risk for patients in the event something should go wrong.

Such a move will deliver an unavoidable outcome at some point in time i.e. an increased safety risk for patients.

Any adverse event in the area of sterile chemotherapy compounding would have a significant impact as these patients are immunocompromised and faced with a life threatening disease. Further the medicines they are being treated with are highly toxic.

A lower standard of manufacture of sterile compounded medicines for the treatment of these patients than applies to other medicines is surely illogical.

The key principles underpinning cGMP are:

1. Defined, consistent standards and validation activities
2. Independent and consistent external auditing against those standards.

Licensed compounders manufacture with both criteria i) and ii) (above) in place;

1. PIC/s publishes cGMP standards for medicinal manufacture
2. TGA are the external auditors – providing enforcements services in support of the standard.

Non-licensed compounders have neither of the above criteria in place.

1. Pharmacy standards are state based and open to self adoption – leading to an industry that is inconsistent (with potential for large quality variations within).
2. From an audit viewpoint, the state based, self regulating, systems (again) lead to inconsitency e.g.;
    a. Victoria – has strong audit culture
    b. NSW – has an intemittent audit culture
    c. QLD – has limited audit culture.

This self regulation is a recipe for lower quality. Training standards are relatively weak (in comparison to TGA audited plants) and the myriad of national or international quality systems that can be adopted as the basis for manufacturing platforms provide opportunity for mediocrity.

There are substantial costs associated with building and operating within a TGA licensed environment, and if payment for chemotherapy compounding was the same regardless of whether the provider is TGA licensed, this would create a financial incentive for high volumes of compounding to move from an environment that has substantial compliance requirements which deliver assurance on matters of safety, to an environment that doesn't deliver that same level of assurance.

Like outsourced compounding facilities in the United States which are regulated by the FDA, TGA licensed facilities in Australia are subject to TGA inspections according to a risk based schedule, specific adverse event reporting requirements and other conditions that help mitigate the risks of the drug products they compound. Unlicensed facilities – public or private pharmacies/hospitals - are not subject to the same inspections.

Icon also provides the following general comments in response to the interim review:

...health outcomes and therapeutic difference

Significant doubt exists as to whether "health outcomes" are a reliable measure of the differences that do exist between a TGA licensed and non-licensed compounding facility. Furthermore, there is a potential lack of understanding (by the wider pharmacy and consumer markets) and visibility of the systems, rigorous quality processes in place at a TGA facility.

The key difference is the quality assurance that is able to be delivered regarding the therapeutic consistency within a TGA environment as a result of standardised, validated and routinely independently checked quality procedures.

Whilst non-licensed facilities do not intend and would not accept that they produce a sterile product where the therapeutic outcome is reduced or compromised, the fact remains that without the systems and regulation in place as enforced and audited by the TGA, non-licensed facilities do not know this is the case and therefore hope their processes deliver an equivalent.

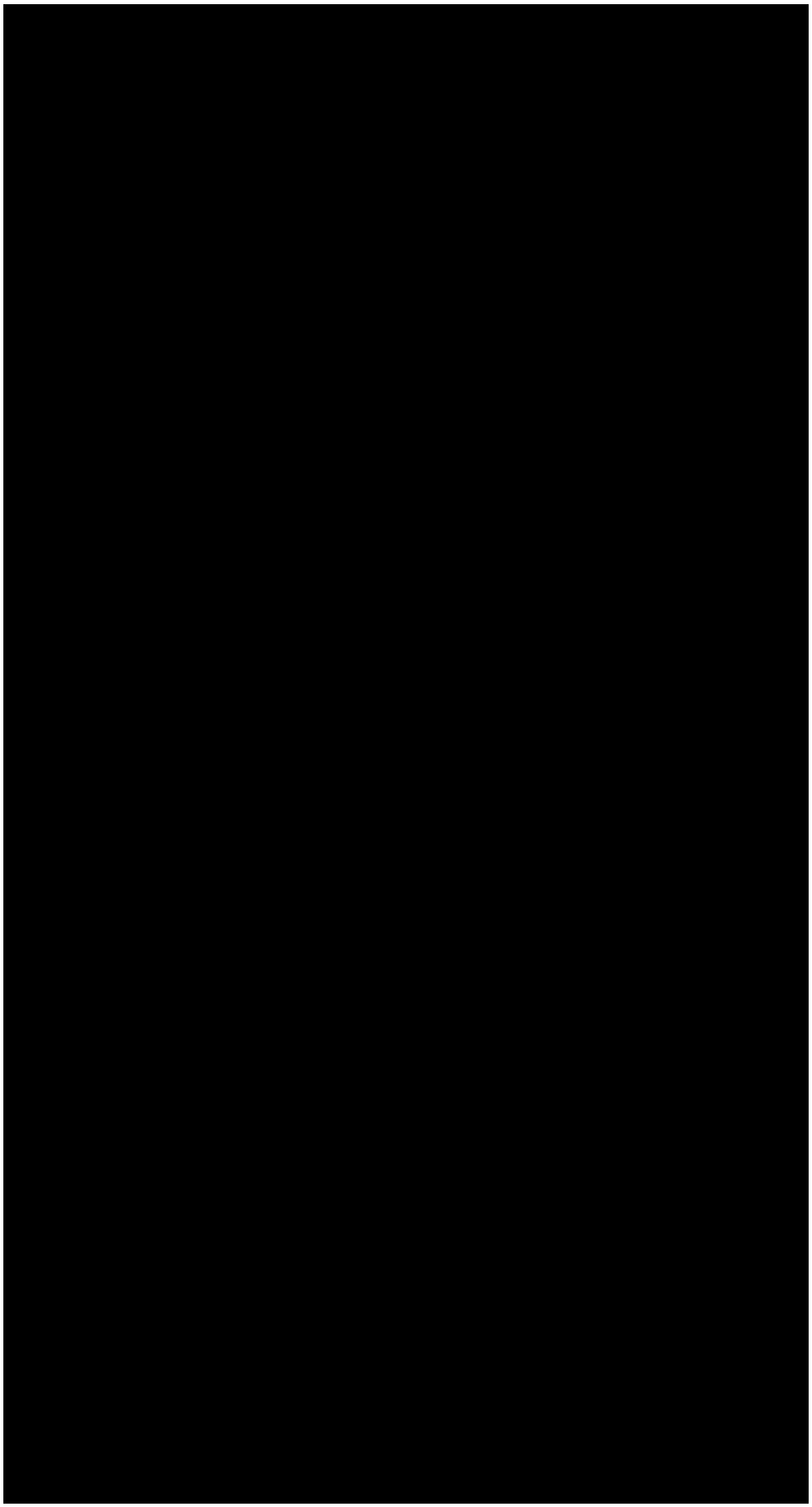
Further adverse patient events, or substandard care events that directly relate to medications supplied by a non-licensed pharmacy are often not reported (there is no requirement to do so). In a TGA licensed facility, it is mandatory to report all adverse events to the TGA.

(Page 162)...Throughout the Panel's national consultations, the majority of stakeholders considered that there is no therapeutic difference between products produced in a TGA-licensed or appropriate non-licensed facility.

This finding is not surprising. There are a small number of compounders in Australia who have taken the significant step up and made the significant investment to operate to the TGA licensing standard. It's in the self-interest of the majority of respondents to state such a view (as above). The vast majority of respondents will have never been inside a TGA licensed compounding facility. As such, they will have limited knowledge of how TGA regulations are enforced, and limited knowledge of the true difference in quality.

Icon, through its own onsite day facilities and through its affiliated Slade and Epic Pharmacies have their own onsite sterile compounding facilities where a small volume of last minute or short shelf life chemotherapy is compounded. Icon, Slade and Epic operate these sterile compounding pharmacies to a high standard however these are not subject to routine independent audit, which has resulted in development of our own audit tools and process to oversight and assurance of these compounding practices. However, they do not have the same cost structure at these pharmacies as those which are in place at Icon's own TGA facilities.

Table 5 below lists the attributes and associated additional cost structures with operating a TGA licensed compounding facility as compared to an unlicensed facility.



It is Icon's strong view that the additional $20/dose for chemotherapy compounded through its TGA licensed facilities fairly reflects the additional costs associated with compounding in a TGA v Non-TGA licensed compounding facility.

Of note is that the bulk of all compounding for patients of Icon day hospitals, Slade and Epic Pharmacies is performed at the Icon TGA facilities, despite the higher associated cost structure. The reason for this is due to the greater quality assurance associated with having large volumes of infusions prepared in a TGA facility.

(Page 162) ...A number of local compounding facilities that were not TGA licensed emphasised that they were ... producing products that were 'identical' to those compounded in TGA facilities.

It's in the self-interest of the majority of respondents to claim such. In the eyes of the regulators (e.g. TGA and USFDA) and in the judgement of the customer base (e.g. public hospitals) whose tenders' insist compounded supply is sourced from a TGA licensed facility, products sourced from a non-licensed facility are not identical to those sourced from a TGA licensed facility.

(Page 162) ...PSA has received feedback from pharmacist members which indicates that the new two-tiered fee structure for chemotherapy compounding, implemented on 1 July 2015, has disadvantaged pharmacies which are not TGA licenced. Additionally, the feedback indicates that the 'one size fits all' approach of the new structure may disproportionately affect rural and remote consumers who rely on local manufacturers for timely access to compounded chemotherapy....

TGA licensed manufacturers are not pharmacies. They are licensed manufacturing facilities. There has been no disadvantage to pharmacies which are not TGA licensed. Sterile compounding pharmacies receive an additional $40 to prepare sterile infusions. This amount reflects that they don't incur the same cost structures associated with quality and compliance to cGMP standards. As an operator of both TGA and non-TGA licensed compounding centres, Icon has a comprehensive understanding of the differential in cost structures and is well placed to make this statement.

Icon, Slade and Epic Pharmacies all made a decision to pursue the sourcing of at least 90% of compounded product from TGA licensed facilities well in advance of the introduction of the differential in compounding fee – this decision was based purely on quality and safety grounds.

The Icon group is deeply concerned with pharmacy models built on economic outcome rather than patient outcome, and a model that promotes a shift away from TGA licensed compounding facilities for economic grounds is in direct conflict with the public interest.

We don't believe there is a material adverse effect on rural and remote customers. All of Icon's TGA facilities can deliver anywhere in Australia within 24 hours. In emergency circumstances, same day delivery can also be organised. In most cases, due to the longer expiry placed on compounded products made in TGA facilities, 95% of product is delivered well in advance of patient treatment. As stated above, local (non-TGA licensed) manufacturers are adequately funded to provide small volume compounding for last minute and very short shelf life products.

(Page 162) ...PSA acknowledges that the new fee structure was implemented to reflect the additional costs associated with TGA licensing, however, it also recognises that the new funding model encourages the centralisation of chemotherapy compounding to TGA licensed facilities, and that some States and Territories, namely Tasmania and the Northern Territory, lack any TGA licensed compounders.

Chemotherapy product can still be sourced from local pharmacies within these states if the customer chooses, regardless of whether a TGA facility exists within that state.

In relation to sourcing TGA compounded products, these can be delivered by TGA licensed compounders to these states within 24 hours of order placement. In 95% of cases, the doses will be compounded in advance, ahead of the scheduled patient treatment date to ensure timely access to high quality sterile compounded medicines.

4.3 REMUNERATION FOR DISPENSING SERVICES

The government should set the same remuneration for dispensing for all community pharmacies, regardless of a specific pharmacy business model.

OPTION 4-2: REMUNERATION TO BE BASED ON EFFICIENT COSTS OF DISPENSING

The remuneration for dispensing paid by government and consumer co-payments to community pharmacy should be based on the costs of dispensing for an efficient pharmacy.

Table 5 on page 81 of the Interim Report indicates a cost per dispense of $6.66 to $12.33. There is no data presented to provide any weighting to this range, or in the concept of an efficient dispense where the bell curve sits.

While included for illustrative purposes only, the $10 flat dispensing fee example results in a reduction of total remuneration to the pharmacy sector for dispensing of 12.5%, and if the Table on page 85 is considered, with the exception of the most simple dispensing tasks leaves pharmacy with a loss for each dispensing activity.

Even at the top end of the range suggested on page 84, there are just as many activity categories that will deliver a loss as there are that are sustainable. This is clearly a flawed model and approach, and must be disregarded.

The pharmacy sector has already raised significant concerns in relation to the current level of remuneration in the context of financial risk and carrying cost associated with $20,000+ Hepatitis C listings, as challenge of the current capped remuneration structure. Another obvious example of the unsustainability of this approach is that the insurance cost associated with some refrigerated lines will exceed the annual flat dispensing fee associated with supply were this style of fee model to be adopted.

A one-size fits all, flat fee dispensing approach is neither appropriate nor sustainable, if the key tenets of the National Medicines Policy regarding equitable and timely access to medications is to be maintained.

Separately on page 90, there is a reference under the remuneration structure that there is no equivalent to the price disclosure process for PBS payments to hospitals. This is an absolute error in fact.

6.3 PROCEDURES AND REMUNERATION FOR THE SUPPLY OF HIGH-COST MEDICINES

The supply of complex and high-cost medicines does not sit well within existing supply chain and pharmacy remuneration arrangements. Supplying these medicines is of significant concern for a number of pharmacies.

OPTION 6-1: COMMUNITY SERVICE OBLIGATION REMOVAL, RETENTION OR REPLACEMENT

The recommendation in Option 6.1 is to remove the CSO, standardise trading terms that wholesalers offer, and increase regulation of wholesalers. This appears in direct conflict with all commentary and options through the Interim Report in relation to remuneration and location rules and there interfacing with "competition", which attempt to make arguments for pharmacy and medicines to be treated as ordinary items of commerce, yet here increases regulation and reduces competition.

While there are new challenges for the sector to consider in relation to high costs medicines, the proposals in Option 6.1 and 6.2 are flawed and must be dismissed. Implementing such an approach would completely dismantle the current supply chain, and it must be accepted as a logical conclusion that this would only expand the current challenges faced by the sector regarding stock shortages and out of stocks

10.5 TIGHTENING THE LISTING OF GENERIC MEDICINE

A more targeted approach to listing PBS medicines can improve supply chain efficiency and reduce costs to the Australian community.

Option 10-5 does not reflect current manufacturer behaviour, where new brands may list over a period of time, and is restricting competition and market forces, which have been seen to be highly effective and continue to be so in delivering substantial savings to the government via price disclosure. Indeed, these savings continue to exceed forecast savings with the release of each Federal Budget, indicating the policy and market are more effective than government can reliably forecast.

This option also ignores Australia's position within a global economy, and the interruption to the supply chain that regularly occurs across various medicines from time to time, whether due to complete interruption of supply or interruption of supply to Australia as better economic outcomes are available in other countries when supply is limited. Limiting the number of listed medicines, and how the manner in which they may be listed, is not certain to deliver improved savings to the government, but will increase disruption to the supply chain and reduces competition within the sector, and may place consumers at increased risk.