



Introduction:

The Wesley Pharmacy is a section 90 pharmacy that is also a TGA licensed compounding facility.

Our customer base is currently in regional Queensland, South East Queensland and New South Wales. Customers are licensed day hospitals, regional hospitals with day oncology units and other section 90 pharmacies.

Prior to achieving TGA licensed status, The Wesley Pharmacy had been compounding cytotoxic infusions as a non-TGA licensed compounding pharmacy for in excess of 20 years.

TGA licensing was achieved in 2011 upon completion of our current facility during 2009-2010. This made us the first wholly owned TGA licensed cytotoxic compounding facility in Australia, competing with the internationally owned Multinational Pharmaceutical Companies, Baxter and Fresenius Kabi. This significant investment resulted in a marked improvement to the quality and safety of compounded product that we provide to our patients.

Being a TGA licensed compounder has significantly increased our cost of preparing infusions as a result of licensing costs, audit costs, increased staffing requirements, increased use of consumables and increased environmental monitoring costs.

Question 1

See Figure 1 Model of Care for Provision of Chemotherapy.

Question 2

The processes are outlined in [Figure 1]. Whether we are selling to a pharmacy or a hospital, the end user is a patient receiving treatment in a licensed private oncology clinic of some description.

Nurses employed by the clinics perform the task of administering the medicine to the patient, supervising the infusion and responding to any relevant symptoms. Their services are funded through health fund payments to the clinics. The nurses are also part of the patient education process with regard to information on how to manage the side effects of their treatments.

Pharmacists employed at The Wesley Pharmacy perform a dose and protocol review for each dose that is prepared. The responsibility of liaising with doctors (prescribers) and nurses about any changes, dose errors, scheduling errors, omissions, changes in patient particulars resulting in dose changes falls to the pharmacist.



In the case of our pharmacist customers, they work closely with our pharmacists but are generally the ones to liaise with patients, doctors and nurses in the clinics that they service.

The funding for these significant risk mitigation elements of the dispensing process comes from the margin made through a combination of generic margin (which, under the current model, is destined to evaporate) and the fee and mark-up structure provided by the PBS.

In some cases we have been able to negotiate to charge an additional compounding fee to the clinic which further assists in subsidising this service provision. However, most clinics (especially the regional ones) have indicated that an additional charge would result in unsustainable businesses for them.

The doctors are funded through personally retaining between 92 % and 75% of their Medicare revenue (i.e. Paying a service fee of between 8% and 25% of Medicare income) or through salary agreements.

Question 3

The most concerning development in the chemotherapy space has been an unintended consequence of the move from section 85 of the PBS to section 100.

Section 100 does not have a maximum price to pharmacist. This means that we have a fixed selling price but a free market economy driving our purchase price.

For genericised medicines, in the short term, this is fine. Market forces will ensure that competition for market share between generic vial manufacturers should ensure that the pharmacist can acquire vials of PBS listed cytotoxic medicines for “PBS base price” or less. (It should be noted though, that price disclosure will eventually result in a floor PBS price being achieved which will likely result in generic brands exiting the market. Since there is no mechanism within price disclosure for the DWAP to cause a PBS price increase, this reduced competition and could result in market prices for generics being more than the PBS base price.)

For on-patent medicines we are in a bind. As newer drugs are become more expensive wholesalers are forced to require more margin than the theoretical \$24 wholesaler fee to cover their holding, handling, distribution and capital costs.

Take Jevtana (carbazitaxel) as an example. The total reimbursement paid by Medicare to our pharmacy for a 60mg infusion would be \$6,022.40 (including co-payment, all fees, all mark-up). Our purchase price for this line is \$5,925.22. We achieved this price after very heated negotiations with our wholesaler. Our margin on this episode is \$97.18. Prior to the additional temporary \$60 fee our margin was \$37.18. We have previously demonstrated a cost to serve of around \$150-160 per dose prepared. This cost appears to be industry wide (as supported by the independent Pitcher Partner report and multiple other submissions to the senate enquiry into supply of chemotherapy drug such as docetaxel earlier this year.)



In the long term as generic margin reduces, our capacity to absorb the episodes where the cost to serve exceeds the revenue derived from the service will cease.

Question 4

We are a third party compounder as well as being a section 90 pharmacy. As such we have no requirement to use a third party compounder. Our pharmacist customers choose to purchase compounded infusions from us because the investment required is significant. This challenge is both financial, in terms of capital outlay and ideological in terms of time and effort to manage the project and acquire appropriate expertise to design, build and operate a facility such as ours.

Similarly the recurrent costs and continual effort required to operate such a facility is onerous. Another limiting factor facing new entrants into the sterile compounding space is the fact that the sector is heavily reliant on government funding and the risk that government policy will change.

If a pharmacy’s chemotherapy business is not underpinned by sufficient chemotherapy volume it is simply not economically viable to compound in house. Our service to pharmacies facilitates the local or co-located pharmacy to be able to have close working relationships with the doctors and nurses of the various clinics at a local level, whilst being able to access high quality, sterile, safe compounded products from a central compounding centre.

Question 5

Pharmacist customers enter into a contract with The Wesley Pharmacy as their compounding service provider. This agreement outlines pricing and task responsibility for both parties.

Hospital/Clinic customers enter agreements with The Wesley Pharmacy to provide compounding and pharmacy services. This agreement outlines pricing and task responsibility for both parties.

Question 6

The suggestion that the pharmacist’s costs or effort involved a dispensing episode of a prescription for Warfarin is comparable to those of dispensing a prescription for a chemotherapy medicine has created my first “ROFL” (rolling on the floor laughing) moment in writing this submission.

- A new warfarin patient comes into the pharmacy, my assistant confirms their Medicare card and address.



The Wesley Pharmacy & Associated Pharmacies

“Specialised Services for Special Needs”

- The pharmacist dispenses the prescription (3 minutes maximum) which is likely to be for two strengths of warfarin. (Total cost of stock on shelf for 2 strengths = \$10.42. Total profit made by the pharmacy for dispensing 2 strengths = \$14.82)
- The pharmacist then counsels the patient and provides a CMI. \$14.82 for 5 minutes work with no significant consumable expense.

Compare this to the Jevtana example outlined above. \$5,925.22 of stock on the shelf.

- Dose and protocol review
 - Is this the correct dose for this patient based on their body surface area?
 - Is this dose due now?
 - Are all of the relevant other drugs ordered for the patient
 - Is the patient well enough for this dose.
- This takes around 15 minutes if no intervention or further information gathering is required.
- Preparation of batch documentation for compounding in accordance with our TGA licencing conditions takes a minimum of 10 minutes of scientist time.
- Preparation of batch components takes around 5 minutes.
- Pre-decontamination checks another 5 minutes.
- Initial component decontamination from staging area to D grade cleanroom takes 2 minutes.
- Second decontamination for transfer into the B grade cleanroom takes 2 minutes. (No time has been allocated in this example to account for the time taken for the team member to gown and scrub into the D grade area.)
- Dose is prepared inside the grade A cytotoxic drug safety cabinet in accordance with the manufacturer’s instructions. (Let’s assume that the two manufacturing operators required to perform this step are already appropriately scrubbed and gowned – it takes around 20 to 30 minutes to enter a cleanroom properly attired.) Reconstitution in accordance with the manufacturer’s instructions takes around 10 minutes as the vial is slow to dissolve and foaming within the vial would result in an unsafe product. The vial then stands for 5 minutes prior to being drawn up and injected into the final product container. Conservatively this step takes 18 minutes total.
 - Consumables directly used in the preparation of this dose; 2 drawing needles, 2 hydrophilic vents, 2 syringes, final product container (5% glucose), final container seal cost near to \$15.00.



- Amount of active ingredient is checked by a second manufacturing operator as it is drawn from the vial.
- Final product is checked for leakage and sent to labelling area. Pharmacist applies final product labels, checks against original order to ensure patient safety. (4 minutes)
- Final product is inspected for particulates under 10,000 lux in accordance with the Japanese Pharmacopeia and released by Quality Assurance team member. (5 minutes)
- Product is packed for shipping to the customer clinic. (5 minutes)

Total staff time required to prepare this dose =71 minutes. Total margin (without the temporary fee increase of \$60 per infusion) = \$37.18.

\$ of gross profit per minute worked for Jevtana = \$0.52.

\$ of gross profit per minute worked for Warfarin = \$1.85.

Note this does not include any of the significantly higher costs of running clean rooms, holding the high value, low margin stock, higher staff costs due to specialisation etc.

Any argument that the pharmacists manage the dose adjustment element of warfarin therapy is a falsehood. This service is provided by the pathology lab performing the tests and the prescriber. So, whilst it could be said that there are significant risks involved with warfarin therapy it is ridiculous to compare this to the seriousness of a medication misadventure in the chemotherapy space.

In any case, thanks for the laugh!

Question 7

The simplest fix for the broken system is to ensure that fees are sufficient to fund the service provision. I am of the view that the current \$101.33 fee (i.e the official compounding fee of \$41.33 plus the additional interim fee of \$60.00) is about \$40 too light once generic cross subsidisation has ceased.

The other thing that would appear simple to fix would be to restore the legislative protections afforded to section 85 PBS listed medicines in terms of maximum price to pharmacist to the chemotherapy infusions that are now in section 100.

If a regulatory environment that allows for the continuation of Third party compounders is to continue, the DWAP calculation must take into account Third party selling prices to pharmacists in a ready to use form. The current arrangement is akin to



SANDOZ selling me paracetamol powder and this being the price used for the DWAP price calculation for PBS listed paracetamol tablets.

1E Question 1

Generally, the process for preparation of all cytotoxic infusions follows the same steps. Dose and protocol review, preparation of batch documents, some sort of billing step, batch component assembly, decontamination, manufacture in cytotoxic drug safety cabinet, labelling, quality release and shipping to the end user.

Any variation in process relates to either method of dissolution or final container type. For example, filling a CADD cassette is more time consuming than filling an Ecoflac container as the CADD cassette needs to have all air bubbles removed and this can be very time consuming. Another example is the slow dissolution of carboplatin solutions which can take up to 20 or 30 minutes to dissolve.

A significant cost that is often overlooked is vial breakage or bung coring. A dose with a piece of polyisoprene bung in it could be lethal to a patient. In some cases this bung is introduced by the needle used to pierce the vial. If this is an item with a vial cost of \$5,925.22 it is a significant expense. Similarly dropping a \$5,925.22 vial and breaking it, is a significant expense.

Please refer to our response to question 6 above for a better understanding of the number of times a vial is handled in the preparation of each dose.

Drugs with short expiry times (sometimes as little as 6-8 hours) once reconstituted pose an additional challenge in that their manufacture time must be scheduled in concert with the patient's scheduled treatment time.

1E Question 2

It would seem appropriate that the commercial risks involved in handling higher cost medicines should be compensated in some way. Perhaps broken vials should be claimable and this element of funding subject to audit to avoid rorting/the introduction of carelessness as a result.

Rural and regional Question 1

Currently the pharmacy absorbs the cost of freight to regional locations. Regional hospitals/clinics are under more financial pressure than their urban counterparts because they need to pay more for staff and sometimes receive a lower DRG payment for the same service due to less bargaining power when negotiating health fund contracts.



The freight costs for each clinic would be around \$500 per week.

For items with 8 hour expiry, significant effort is required to schedule the patient and prepare the dose to link with a flight or courier to ensure that the dose is available for the patient. 8 hour expiry drugs cost us around \$100 per patient day in additional freight.

If there is insufficient margin for the pharmacy to absorb these costs, some of the hospitals that we service have indicated that they would be unable to continue these treatments.

Rural and regional Question 2

Regional consumers often need to travel significant distances to receive their treatment. Most cancer patients are not well enough to attend the regional centre alone. Their carers need to take time off from work which adds enormously to the stress involved in accessing these services.

Regional consumers must absorb travel and accommodation costs in order to receive their treatment. This increases the pressure on pharmacy service providers to ensure that our deliveries arrive to the correct place, on time.

Currently, the additional freight and logistical costs that are required for treatment in regional centres are absorbed by the Pharmacy. In the future, this may need to be another cost that is borne by the patient.

Rural and regional Question 3

We are very proud of the level of service that we provide to our regional clinics. The quality of infusions that are received by our urban and regional patients is exactly the same.

The main service differences relate to scheduling due to freight and logistical challenges.

Another contrast in the regional and rural setting level is that the oncologists/haematologists often defer management of these patients to the local physician. Perhaps there is a difference in patient outcome as a result of this but it is doubtful as most of these physicians are excellent practitioners who have a genuine desire to care for their patients and work closely with city based oncologists/haematologists.

Rural and regional Question 4

Whist it remains viable, we will be absorbing freight costs for our regional clinics. As generic margin dissipates this will become impossible.

A fee to cover freight costs would be a move to a more transparent system. This could be managed as an additional claim based on clinic post code or similar.



Quality of Infusion preparations Question 1

Due to our range of licenses The Wesley Pharmacy satisfies the complete gamit of regulations relevant to cytotoxic drug preparation and supply.

1. As a TGA licensed manufacturer we are subjected to a 3 day onsite audit every year to ensure that we are in compliance with all relevant legislation.
 - a. In order to maintain our status as a licensed compounding facility we must comply with;
 - b. Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). Including;
 - i. Annex 1 – Manufacturing of sterile medicinal products
 - ii. Annex 11 – Computerised Systems
 - iii. Annex 15 – Qualification and validation
 - iv. Annex 20 – Quality and Risk management
2. As pharmacists owning pharmacies in Australia we are accountable for the actions of all of our pharmacists through the Australian Health Practitioners Regulation Authority. Awareness of this accountability is a driver for ethical decision making in all facets of pharmacy practice.
3. As a pharmacy located in Queensland we must also comply with the Health (Drugs and Poisons) Regulation 1996.
4. As a Queensland based manufacturer of restricted Drugs we are also licensed under section 18(1) of the Health (Drugs and Poisons) Regulation 1996. We were inspected by Queensland Health for 1 day prior to this license being granted.
5. We also require Authorisation under the Work Health and Safety Regulation 2011 (Qld) to handle and store a restricted carcinogen: cyclophosphamide. We were inspected by Workplace Health and Safety Queensland for 1 day prior to this authorisation being granted.

Adverse events are monitored through our complaints register and if relevant are reported to the TGA via ADRAC (Adverse Drug Reactions Advisory Committee). The TGA auditor has access to this register during the site visit.

In the 20 or so years that we provided these services as a non-TGA licensed compounder we were not inspected once by Queensland Health.

In our view there needs to be better regulatory oversight of non-TGA licensed compounders.



Quality of Infusion preparations Question 2

The list of compliance requirements outlined above is quite onerous. What adds significantly to the challenge of being a TGA licensed manufacturer is the fact that the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) is not designed for the model of pharmaceutical manufacture that occurs in our sector. It is better suited to manufacture based around many units per batch, with a batch taking months or weeks to prepare. Manufacture in our space involves single units per batch with multiple batches occurring per day.

Ideally, a set of regulations specifically designed for manufacturing in our context should be implemented. Given that a groundswell of support for this concept is growing internationally (especially given the events at the New England Compounding Centre), it would seem prudent to wait until this is addressed by the PIC/s committee in Geneva.

As a TGA licensed compounding centre it suits me to claim that only TGA approved compounders should be able to claim PBS benefits for compounding cytotoxic infusions. I think this would reduce access and increase regulatory cost. Money would be better invested in ensuring that the sector is viable through adequate remuneration to the pharmacists and that the current systems to achieve accountability are enforced.

I am of the view that infusions prepared in licensed compounding centres are of a higher quality than those prepared in an unlicensed compounding centre. It would be difficult to quantify how this enhanced quality improves patient outcomes.

Quality of Infusion preparations Question 3

It seems counter intuitive to increase regulatory burden as we reduce remuneration unless the desired end point is reduced access to services. If and when and the PIC/s committee in Geneva takes a position on licensing compounding centres, Australia should be an early adopter. Until then, the checks and balances in the current system are sufficient and could be made more effective through renewed vigour from the existing regulatory authorities.

Other Matters Question 1

The clerical burden of processing paper prescriptions and filing repeats and sorting for the PBS claim and chasing up Medicare for unpaid prescriptions or reprocessing rejected prescriptions does nothing to reduce Medicare fraud, does nothing to improve patient safety and does nothing to improve patient access to services.

In our sector, prescription writing, management and processing is seen as a chore that needs to be completed so that the real work of treating patients can continue.



Other Matters Question 2

This could be quickly and easily fixed with the introduction of a standard order form (i.e. drug chart), a copy of which could be used for PBS claiming. This would enhance traceability and reduce potential for transcription errors resulting in better patient safety, better safeguards against fraud and less clerical chores for all involved in the sector.

It would also reduce Medicare’s cost to serve by reducing staff time allocated to “nit picking” reasons to reject or slow payment. Less clerical time for doctors, pharmacists and nurses should mean more time delivering health care services.

Other Matters Question 3

There are a number of chemotherapy drugs that we are unable to acquire at the official PBS ex-manufacturer price. This defies the principle of equity of access which underpins the PBS. This should be simple to fix by setting a maximum price to pharmacists.

The Department of Health and Ageing’s unreasonable manipulation of the PBS pricing algorithm seems to be a cynical attempt to further reduce margin available to pharmacies involved in the cancer care sector. This should be altered to reflect the mark-ups as agreed in 2010. Full fees should apply regardless of the dose. The current position is illogical because the cost to serve is not a factor of actual dosage prepared.

The point of calculation for DWAP should be the price paid by the pharmacy to the Third party compounder of the cytotoxic infusion in a ready to use form. The current position held by DoHA defies the spirit of the price disclosure system by including the input price to the Third party compounder rather than the input price for the dispensing pharmacy. Similarly the inclusion of volumes through the input costing of the Third party compounders derived from public hospital purchases amplifies this effect. Further, the product being used for the DWAP calculation is not in its ready to use form. (See paracetamol example in our response to Question 7).

When vials are unavailable due to manufacturer shortages the nearest vial algorithm should be correspondingly adjusted. It is simply unfair that pharmacists are penalised due to a Multinational Pharmaceutical Giant’s inability to ensure continuity of supply.

It is pointless for the government to claim to fund cancer treatment, add new items to the PBS, to build new Cancer treatment centres, even fund cancer screening programs when an essential element of the system of treatment may not be viable in the future. If the system is to be fixed, it needs to be transparent and ensure remuneration reflects cost to serve.



Figure 1 Model of Care for Provision of Chemotherapy

