

Chapter 2

Background to Inquiry

Introduction

2.1 The 76.2% reduction of the weighted average price for Docetaxel, a cancer treatment drug, in the Pharmaceutical Benefits Scheme (PBS) was announced in the second half of 2012. This price cut has been the catalyst for the raising of concerns about wider issues regarding the ongoing costs of supplying chemotherapy drugs to cancer patients.

2.2 This chapter provides a brief description of the broader context in which the inquiry occurred, including:

- the operation of the Pharmaceutical Benefits Scheme
- the Fifth Community Pharmacy Agreement
- Price Disclosure
- current funding arrangements for the supply of chemotherapy drugs under the PBS

Operation of the PBS

2.3 Chemotherapy drugs are supplied to patients in both private and public hospitals in Australia through the PBS, which is 'the primary means through which the Australian Government ensures Australians have timely and affordable access to pharmaceuticals'.¹ Under the PBS the Commonwealth subsidises the cost of most medicines for most medical conditions, primarily through reimbursements paid to community or hospital pharmacies.

When a pharmacist supplies a medicine that attracts an Australian Government benefit, the pharmacist is paid the PBS dispensed price of the medicine, less any patient contribution.

The PBS dispensed price consists of the cost to the pharmacist (the ex-manufacturer price), a mark-up by the pharmacist, dispensing fees, and any other fees the pharmacist is entitled to.²

1 Department of Health and Ageing, *Portfolio Budget Statements 2012-13*, Outcome 2.2, p. 90.

2 The Department of Human Services, *Explanation of PBS Pricing*, <http://www.medicareaustralia.gov.au/provider/pbs/pharmacists/pricing.jsp#N1021C> (Accessed 3 April 2013). The Department of Human Services also notes that, "The Pharmaceutical Benefits Remuneration Tribunal ... implements agreements between the Minister for Health and Ageing ... and the Pharmacy Guild of Australia, as to how the PBS dispensed price is to be established (Section 98BAA of the Act)."

2.4 The distinct phases of manufacture, wholesale and dispensing of a particular drug are thus recognised in the calculation of the PBS dispensed price. The Department of Health and Ageing have noted that:

While the manufacturer is notionally entitled to be paid the ex-manufacturer price for the medicine and the wholesaler is entitled to be paid the full wholesaler margin, competitive pressures mean that these prices may be discounted as a way of winning or maintaining market share. While PBS medicines are ultimately funded by Government and patient co-payments, it is community pharmacies that purchase these medicines from wholesalers or manufacturers and benefit from any discounting that is available.³

The Fifth Community Pharmacy Agreement

2.5 Commonwealth remuneration to pharmacies supplying drugs under the PBS is currently governed by the Fifth Community Pharmacy Agreement (5CPA), which was agreed to in 2010, and expires in 2015. As described by the Department, the 5CPA:

recognises the key role played by community pharmacy in primary health care through the delivery of Pharmaceutical Benefits Scheme (PBS) medicines and related services.⁴

The Pharmacy Guild of Australia notes that:

Since 1990, the Commonwealth Government and the Pharmacy Guild of Australia have entered into a series of Agreements which set out the remuneration that pharmacists will receive for dispensing PBS medicines and the arrangements regulating the location of pharmacies approved to supply PBS medicines. Over time these Agreements have increased in scope to provide for professional pharmacy programs and services.⁵

2.6 Pharmacy remuneration is one of four main elements covered by the 5CPA, alongside electronic prescriptions, community service obligation arrangements, and programs. Part 2 of the 5CPA:

constitutes an agreement between the Guild and the Minister as referred to in section 98BAA of the Act which sets out the manner in which the Commonwealth price is to be ascertained and to which the Pharmaceutical

3 Department of Health and Ageing, *The Impact of PBS Reform – Report to Parliament on the National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*, 2010, p. 20.

4 Department of Health and Ageing, *Pharmacy and Government Arrangements - Fifth Community Pharmacy Agreement*, 25 July 2012, <http://www.health.gov.au/internet/main/publishing.nsf/Content/fifth-community-pharmacy-agreement-copy> (Accessed 1 May 2013).

5 The Pharmacy Guild of Australia, *The 5CPA – History of the Agreements*, http://www.5cpa.com.au/sites/5CPA/The_5CPA/History_of_the_Agreements/History%20of%20the%20Agreements.page (Accessed 1 May 2013).

Benefits Remuneration Tribunal must give effect in determining the Commonwealth price.⁶

Clauses 8 to 11 of the 5CPA outline the elements that constitute the dispensed price of drugs supplied through the PBS.

Price Disclosure

2.7 Reforms to the PBS in 2007 introduced a system of price disclosure, which has operated to reduce the dispensed price of PBS medicines that are subject to generic competition on the basis of sales information collected from pharmacies and manufacturers. The 76.2% cut to the dispensed price of Docetaxel was implemented under Expanded and Accelerated Price Disclosure (EAPD). EAPD was introduced in 2010 as an extension to existing price disclosure arrangements, and was agreed to in a Memorandum of Understanding between Medicines Australia and the Commonwealth (the MOU).⁷ The MOU was negotiated as part of a wider package of reforms to ensure PBS sustainability. The content of this MOU was known at the time the 5CPA was signed and accommodated within the Agreement. The mechanism underpinning EAPD has remained unchanged since 2010.

Chemotherapy Drugs in the PBS

2.8 Pharmacies supplying chemotherapy drugs are able to recoup both the dispensed price for chemotherapy drugs listed on the PBS, and additional funding that recognises the extra preparation involved in supplying chemotherapy drugs. This second stream of funding is administered under the Revised Arrangements for the Efficient Funding of Chemotherapy Drugs Initiative (EFC) under section 100 of the National Health Act.⁸ The government first announced this initiative in the 2008-09 budget. The final form of EFC was based on a proposal – the *Alternative Funding Model for Chemotherapy* – prepared by chemotherapy pharmacy groups and submitted to the Department of Health and Ageing by the Guild during the 5CPA.⁹ The EFC covers chemotherapy drugs administered through infusion or injection,

6 Commonwealth Government & the Pharmacy Guild of Australia, *The Fifth Community Pharmacy Agreement between the Commonwealth of Australia and the Pharmacy Guild of Australia*, May 2010, cl. 7.

7 Commonwealth Government & Medicines Australia, *Memorandum of Understanding*, 6 May 2010, <http://www.health.gov.au/internet/main/publishing.nsf/Content/further-PBS-reforms-Agreement> (Accessed 3 April 2013).

8 See, the Department of Health and Ageing, *Revised Arrangements for the Efficient Funding of Chemotherapy Drugs & Streamlined Authority Data Capture*, <http://www.pbs.gov.au/info/publication/factsheets/shared/revised-arrangements-for-chemotherapy>; and Department of Health and Ageing, *Pharmacy and Government Arrangements - Fifth Community Pharmacy Agreement*, <http://www.health.gov.au/internet/main/publishing.nsf/Content/fifth-community-pharmacy-agreement> (Accessed 8 April 2013).

9 Community Pharmacy Chemotherapy Services Group, *Submission 20*, p. 1, and *Submission 20a*; the Department of Health and Ageing, *Submission 35*, p. 5.

including Docetaxel. Under the EFC, pharmacies can recoup additional fees for the dispensing, preparation, storage, and dilution of chemotherapy drugs. Currently, an in-house pharmacy at a private hospital can recoup \$76.37 in fees for each dose of a chemotherapy drug prepared for a patient.

2.9 Pharmacy groups have argued that the amount recouped in fees under the EFC is not sufficient to cover the actual costs of preparing chemotherapy drugs for supply to patients, as the processes involved are highly specialised and complex. Each dose of chemotherapy drugs must be compounded for the individual patient, and this requires the pharmacist to be involved in clinical consultations with patients. As chemotherapy drugs are cytotoxic, community and hospital pharmacies involved in their supply also invest in specialised equipment and facilities to ensure that the drugs are administered in a way that is safe for both the patient and any clinicians involved in preparing and administering the drugs.

2.10 According to pharmacy groups, the extra funding received from Docetaxel payments before the PBS price cut was cross-subsidising the expenses incurred in the preparation of chemotherapy drugs by pharmacies working with private hospitals and clinics. Although other chemotherapy drugs have been subject to price disclosure, the 76.2% price cut for Docetaxel resulted in a \$41.5 million reduction in government funding of chemotherapy drugs. This reduction equates to just over 20%, of the savings achieved to date as a result of price disclosure applied to chemotherapy drugs.¹⁰

10 Pharmacy Guild of Australia, *Submission 25*, p. 20.