

Pneumococcal AMC – Inflation Review Application Process

Pursuant to Condition 8 of the AMC Terms and Conditions as set forth in the Offer Agreement, manufacturers who are interested in submitting an Inflation Review Application are requested to do so using the following process. A numeric example is included in Annex 1 of this document.

- a) The OECD provides an online statistic database named the OECD Stat Web Browser located on <http://stats.oecd.org/index.aspx>. The GDP deflator data is currently located under National Accounts → Quarterly National Accounts → Quarterly National Accounts → Volume & Price Indices – GDP Expenditure Approach. To run the correct query, the user must choose in the **Subject field**: B1_GE: Gross Domestic Product Expenditure Approach and for **Measure**: DOBSA Deflator, OECD reference year, seasonally adjusted. The OECD Total GDP Deflator will be used. The figure is located in the row in the table entitled “OECD-Total”.
- b) This database is updated approximately 1-2 months after a calendar quarter is closed. To ensure that a consistent, uniform set of information is used by each manufacturer in any Inflation Review Application, the AMC Secretariat will post on the AMC website a ‘freeze frame’ of the OECD published data. This information will be obtained by the AMC Secretariat on the last IBRD Business Day of Quarter 3 of each calendar year (or on the day thereafter when the data are made available by the OECD on its website) and posted on the following IBRD Business Day on the AMC website by 18:00 GMT+1. Once this information has been posted, it will not be changed.

The Base quarter GDP Deflator is the published GDP deflator for Q2-2009 – the first calendar quarter end after the AMC Offer Agreement became effective (June 12, 2009). The Q2-2009 GDP deflator has been obtained and frozen as of January 4, 2010. This will be posted on the AMC website. Note: In a quarter that a Tail Price Cap increase is approved, the Base Quarter GDP Deflator will be re-set to be the GDP Deflator for that quarter-end.

- c) The AMC Secretariat will publish the OECD published data under the title “Pneumococcal AMC: OECD GDP Deflator Data”. Such OECD data is the data that manufacturers will use to calculate any inflation adjustment request in an Inflation Review Application. Note – if the OECD is delayed in posting the most recent calendar Quarter 2 figure, the percentage change in the OECD Total GDP Deflator will be calculated using the latest Quarter 2 data posted by the AMC Secretariat.

Tail Price Cap increase – see Example 1 in Annex 1

- d) Based on the frozen OECD data, the cumulative percentage change in the GDP deflator is calculated as:
- $$= (\text{Latest Q2 published GDP Deflator} - \text{Base quarter GDP Deflator}) / \text{Base quarter GDP Deflator}$$

For example, if a manufacturer applies for a Tail Price Cap increase during Q1-2014 the applicable % increase in the Inflation Index would be:

$$= (\text{Q2 2013 GDP Deflator} - \text{Base quarter GDP Deflator}) / \text{Base quarter GDP Deflator}$$

However, if a manufacturer applies for a Tail Price Cap increase during Q3-2014 the % increase in the Inflation Index would be:

$$= (\text{Q2 2014 GDP Deflator} - \text{Base quarter GDP Deflator}) / \text{Base quarter GDP Deflator}$$

Tail Price increase (when the tail price is less than the AMC Tail Price Cap) - see Example 2 in Annex 1

- e) Based on the frozen OECD data, the applicable annual percentage change in the GDP Deflator is:
- $$= (\text{Most recent Q2 GDP Deflator} - \text{Previous Q2 GDP Deflator}) / \text{Previous Q2 GDP Deflator}$$

For example, if a manufacturer has an AMC Tail Price of \$2/dose and submits an AMC Inflation Review Application to the AMC’s Independent Assessment Committee (“IAC”) in Q1-2011 the applicable annual % increase would be:

$$= (Q2\ 2010 - Q2\ 2009) / Q2\ 2009$$

However, if the same manufacturer submits an AMC Inflation Review Application to IAC in Q3-2011, the applicable annual % increase would be:

$$= (Q2\ 2011 - Q2\ 2010) / Q2\ 2010$$

- f) For the avoidance of doubt, pursuant to Clause 8.5 of the AMC Terms and Conditions set forth in the Offer Agreement, an AMC-Registered Manufacturer can apply for a Tail Price Cap increase at any time on or after the earlier to occur of (a) each third anniversary of the date of the Offer Agreement (June 12, 2009) or (b) a cumulative 7 percent increase in the OECD GDP deflator or since the date of the last IAC Inflation Review, whichever is later. For a requested increase greater than the increase in the OECD GDP Deflator, relevant cost information must be provided as support.
- g) For the avoidance of doubt, pursuant to Clause 8.2 of the AMC Terms and Conditions set forth in the Offer Agreement and in the situation where the Tail Price specified in the Supply Agreement is less than the Tail Price Cap, an AMC-Eligible Manufacturer can notify the IAC of an increase in the Tail Price once per year at any time. The rate of the Tail Price increase requested can be below or equal to the annual increase in the OECD GDP Deflator, up to the then applicable Tail Price Cap. Where the requested increase is greater than the annual increase in the OECD GDP Deflator up to the Tail Price Cap, relevant cost information must be provided as support.

Annex 1

AMC Inflation Review Application Process

Example Calculation

** these numbers are for illustration purposes only*

Relevant data

	GDP Deflator
2009 - Q2	123
2010 - Q2	125
2011 - Q2	126
2013 - Q2	126
2014 - Q2	129

Example 1 - Tail Price Cap increase

Current Quarter	% Index increase
-----------------	------------------

2014 - Q1	2.44%	$= (\text{Q2 2013 GDP Deflator} - \text{Base quarter GDP Deflator}) / \text{Base quarter GDP Deflator}$ $= (126 - 123) / 123$
-----------	-------	--

2014 - Q3	4.88%	$= (\text{Q2 2014 GDP Deflator} - \text{Base quarter GDP Deflator}) / \text{Base quarter GDP Deflator}$ $= (129 - 123) / 123$
-----------	-------	--

Example 2 - Tail price increase

Current Quarter	% Index increase
-----------------	------------------

2011 - Q1	1.63%	$= (\text{Q2 2010} - \text{Q2 2009}) / \text{Q2 2009}$ $= (125 - 123) / 123$
-----------	-------	---

2011 - Q3	0.80%	$= (\text{Q2 2011} - \text{Q2 2010}) / \text{Q2 2010}$ $= (126 - 125) / 125$
-----------	-------	---