



Australian Government

Department of Health

PRICE DISCLOSURE ADMINISTRATIVE DISPUTE RESOLUTION PROCESS GUIDANCE MATERIAL

Introduction

The purpose of this Guidance Material is to assist an Authorised Representative who, on behalf of a Responsible Person, wishes to lodge a dispute with the Department of Health (the **Department**) in relation to the determination of direct (i.e. not flow-on) price disclosure reductions for brands listed on the Pharmaceutical Benefits Scheme (**PBS**).

Division 3B of Part VII of the *National Health Act 1953* (Cth) (the **Act**) and Part 7 of the *National Health (Pharmaceutical Benefits) Regulations 2017* (the **Regulations**) contain the legal basis for price disclosure reductions. Further information on price disclosure can be found on the [PBS website](#) and in the Price Disclosure Guidelines.

While there is no process for dispute resolution contained within the Act or Regulations, in February 2011 the Department agreed with industry representatives at a meeting of the Price Disclosure Working Group to introduce a Price Disclosure Dispute Resolution Administrative Process. While Responsible Persons have the right to raise a dispute, it should be noted that lodging a dispute is a serious matter which places obligations on responsible persons and involves a number of formal steps. These steps are outlined in the **Dispute resolution process** section below.

This document is intended to provide guidance on the process involved in notifying a dispute, and the types of matters, and supporting information, that may be considered relevant to the dispute resolution process. It is not intended to be, and should not be treated as, legal advice, and Authorised Representatives and Responsible Persons raising a dispute should seek their own legal advice where appropriate.

This Guidance Material explains the process that the Department will usually follow if a dispute is raised with respect to an announced price disclosure reduction, but the Department is not bound by law to do so. Nothing in this Guidance Material in any way limits the operation of the Act or affects or fetters any function or power of the Minister or any other person or body under the Act.

Price disclosure determinations

All brands of pharmaceutical items containing a drug on the F2 formulary are subject to price disclosure, unless they are exempt items. For a price disclosure reduction to apply to a brand

the Minister for Health and Aged Care (or the Minister's delegate)¹ (the **Minister**) must determine both a weighted average disclosed price (**WADP**) for a data collection period, and a reduction day, for the brand under Division 3B of Part VII of the Act.

In some instances, the Minister may determine a WADP but not a reduction day for a brand of pharmaceutical item. This generally occurs when the WADP does not exceed the relevant threshold (10% or 30%) under s99ADH(1)(c) of the Act (please refer to the Price Disclosure Guidelines, Part 9.2 Thresholds for application of reductions for further information). Where the Minister determines a WADP and not a reduction day for a brand, there will not be a price disclosure reduction for the brand for that price disclosure cycle.

When the Minister may choose to amend a WADP or not determine a reduction day

As part of the dispute resolution process, a Responsible Person may request that the Minister amend the WADP that has been determined for a brand of pharmaceutical item, or exercise their discretion not to determine a reduction day for a brand of pharmaceutical item even though the WADP exceeds the relevant threshold.

The Minister may amend the WADP for a brand of pharmaceutical item where there is an error in the determination – for instance if there was an anomaly in the calculation of the WADP, such as the use of incorrect data.

The Minister may decide to revoke a determination of a reduction day for a brand if an incorrect price disclosure threshold has been applied, and the brand is not required to take a price reduction. The Minister may also sometimes decide not to determine a reduction day for a brand of pharmaceutical item, even if the unadjusted price reduction meets the relevant threshold, for reasons including the following:

- a price disclosure reduction may cause, or increase the risk that there will be, a shortage in the supply of that brand or that pharmaceutical item; or
- the Minister otherwise considers that a reduction would be inconsistent with the purpose of the price disclosure regime. This may, for example, arise if there has been unusual market behaviour for a short period of time, such as short-term 'stock dumping', that has distorted the WADP calculation.

Dispute resolution process

Notifications of upcoming price disclosure reductions are provided to Authorised Representatives (whose details are registered within the Health Products Portal) for all brands subject to price disclosure. Notifications are sent via email in June and December each year. Please refer to the Price Disclosure Guidelines, Part 5.1 Annual price disclosure cycles for further information about timeframes.

¹ All references to the Minister are also a reference, if applicable, to the Minister's delegate.

If Responsible Persons have any concerns regarding determinations of a WADP or of a reduction day, they may choose to formally lodge a dispute with the Department. All disputes will be investigated by the Department, and the Price Disclosure Data Administrator (PDDA) where necessary, and assessed on a case-by-case basis.

The dispute resolution process, including the relevant timeframes, is set out in **Table 1** below.

Table 1: Dispute resolution process

Step	Milestone	Maximum working days ² after notification of price disclosure outcomes
1	The Department notifies Responsible Persons of Price Disclosure calculation outcomes and reductions (if applicable).	0
2	Responsible Person formally notifies a dispute to the Department (including the nature of the dispute) within 10 working days from the published outcome. See Lodging a dispute section below.	10
3	The Department acknowledges receipt of dispute and notifies all affected Responsible Persons within 3 working days of receiving dispute.	13
4	The Responsible Person who lodged a dispute supplies detailed information to justify the dispute within 5 working days of lodging a dispute.	15
5	The Department, with assistance from the PDDA and Responsible Persons (as required), reviews the information provided and evaluates the dispute. See What will be considered when evaluating a dispute? section below. Dispute outcomes are finalised by the Minister.	43
6	All affected Responsible Persons are advised of the dispute outcomes within 2 working days.	45
	Amendments are made to the Minister's determinations of WADPs and reduction days as necessary.	
	Reduction Day	

Lodging a dispute

Notifications of disputes must be lodged with Department via email to pricedisclosure@health.gov.au, and should include:

- which of the Responsible Person's brand(s) are affected;
- whether the Responsible Person is seeking a change in the determined WADP and/or for the Minister to no longer determine a reduction day;
- details of the nature of the dispute (see the **What will be considered when evaluating a dispute?** section below); and

² Excludes all weekends, [recognised public holidays](#) and the Department of Health shutdown period between Christmas and New Year's Day.

- any supporting documents and calculations.

Giving false or misleading information is a serious offence.

What will be considered when evaluating a dispute?

Guidance is provided below on the matters, and the types of information relating to those matters, that might be considered relevant to the Department when evaluating a dispute and to the Minister deciding whether to amend a WADP or not determine a reduction day.

This is not an exhaustive list, and is intended only as a guide. It is not necessary for Responsible Persons to address all of the matters, or provide all of the information listed, when lodging a dispute or providing supporting information. Responsible Persons may raise other matters, or submit additional information, if they consider that may assist the Minister in reaching a decision about the dispute.

The matters, and types of supporting information, that may be relevant to a dispute are:

Errors in WADP calculations, including, but not limited to:

- incorrect disclosure by Responsible Persons of brand data that was collected during the data collection period;
- incorrect or incomplete calculations undertaken by the PDDA; or
- incorrect determinations made by the Minister.

Application of the incorrect price disclosure threshold, including, but not limited to circumstances in which a Responsible Person believes that the incorrect threshold has been used, because application of the correct threshold to the determined WADP would not result in a price disclosure reduction.

Market behaviour, including, but not limited to:

- the actions of Responsible Persons during the current and previous data collection periods, such as unusual or aggressive discounting, that have impacted the calculation of the WADP; or
- ‘stock dumping’, where the Responsible Person for one brand may discount that brand aggressively with the intention of delisting from the market. This pattern may be observed across more than one data collection period.

Clinical issues, including but not limited to:

- a risk that applying the price disclosure reduction will result in a prolonged shortage or withdrawal of a brand or of a pharmaceutical item from the market;
- should there be a high risk of a prolonged shortage or withdrawal, and whether patients will continue to have access to an alternative brand of the pharmaceutical

item or access to a pharmaceutical item which the Pharmaceutical Benefits Advisory Committee (**PBAC**) has advised would be interchangeable, or which has been recommended on a cost minimisation basis, with the brand of the pharmaceutical item subject to the dispute; or

- should there be a high risk of a prolonged shortage or withdrawal and alternatives are available, whether alternatives will be able to meet market demand.

Provision of additional material that is relevant to the dispute is not a requirement but may assist in the evaluation of the dispute. Examples of additional material that may be relevant include, but are not limited to:

- data that was incorrectly disclosed or data that was inadvertently not disclosed;
- evidence of expected WADP calculations and price disclosure outcomes based on data available to Responsible Persons;
- evidence of ‘stock dumping’;
- evidence of unusual or aggressive discounting;
- the Responsible Person’s plans for the brand of pharmaceutical item should the WADP not be amended and/or the reduction day still be determined, including whether the price disclosure reduction will result in a shortage or discontinuation of the product; and
- cost of goods information outlining where a price disclosure reduction may take the AEMP below this amount.

Investigation of disputes

Information provided in support of a dispute lodged with the Department under this process will, as appropriate, be treated as commercial-in-confidence, and the identity of the Responsible Person who has raised the dispute will not be shared with other Responsible Persons. Responsible Persons for related brands that have the same drug and manner of administration as the brand the subject to the dispute will be informed that a dispute has been raised and are expected to cooperate with the dispute resolution process.

Depending on the nature of the dispute, the Department may request information from Responsible Persons for related brands. Should data need to be resubmitted or reconfirmed, the PDDA will make this request via the Price Disclosure Software Utility software, and an email alert will be sent to the Responsible Person’s authorised representatives. Unless agreed specifically by the Department, data must be reconfirmed within five working days from any request being made.

Resolution of dispute

The Department has responsibility for evaluating disputes received through the dispute resolution process. The Department will provide the Minister with material relevant to the

dispute, including the material provided by the Responsible Person together with a summary of the request and a recommendation.

Potential outcomes, following evaluation of a dispute, are as follows:

- No change is made to the determined WADP or the reduction day for the brand of pharmaceutical item. The price disclosure reduction previously notified will apply.
- The Minister decides no longer to determine a reduction day for the brand of pharmaceutical item, and a price disclosure reduction will not apply.
- The Minister decides to change the WADP that was previously determined for the brand of pharmaceutical item. Responsible Persons will be advised of the new WADP and what the new AEMP will be. It is possible that a new WADP will be less than the applicable threshold (see the Price Disclosure Guidelines, Part 9.2 Thresholds for application of reductions for further information). If this occurs a price disclosure reduction will not apply, and accordingly the Minister may decide no longer to determine a reduction day for the brand of pharmaceutical item.

Withdrawal of a dispute

If the Responsible Person decides to withdraw their dispute after further considering the evidence, they must notify the Department as soon as possible. The Department may, but is not obliged to, accept the withdrawal of the dispute and notify all affected Responsible Persons that the dispute has been withdrawn. Whether the Department will accept a withdrawal will depend on the nature of the dispute, the stage of the dispute resolution process at which the notification of withdrawal is received, and the impact the dispute may have on related brands.