The Pharmacy Guild of Australia

Supplementary submission to Senate Community Affairs Committee Inquiry: Supply of chemotherapy drugs such as docetaxel

April 2013

Contact:

Stephen Armstrong
National Director, Health Economics
The Pharmacy Guild of Australia

This supplementary submission should be read in conjunction with The Pharmacy Guild of Australia's ('the Guild's') original submission to this Inquiry (March 2013). The Guild is providing this supplementary submission to ensure that the Committee is fully informed and to respond to the Department of Health and Ageing (DoHA) submission that was released on 5 April 2013. We urge the Committee to consider the content of this supplementary submission when compiling its report.

CONTENTS

Section 1: The *Efficient Funding of Chemotherapy (EFC)* budget measure is separate from the Fifth Community Pharmacy Agreement..... 2

Section 2: Community Pharmacies cannot pay for the Chemotherapy shortfall..... 7

Section 3: Other Important Considerations & Issues 8

SECTION 1:
THE *EFFICIENT FUNDING OF CHEMOTHERAPY (EFC)* BUDGET MEASURE IS SEPARATE FROM THE FIFTH COMMUNITY PHARMACY AGREEMENT

Overwhelming documentary evidence from 2008 onwards that the chemotherapy arrangements are separate to the Community Pharmacy Agreement.

Confirmed by DoHA in April 2010.

No attempt was made to recoup from the 5th Agreement the reduction in anticipated savings from the EFC measure announced in the 2010 Budget.

No references to chemotherapy in 5th Agreement or official Agreement-related information.

No references to 5th Agreement in EFC arrangements or related information.

In its submission to this Inquiry DoHA contends that "the Fifth Community Pharmacy Agreement has been identified by the Government as the appropriate source for funding chemotherapy fee changes" on the basis that it "was negotiated in the context of three interlinked measures (including the Fifth Community Pharmacy Agreement)". DoHA cites as evidence the fact that while the Efficient Funding of Chemotherapy Measure (EFC) was first announced in the 2008-09 Budget entirely separately to any Community Pharmacy Agreement, it was renegotiated in parallel with the Fifth Community Pharmacy Agreement. DoHA refers to an alternative funding model for chemotherapy being agreed by the Commonwealth and the Guild in negotiations that ran parallel to the Agreement negotiations and asserts that details of the EFC were announced in the 2010-11 Federal Budget as part of a wider announcement of the Agreement, despite the fact the Agreement was announced separately and prior to the Budget without any mention of the EFC.

The Guild and its members cannot and will not accept the Department's position in relation to the source for funding chemotherapy fee changes. It would result in a significant and totally unfair impost on Australia's 5,240 community pharmacies, 98% of which do not deal with chemotherapy medicines and are struggling with the increasing impact of price disclosure. The claim by DoHA that the Community Pharmacy Agreement is "the appropriate source for funding chemotherapy fee changes" has no legal or factual basis and would require a retrospective and unilateral rewriting of the Agreement to the considerable detriment of Australia's community pharmacies, which are separately already providing savings to the Government under the Agreement of over $1 billion between 2010 and 2015 as well as indirect savings through price disclosure. These pharmacies have already experienced a 10.8% real reduction in remuneration over the past three years, and further reductions are likely to flow from price disclosure over coming months and years.

Given the DoHA submission and evidence to the inquiry, it is important to put all the pertinent facts on the table on the question of whether the chemotherapy shortfall should be funded from the Agreement. The original EFC budget measure was announced in May 2008 separately to any Community Pharmacy Agreement. It was postponed because of its flawed nature, first to enable further consultation with stakeholders and again to be considered in the context of the 5th Community Pharmacy Agreement. In late 2009, the Government and the Guild expressed an agreed intent to achieve $120.6m in savings from the EFC over 5 years, with any shortfall in these savings to be applied to pharmacy remuneration. At the same time, the Government and the Guild expressed an agreed intent that community pharmacies would receive additional funding for professional services or quality measures (not remuneration) in lieu of the flow-on impacts of the proposed price disclosure MOU which was separately being negotiated with Medicines Australia.

The latter expression of intent in relation to the Medicines Australia MOU was carried through to the Fifth Agreement; however there is no provision in the Agreement for the amount provided for professional services or quality measures to now be redirected to address the loss of remuneration from the chemotherapy shortfall and, in any event, the amount of funding available would be clearly insufficient to meet this shortfall without emasculating these programs. In stark contrast, the expression of intent in relation to chemotherapy savings was never followed through by the Government either in terms of maintaining the levels of savings or imposing a requirement in the Agreement or elsewhere that any shortfall be sourced from pharmacy remuneration.

In the May 2010 Budget, the Government announced that the EFC would reduce the previously booked savings (from the 2008 Budget measure) by $95.3m over 5 years. There was no reference in either the EFC budget measure or in the already announced 5th Community Pharmacy Agreement and the accompanying collateral of any funding interlinking between the two initiatives. On the contrary, a matter of days prior the public announcement of the 5th Community Pharmacy Agreement, the Department confirmed in writing that the EFC model had been agreed and was separate from the Agreement. Nor did the Government at the time or subsequently ever approach the Guild to seek recoupment of the EFC shortfall between the $120.6m agreed in-principle in late 2009 and the 2010 Budget announcement which reduced the savings to below $100m.

It is important to point out that Clause 33 of the Fifth Agreement states that "this Agreement constitutes the entire agreement of the parties about its subject matter and supersedes all previous agreements." The importance of this provision is that it makes clear that unless a matter is covered by the Agreement, it is outside of it regardless of whether it was the subject of earlier consideration or not. This is a fundamental element of the Agreement and of prior agreements, which is included to provide certainty to both parties during the life of the Agreement. For any shortfall in chemotherapy remuneration to be recouped from the Agreement, this would need to have been expressly provided for in the Agreement, and the fact that it was not is hardly surprising given the EFC, which seeks to fund the unique costs incurred by chemotherapy pharmacists, was always a budget measure separate to the Agreement, as confirmed by DoHA shortly before the Fifth Agreement announcement.

It is also important to point out to the Committee that the funding shortfall now facing chemotherapy pharmacists is a direct result of their loss of trading terms due to the impact of the price disclosure arrangements on chemotherapy medicines. These price disclosure arrangements and the savings the Government is deriving from them are separate both from the Agreement and the EFC. The level of savings being derived by the Government from the impact of price disclosure on chemotherapy medicines far exceeds the savings attributed to the EFC. In fact, the Guild estimates that the savings from the impact of price disclosure on chemotherapy medicines will be $210m in 2013-14 alone.

Finally, given the statements in the DoHA submission that the Agreement is "the only other source of available funding" and "the appropriate source for funding chemotherapy fee arrangements", it is important to emphasise the difficult position in which chemotherapy pharmacists find themselves in seeking to find a solution to their shortfall. Unlike other pharmacists whose remuneration is covered by the Agreement and medicine innovators and generic medicine providers who are subject to the Medicines Australia MOU, the chemotherapy pharmacists have no formula, established process or

designated time that they can rely upon to have their remuneration issues reviewed or reconsidered. They face a situation where they have, as a result of significant reductions in their remuneration, reached a point where their businesses are increasingly unviable, but have no recourse other than to request direct assistance from the Government.

In summary, both the source of the problem facing chemotherapy pharmacists (price disclosure and inadequate funding for the costs entailed in preparing and dispensing chemotherapy medicines once the trading terms cross subsidy has been eliminated) and the measure to resolve the problem (enhancements to the EFC which funds these costs) are separate to the Fifth Community Pharmacy Agreement. There is no legal or factual basis for asserting that there is a funding link between the Agreement and the EFC. Any attempt to derive the shortfall from the Agreement would come at the expense of community pharmacies who have no involvement in chemotherapy; are already providing over $1 billion in savings separately to the Government through the Agreement; and who themselves are increasingly being impacted by the multiple billions of dollars in savings the Government is deriving from price disclosure.

The claim by DoHA that the Agreement is "the only other source of available funding" may be their view of the current budgetary environment. However, in reality the most "appropriate" means of addressing this issue would be to return what would amount to a relatively small proportion of the savings generated from price disclosure to cover this shortfall in remuneration.

The table below details the history of the Efficient Funding of Chemotherapy (EFC) budget measure and the separate 5th Agreement.

Date	Details	Evidence of no linkage with Community Pharmacy Agreement
13 May 2008	Government announces a budget measure that "more efficient arrangements" will be implemented for chemotherapy drugs, saving $96.9m over four years to 30 June 2012.	1. The Guild was not consulted in the lead-up to the budget and knew nothing about the measure until it was announced. 2. The Government did not link this budget measure to the 4th Agreement in any way. 3. No funds were allocated back to the 4th Agreement as a result of this savings measure. 4. The Guild recognised that chemotherapy was not part of the 4th Agreement so did not contend that the introduction of this measure would be a breach of that agreement.
26 April 2009	Minister announces delay "to enable sufficient time to negotiate with industry stakeholders".	5. No linkages were drawn to the 4th Agreement in this announcement.
20 August 2009	Minister announces further delay "to discuss the measure further in the context of negotiations for the Fifth Community Pharmacy Agreement".	6. As shown by this statement, it remained a separate measure.
Late December 2009	The Guild and Minister agree to continue to discuss a proposal with an intended target savings	7. The $120.6m savings target was expressly in addition to, and separate to, the $1,001.0m in savings to be generated from the 5th Agreement.

Date	Details	Evidence of no linkage with Community Pharmacy Agreement
	level of $120.6m over the five years to 30 June 2015, a reduction of $68.4m in savings compared with the 2008 budget measure over this five year period.	The chemotherapy arrangements remained a separate budget measure. 8. The $120.6m was an intended target at this time but was further reduced through the 2010 Budget (see below). The difference was not recouped from the 5th Agreement funding pool. 9. The negotiations anticipated that community pharmacy may receive additional funding for professional services or quality measures (not remuneration) in lieu of the flow-on impacts of price disclosure, which was carried through to the Agreement 10. There was however no such arrangement pursued in the Agreement to meet any shortfall in the budget savings from the EFC.
February 2010	Additional financial model information from Community Pharmacy Chemotherapy Services Group (CPCSG)	11. In this revised paper provided to the Government by the Guild on behalf of the chemotherapy pharmacists, the savings for chemotherapy over five years (as estimated by the CPCSG) were reduced to $95m. While this amount was significantly lower than the late 2009 discussion, no adjustment to the Community Pharmacy Agreement was anticipated nor made.
March-April 2010	Drafts of the 5th Agreement produced by DoHA.	12. Neither the first draft nor any subsequent draft contained any reference to chemotherapy fees or any arrangements to recoup any shortfall in the EFC savings.
Late April 2010	The Guild receives confirmation in writing from DoHA that "the measure remains separate from the Fifth Agreement".	13. This was final confirmation that the chemotherapy arrangements were not part of the Agreement and remained completely separate to it. 14. It also confirmed that the proposal from the Community Pharmacy Chemotherapy Services Group had been accepted but final calculated savings were not provided to the Guild prior to the Budget.
3 May 2010	5th Agreement signed by Guild and Minister	15. The 5th Agreement contains no reference to chemotherapy arrangements or fees. 16. The Pharmacy Remuneration element of the funding table in the 5th Agreement lists all fees that are part of the agreement but does not mention the chemotherapy fees. 17. The 5th Agreement information document released by DoHA following the signing of the agreement contains no reference to chemotherapy. 18. The savings generated by the chemotherapy measure are not announced with the 5th Agreement and are not included in the $1,001.0m savings flowing from the 5th Agreement.

Date	Details	Evidence of no linkage with Community Pharmacy Agreement
		19. Clause 33 states that "This Agreement constitutes the entire agreement of the parties about its subject matter and supersedes all previous agreements."
9 May 2010	EFC measure announced in Budget.	20. Budget paper references to the EFC made no link with the 5th Agreement. 21. This budget reduced the savings from the 2008 budget measure by $95.3m over the five years to 30 June 2010. This reduction was $26.9m more than the target established in late December 2009 (see above). The Guild was unaware of this final figure until the Budget and there was no approach made by the government to seek to recover this $26.9m shortfall from the 5th Agreement. The EFC had remained a separate measure, as it was in 2008, and as had been confirmed in writing in late April 2010.
Late 2010 to 2011	DoHA and the Department of Human Services publish various materials on the EFC.	22. None of these EFC materials contain reference to the 5th Agreement.
1 December 2011	EFC implementation date.	23. The new arrangements and fees took effect from this date. No amendments were made, or suggested to be made, to incorporate the fees and arrangements into the 5th Agreement.

SECTION 2:
COMMUNITY PHARMACIES CANNOT PAY FOR THE CHEMOTHERAPY SHORTFALL

Community pharmacy contributed $1 billion through 5th Agreement, plus additional impact from PBS Reforms and other price reductions.
Remuneration per prescription for non-chemotherapy dispensing down almost 11% in real terms since 2009, and is likely to drop further with more price reductions to come.
Weak and declining retail sales and intense competition from pharmacies and other retailers.
Record levels of bankruptcies and receiverships in general community pharmacy, including new announcements this month.

The previous section listed the documented evidence that the EFC arrangements are a separate and unrelated budget measure with no linkages to the 5th Agreement. It is also important to recognise that the approximately 97% of community pharmacies that dispense no chemotherapy are not in a position to pay for the shortfall that has been created by underfunding of chemotherapy.

Savings of $1 billion were derived directly from community pharmacy over the term of the 5th Agreement. These savings included the direct impact of PBS Reform price reductions on 1 February 2011 and 1 April 2012 (as a result of the government's Memorandum of Understanding with Medicines Australia) however they did not account for the indirect impact of those reductions on trading terms. Nor did those savings include the additional loss in income that has resulted from more recent price reductions such as those in December 2012 to the top two drugs on the PBS, the reductions on 92 drugs on 1 April 2013, an uncertain number (likely to be around 50) on 1 August 2013, with many more to come over the remainder of 2013 and beyond.

For regular (non-chemotherapy) PBS dispensing, community pharmacy remuneration per prescription through the 5th Agreement is lower today than in 2009, even without adjustment for inflation over this period. In real terms the reduction in remuneration per prescription since 2009 is 10.8%. Further reductions in PBS prices that will occur throughout the remaining two years of the 5th Agreement are likely to result in even lower levels of overall remuneration. This is difficult enough for community pharmacies to sustain without also being asked to fund a shortfall that has no relationship to more than 97% of those pharmacies and no relationship to the agreement that determines their remuneration.

Community pharmacies have also been significantly affected by a variety of increases in labour, leasing and other costs, that with the highly regulated nature of the PBS they are not able to pass on like other businesses. They are also impacted by the current weak retail conditions, with a reduction in retail sales of 2.3% recorded for the 2012 calendar year and margins weakening in the face of intense competition both within pharmacy and from supermarkets and other retailers.

Community pharmacy receiverships and bankruptcies are running at record levels. Only this month it has been announced that a highly regarded and well-established group with 15 pharmacies across four states and territories (Harrisons Group) has been put into receivership.

Community pharmacy simply cannot afford to fund a chemotherapy shortfall on top of the impact of the 5th Agreement, ongoing PBS Reforms, intense competition, increasing running costs and a prolonged and severe slowdown in retail.

SECTION 3:
OTHER IMPORTANT CONSIDERATIONS & ISSUES

Cost shifting from public system and private insurers.

No protection from price rises by third party compounders.

No certainty of purchase price of drugs.

Several issues with implementation of the EFC measure and price disclosure.

The Guild wishes to ensure that members of the Committee are reminded of the additional issues listed below. While not gaining significant attention at the Inquiry Hearing on 28 April or in other submissions, these do require consideration in order to establish a transparent funding model that is sustainable and workable for the long term. Funding for many of the items has historically been attained through the trading terms for chemotherapy. This is no longer the case because of the new price disclosure arrangements. **The issues below are in addition to the fundamental shortfall in the preparation fee and dispensing fee, compared with the costs associated with preparation and dispensing.**

The additional issues include and are not limited to:

1. possible cost-shifting from state/territory governments to the Commonwealth, increasing the costs of the PBS;
2. possible cost-shifting from private health insurers to the PBS for services provided by private hospitals/clinics;
3. the lack of visibility of cost structures in some vertically integrated corporate models of chemotherapy supply;
4. the absence of monitoring of, or protection against, arbitrary price rises applied, independently of drug cost, by third party chemotherapy compounders who supply the pharmacies (or other purchasers). This can effectively force the supply pharmacies to supply the final prepared medicine infusion at a loss;
5. the absence of a mechanism to ensure that prices paid by pharmacies (or other purchasers) for chemotherapy drugs are limited to the price agreed between the manufacturer and the Commonwealth (again, this can force the supply pharmacies to supply at a loss);
6. a shortfall in mark-up, compared with the levels expected by the sector, due to the algorithm having been implemented in an illogical manner inconsistent with PBS policy intent;
7. the lack of any specific reimbursement for containers and drug delivery devices;
8. the lack of consideration in the price disclosure mechanism for the differences in the supply chain that exist with chemotherapy drugs, where most purchasing of drugs from manufacturers is by third party compounders and does not reflect the prices paid by community pharmacies.