

Revisions to the CADTH Common Drug Review Procedure and Submission Guidelines Regarding Submitted Price

For all drug applications filed for review through the CADTH Common Drug Review (CDR) process on or after April 1, 2016, CADTH will no longer accept confidential submitted prices. The submitted price will be disclosed in all applicable CDR review reports, as well as CADTH Canadian Drug Expert Committee (CDEC) recommendation documents posted on the CADTH website.

Effective for all submissions and resubmissions filed on or after April 1, 2016, the revisions noted in Table 1 and Table 2 will replace the applicable sections of the [Procedure for Common Drug Review](#) (August 2014) and the [Submission Guidelines for the CADTH Common Drug Review](#) (August 2014).

Table 1: Revisions to the Procedure for the CADTH Common Drug Review

Section	2014 CDR Procedure	2016 Revisions
8.5.1(g)	The submitted reduced price may be a confidential price that will become effective following release of the <i>CDEC Final Recommendation</i> . The manufacturer must guarantee that the reduced price will be available to all drug plans.	The submitted reduced price will not be considered confidential and the manufacturer must guarantee that the reduced price will be available to all drug plans.
Appendix 3 (Definitions)	Confidential Price — a price per unit that is submitted in confidence, as part of the CDR submission requirements and to which the provisions of the <i>CADTH Common Drug Review Confidentiality Guidelines</i> apply.	This definition is no longer applicable.
	Submitted Price — the price per unit that is submitted to CDR and that must not be exceeded for any of the drug plans following release of a <i>CDEC Final Recommendation</i> , irrespective of the type of recommendation made and whether or not the CDEC criteria for listing are the same as the criteria requested by the manufacturer.	Submitted Price — the price per unit that is submitted to CDR and that must not be exceeded for any of the drug plans following release of a <i>CDEC Final Recommendation</i> , irrespective of the type of recommendation made and whether or not the CDEC criteria for listing are the same as the criteria requested by the manufacturer. The submitted price can be an anticipated or current market price in Canada.

CDR = CADTH Common Drug Review; CDEC = CADTH Canadian Drug Expert Committee.

Table 2: Revisions to the Submission Guidelines for the CADTH Common Drug Review

Section	2014 CDR Submission Guidelines	2016 Revisions
5.1.1 (a,ii) 5.1.2 (a,ii)* 5.1.3 (a,ii) 7.1 (a,ii) (Signed Cover Letter)	A statement confirming whether the submitted price is the anticipated or current marketed price, or the confidential price per unit that is submitted to CDR, and that must not be exceeded for any of the drug plans following release of a <i>CDEC Final Recommendation</i> , irrespective of the type of recommendation made and whether or not the CDEC criteria for listing are the same as the criteria requested by the manufacturer.	A statement confirming whether the submitted price is the anticipated or current marketed price, and that will not be exceeded for any of the drug plans following release of a <i>CDEC Final Recommendation</i> , irrespective of the type of recommendation made and whether or not the CDEC criteria for listing are the same as the criteria requested by the manufacturer.
5.1.1 (e,i) 5.1.2 (e,i)* 5.1.3 (e,i) 7.1 (d,i) (Submitted Price)	<ul style="list-style-type: none"> The submitted price is the price per unit that is submitted to CDR and that must not be exceeded for any of the drug plans following release of a <i>CDEC Final Recommendation</i>, irrespective of the type of recommendation made and whether or not the CDEC criteria for listing are the same as the criteria requested by the manufacturer. The submitted price can be an anticipated or current market price in Canada, or a confidential price. Only one price (anticipated or current market price, or confidential price) to four decimal places per dispensable unit is to be submitted per drug that is to be reviewed under the CDR process (i.e., only one price for all indications undergoing review by CDR concurrently). 	<ul style="list-style-type: none"> The submitted price is the price per unit that is submitted to CDR and that must not be exceeded for any of the drug plans following release of a <i>CDEC Final Recommendation</i>, irrespective of the type of recommendation made and whether or not the CDEC criteria for listing are the same as the criteria requested by the manufacturer. The submitted price can be an anticipated or current market price in Canada. Only one price (anticipated or current market price) to four decimal places per dispensable unit is to be submitted per drug that is to be reviewed under the CDR process (i.e., only one price for all indications undergoing review by CDR concurrently).
8.2 (a)	Indicates if the reduced price is a confidential price.	This requirement is no longer applicable.
Appendix 2 (Definitions)	Confidential Price — a price per unit that is submitted in confidence, as part of the CDR submission requirements and to which the provisions of the <i>CADTH Common Drug Review Confidentiality Guidelines</i> apply.	This definition is no longer applicable.
Appendix 2 (Definitions)	Submitted Price — the price per unit that is submitted to CDR and that must not be exceeded for any of the drug plans following release of a <i>CDEC Final Recommendation</i> , irrespective of the type of recommendation made and whether or not the Canadian Drug Expert Committee criteria for listing are the same as the criteria requested by the manufacturer.	Submitted Price — the price per unit that is submitted to CDR and that must not be exceeded for any of the drug plans following release of a <i>CDEC Final Recommendation</i> , irrespective of the type of recommendation made and whether or not the CDEC criteria for listing are the same as the criteria requested by the manufacturer. The submitted price can be an anticipated or current market price in Canada.
Appendix 8 A to G (Checklists)	Confirmation of whether submitted price is the anticipated or current market price, or a confidential price.	Confirmation of whether submitted price is the anticipated or current market price.

CDR = CADTH Common Drug Review; CDEC = CADTH Canadian Drug Expert Committee.

*Refers to revised [Category 1 Requirements for New Combination Products with Funded Components or CADTH-Designated Tailored Reviews \(March 2015\)](#) as provided in [CDR Update – Issue 110](#).