

### **3.01 TOFACITINIB**

**Tablet 5 mg,**

**Tablet 10 mg,**

**Xeljanz<sup>®</sup>,**

**Pfizer Australia Pty Ltd**

#### **1 Purpose of Application**

- 1.1 The minor submission requested the PBAC review its advice that tofacitinib should be treated as interchangeable on an individual patient basis with other drugs, for moderate-to-severe ulcerative colitis (MSUC) and severe psoriatic arthritis (PsA), under section 101(3BA) of the *National Health Act 1953* ('the Act'). The submission also requested the PBAC review its advice on which medicines can be treated as interchangeable for bDMARDs listed on the PBS for severe active rheumatoid arthritis (RA) and severe chronic plaque psoriasis (CPP).
- 1.2 The submission also requested the PBAC consider providing further explanation in minutes and public summary documents (PSDs) on the rationale for its advice on medicines being treated as interchangeable made during its consideration of applications.

#### **2 Background**

- 2.1 Tofacitinib is TGA registered for the treatment of rheumatoid arthritis, psoriatic arthritis and ulcerative colitis.
- 2.2 On 1 August 2007, section 84AG of the Act was introduced, which allows the Minister to determine therapeutic groups, and to determine that two or more listed drugs are in the same therapeutic group. Section 84AG(1A) of the Act requires the Minister to obtain the advice in writing of the PBAC in relation to a proposed determination of a therapeutic group.
- 2.3 Pursuant to section 84AG(3) of the Act, in making a determination that two or more drugs are in the same therapeutic group, the Minister may have regard to advice (if any) given by the PBAC to the effect that a drug or medicinal preparation should, or should not, be treated as interchangeable on an individual patient basis with another drug or medicinal preparation.
- 2.4 The Explanatory Memorandum to the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007* states:
  - Therapeutic groups are “groups of drugs which are interchangeable on an individual patient basis. They are grouped together for pricing purposes – because the drugs provide the same health outcome, they are priced similarly” (p. 6).

- “The Minister may, by legislative instrument, determine therapeutic groups and the drugs that are to be in those groups. The Minister may have regard to advice from the Pharmaceutical Benefits Advisory Committee (PBAC) in relation to the drugs that should be in a therapeutic group, but is not required to follow that advice” (p. 7).
- 2.5 On 1 August 2007, section 101(3BA) of the Act was introduced. Under section 101(3BA) of the Act, if the PBAC makes a positive recommendation for a drug or medicinal preparation, it must specify whether the drug or medicinal preparation and another drug or medicinal preparation should be treated as interchangeable on an individual patient basis.

### **Previous PBAC consideration**

- 2.6 At its July 2017 meeting, the PBAC considered a submission from Gilead Sciences Pty Limited, which sought a review of advice provided by the PBAC with regards to the interchangeability of sofosbuvir with velpatasvir (Epclusa®) with other direct acting antiviral (DAA) regimens used in the treatment of chronic hepatitis C infection. The submission argued the PBAC provided interchangeability advice incorrectly on the basis of hepatitis C virus genotype alone, and that a number of factors define whether individual patients or the majority of patients can reasonably be expected to achieve the same health outcome. The PBAC rejected the application, stating that in its view,<sup>1</sup>
- ‘For the purposes of providing advice under Section 101(3BA) of the Act, therapies with comparative health outcomes at the population level do not need to be identical with regards to patient-specific considerations, as these factors are a clinical practice decision taken into account when selecting the appropriate treatment for an individual patient. The PBAC considered that it was likely that, for some patients, sofosbuvir with velpatasvir would be the preferred treatment because of a particular combination of patient genotype, intolerance to other therapies, potential drug interactions, contraindications and patient baseline characteristics such as decompensated liver disease or renal function, however these factors were considered on a patient-by-patient basis, rather than at the broader CHC [chronic hepatitis C] population level.’* (Paragraph 6.3, sofosbuvir with velpatasvir PSD, July 2017 PBAC Meeting).

## **3 Current situation**

- 3.1 The submission requested the PBAC review its advice for tofacitinib and whether it should be treated as interchangeable with other PBS listed drugs for MSUC, PsA and RA. The submission also requested the PBAC review its advice for bDMARDs listed on the PBS for CPP.

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<sup>1</sup> Sofosbuvir with velpatasvir: Tablet containing 400 mg sofosbuvir with 100 mg velpatasvir; Epclusa®. [Publication available on the Department of Health Website.](#)

- 3.2 The submission argued the more recent advice given by the PBAC with respect to whether these drugs should be treated as interchangeable on an individual patient basis is inconsistent with previous advices of the PBAC. In particular, the submission claims that:
- The PBAC has previously provided advice that some drugs with the same mechanism of action should not be treated as interchangeable with one another, which is inconsistent with the advice that they should now all be treated as interchangeable with tofacitinib.
  - For the MSUC and PsA indications, not all of the drugs the PBAC advised should be treated as interchangeable were considered to be of non-inferior safety and efficacy to each other.
- 3.3 The submission also argued that the current advice provided for these drugs is inconsistent with the interpretation of “interchangeable on an individual patient basis” in statements made by Department officials and a previous Chair of the PBAC to parliamentary inquiries in 2007 and 2010. Specifically, the submission claims that the PBAC’s current advice is not appropriate due to the following factors:
- Tofacitinib does not belong to the same therapeutic class as the other drugs with which the PBAC has said it should be treated as interchangeable.
  - Tofacitinib has a different mechanism of action to other drugs with which the PBAC has said it has should be treated as interchangeable.
- 3.4 Finally, the submission requested that PSDs include a detailed explanation of the basis on which PBAC provides its advice that a medicine should be treated as interchangeable.
- 3.5 Summaries of PBS-listed drugs for the treatment of RA, PsA, MSUC and CPP, and the current advice on interchangeability for those drugs for MSUC and PsA (as recorded in their respective PSDs<sup>2</sup>) are outlined below.

### ***Ulcerative colitis***

- 3.6 The following drugs are PBS-listed (or recommended and not currently listed) for the treatment of MSUC:
- Tumour necrosis factor- $\alpha$  (TNF- $\alpha$ ) inhibitors: infliximab, adalimumab and golimumab
  - $\alpha 4\beta 7$  integrin inhibitors: vedolizumab
  - Janus-kinase (JAK) inhibitors: tofacitinib (not currently listed)
- 3.7 The PBAC’s current advice (paragraph 7.10, tofacitinib PSD, March 2019 PBAC meeting) is that adalimumab, golimumab, infliximab, tofacitinib and vedolizumab

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<sup>2</sup> Public Summary Documents only available from the July 2005 PBAC meeting onwards. References otherwise refer to the PBAC minutes.

should be treated as interchangeable on an individual patient basis. As noted above, the sponsor's submission suggests that this advice was inconsistent with earlier advice for some of those drugs with respect to whether they should be treated as interchangeable.

- 3.8 In March 2016, the PBAC considered adalimumab to be inferior to infliximab for MSUC (Paragraph 7.1, adalimumab PSD, March 2016 PBAC meeting). The PBAC also considered golimumab was non-inferior in terms of efficacy and safety to vedolizumab and adalimumab in both induction and maintenance therapy; and inferior to infliximab for efficacy for induction, but non-inferior to infliximab for safety and for efficacy in maintenance therapy (Paragraph 7.3, golimumab PSD, November 2017 PBAC meeting). When it considered tofacitinib at its March 2019 meeting, the PBAC considered the evidence presented did not support a conclusion that it provided a significant improvement in efficacy or reduction in toxicity compared to any of the currently listed biologics for MSUC (Paragraph 7.5, tofacitinib PSD, March 2019 PBAC meeting).
- 3.9 The PBAC will consider a resubmission for tofacitinib in MSUC at this meeting. This resubmission requests PBAC reconsider and amend the basis on which it recommended tofacitinib for listing for MSUC.

### ***Psoriatic arthritis***

- 3.10 The following drugs and therapeutic classes are PBS-listed (or recommended and not listed) for the treatment of severe PsA:
- TNF- $\alpha$  inhibitors: infliximab, etanercept, adalimumab, golimumab and certolizumab pegol;
  - Interleukin-12/23 (IL-12/IL-23) inhibitors: ustekinumab
  - Interleukin-17 (IL-17) inhibitors: secukinumab, ixekizumab
  - JAK inhibitors: tofacitinib
- 3.11 The PBAC's current advice for severe PsA (paragraph 7.10, tofacitinib PSD, November 2018 PBAC meeting) is that adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab should be treated as interchangeable on an individual patient basis. As noted above, the submission suggests that this advice was inconsistent with earlier advice for some of those drugs with respect to whether they should be treated as interchangeable.
- 3.12 In PsA, the PBAC considered ustekinumab was non-inferior to certolizumab pegol and inferior to adalimumab, and as such this placed both drugs in the south-west quadrant of the cost-effectiveness plane compared to other bDMARDs for PsA (Paragraph 6.5, ustekinumab PSD, November 2015 PBAC meeting). The PBAC also considered secukinumab was of non-inferior comparative efficacy to certolizumab pegol and ustekinumab (Paragraph 7.5, secukinumab PSD, March 2016 PBAC meeting) and that ixekizumab was non-inferior in terms of comparative efficacy and safety versus the main comparator (secukinumab) and supplementary comparators adalimumab,

certolizumab pegol and ustekinumab (Paragraph 7.3, ixekizumab PSD, July 2018 PBAC meeting). When it considered tofacitinib at its November 2018 meeting, the PBAC considered there was some uncertainty around the claim of non-inferior comparative effectiveness to adalimumab, and considered the results of indirect comparisons with certolizumab pegol and ustekinumab undertaken during the evaluation supported a conclusion of non-inferior effectiveness between tofacitinib and these therapies (Paragraphs 7.5 and 7.6, tofacitinib PSD, November 2018).

### ***Rheumatoid arthritis***

- 3.13 The following drugs and therapeutic classes are PBS-listed (or recommended and not listed) for the treatment of severe active RA:
- TNF- $\alpha$  inhibitors: infliximab, etanercept, adalimumab, golimumab and certolizumab pegol;
  - Anti-CD28 antibodies: abatacept
  - Interleukin-6 (IL-6) inhibitors: tocilizumab, sarilumab (not currently listed)
  - Anti-CD20 antibodies: rituximab
  - JAK inhibitors: tofacitinib, baricitinib
- 3.14 The PBAC's current advice for severe RA (paragraph 7.12, sarilumab PSD, November 2018 PBAC meeting) is that abatacept, adalimumab, baricitinib, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, sarilumab, tocilizumab and tofacitinib should be treated as interchangeable on an individual patient basis. As noted above, the submission suggests that this advice was inconsistent with earlier advice for some of those drugs with respect to whether they should be treated as interchangeable.

### ***Chronic plaque psoriasis***

- 3.15 The following drugs and therapeutic classes are or were PBS- listed (or recommended and not listed) for the treatment of severe CPP:
- Anti CD-11 inhibitors: (efalizumab – delisted)
  - TNF- $\alpha$  inhibitors: infliximab, etanercept, adalimumab, certolizumab pegol
  - IL-12/IL-23 inhibitors: ustekinumab
  - IL-17 inhibitors: secukinumab, ixekizumab
  - IL-23 inhibitors: guselkumab, tildrakizumab, risankizumab
- 3.16 The PBAC's current advice for severe CPP (paragraph 7.10, risankizumab PSD, July 2019 PBAC meeting) is that risankizumab, adalimumab, etanercept, guselkumab, infliximab, secukinumab, tildrakizumab and ustekinumab should be treated as interchangeable on an individual patient basis. As noted above, the submission suggests that this advice was inconsistent with earlier advice for some of those drugs.

## 4 PBAC Outcome

- 4.1 The PBAC noted the minor submission requested the PBAC review its advice that tofacitinib should be treated as interchangeable on an individual patient basis with other drugs, for MSUC and PsA, under section 101(3BA) of the Act. The minor submission also requested the PBAC review its advice on which medicines should be treated as interchangeable among the biologics<sup>3</sup> listed on the PBS for severe active RA and severe CPP.
- 4.2 The PBAC noted section 101(3BA) of the Act requires the PBAC, if it is of the opinion that a drug should be made available as a pharmaceutical benefit under Part VII of the NH Act, to:
- “specify whether the drug or medicinal preparation and another drug or medicinal preparation should be treated as interchangeable on an individual patient basis”.*
- 4.3 The PBAC further noted sections 84AG and 101(3BA) were introduced into the Act by the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007* (Cth). The Explanatory Memorandum for the Bill that became the 2007 Act did not provide any detailed explanation of the language<sup>4</sup> and instead referred to:
- section 84AG as providing for *“therapeutic groups. These are groups of drugs which are interchangeable on an individual patient basis. They are grouped together for **pricing purposes** – because the drugs provide the same health outcome, they are **priced similarly**”* [emphasis added];
- and
- section 101(3BA) as requiring the PBAC to *“specify whether a drug or medicinal preparation it is recommending should be available as a pharmaceutical benefit should be treated as interchangeable on an individual patient basis with another drug or medicinal preparation”.*
- 4.4 However, the PBAC noted the Act does not contain a definition of the phrase “interchangeable on an individual patient basis”, nor any guidance as when two drugs “should be treated as” interchangeable.
- 4.5 The PBAC noted the Departmental explanations offered to Parliament in 2007 and 2010<sup>5</sup> identified the following factors as being important, at that time, for determining

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<sup>3</sup> In line with the convention followed in the PBS restrictions for these drugs, for the purposes of this PSD the “biologics” group of drugs includes abatacept, adalimumab, baricitinib, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, risankizumab, rituximab, sarilumab, secukinumab, tildrakizumab, tocilizumab, tofacitinib, , tildrakizumab, upadacitinib, ustekinumab and vedolizumab, where they are subsidised under the PBS for CPP MSUC PsA and RA.

<sup>4</sup> There was also a revised explanatory memorandum, and two supplementary explanatory memoranda, issued before the Bill was passed. None of them provided any additional guidance on the meaning of this language.

<sup>5</sup> See

whether two or more drugs should be treated as interchangeable on an individual patient basis:

The drugs are

- Pharmaceutically related,
- Have the same mechanism of action, and
- Deliver similar therapeutic outcomes at equivalent doses.

- 4.6 The PBAC also noted the Report of the Senate Community Affairs Reference Committee, November 2010, in relation to Consumer Access to Pharmaceutical Benefits quoted evidence before the Committee from the then Chair of the PBAC (Professor Sansom), who said:

*“The PBAC has interpreted the statement of the term ‘interchangeable on a patient basis’ in the following way: drugs within the therapeutic group are very alike—that is, they belong to the same therapeutic class and, in the vast majority of patients, would work just as well as one another. That is, in commencing a patient on any one of the drugs in a therapeutic group it would make no difference in health outcomes for the vast majority of patients. This does not mean of course that each patient will respond exactly the same to every medicine in the group.” (p19)*

- 4.7 The PBAC noted that Pfizer, in its pre-PBAC response, “agrees that it is a matter for PBAC to form an opinion as to whether drugs are (or are not) interchangeable on an individual patient basis”, but contends that the fundamental question that first needs to be answered is what, as a matter of statutory interpretation, is meant by “interchangeable on an individual patient basis”. The PBAC noted Pfizer goes on to say the starting point is to consider the plain meaning of words in order to give effect to the intention of the legislature. Moreover, Pfizer argues, once determined, the meaning should remain consistent.
- 4.8 The PBAC noted Pfizer’s pre-PBAC response contends “there is no ambiguity in the plain meaning of the term “interchangeable on an individual patient basis” which should be read as requiring a decision that the products will produce the same health outcome at a patient level and exert their effect via the same mechanism of action and across the range of indications for which they can be used.”

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- a. pages 60 and 69 of the transcript at [www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/Community\\_Affairs/Completed\\_inquiries/2004-07/nat\\_hth\\_pbs\\_07/hearings/index](http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Completed_inquiries/2004-07/nat_hth_pbs_07/hearings/index).
  - b. Response of Department of Health and Ageing to question on notice, 15.6.07.
  - c. Submission of the Department of Health and Ageing, dated 9 April 2010, to the Senate Community Affairs References Committee’s Inquiry into Consumer Access to Pharmaceutical Benefits.

- 4.9 The PBAC noted the criteria proposed by Pfizer are tighter than those articulated by the Department and the former PBAC Chair in 2007 and 2010, with Pfizer suggesting that two drugs need to have the same mechanism of action and achieve the same outcomes in all patients and in all indications in order to be considered to be interchangeable on an individual patient basis.
- 4.10 However, the PBAC noted that Pfizer’s pre-PBAC response omits a critical part of the relevant legislative provisions - which is that PBAC is only required to specify whether two or more drugs **should be treated** as interchangeable on an individual patient basis. The PBAC considered this plainly to mean that two drugs need not be interchangeable on an individual patient basis for it to express the view they **should be treated** as interchangeable on an individual patient basis. Instead, the PBAC, exercising its expertise, is simply required by the legislation to specify its view as to whether drugs **should be treated** as interchangeable on an individual patient basis.
- 4.11 The PBAC also considered that it is important to recall the context in which the legislation requires it to specify that view. It does so solely for the purpose of informing a possible future decision by the Minister about including two drugs together in a therapeutic group, which in turn is only relevant to the price reimbursed by the Commonwealth for the drugs. The PBAC’s view is not directed to influencing which drugs should be prescribed or dispensed to patients, nor to the price which patients should pay, only (and in very limited circumstances) to the cost to the Commonwealth of the drugs. Therapies that provide comparable health outcomes at the population level do not need to be identical with regards to patient-specific considerations, as these factors are a clinical practice decision taken into account when selecting the appropriate treatment for an individual patient. The selection of most appropriate treatment for a patient remains, first and foremost, a decision for the prescribing clinician.
- 4.12 Against that background, the PBAC considered the most important factor when it is forming a view about whether two or more drugs should be treated as interchangeable on an individual patient basis is whether the drugs provide similar outcomes in terms of effectiveness and safety, at a population level, when treating the same condition. The PBAC noted it takes a range of factors into account when assessing whether two drugs provide similar outcomes in terms of effectiveness and safety, including the applicability of the trial results for the proposed indication, the risk of bias in the trial results, outcomes of clinical and patient relevance (both beneficial and harmful) and durability of effect. The PBAC applies its expertise to synthesize the available information in order to form a view about the expected outcomes from using different drugs.
- 4.13 The PBAC acknowledged that there are occasions where it recommends a new drug for listing even though it has been found that drug to be inferior in terms of effectiveness or safety, at a population level, to one or more other drugs when treating the same condition. The PBAC acknowledged that on these occasions, it

would be unlikely to advise that the new drug should be treated as interchangeable on an individual patient basis with the drug(s) against which it has been compared.

- 4.14 The PBAC considered that the mechanism of action will sometimes also be an important factor, but that will not always be the case – and so sometimes drugs should be treated as interchangeable on an individual patient basis despite the fact that they have different mechanisms of action. The factors taken into account when considering the significance of mechanisms of action may include the circumstances for which the drugs are subsidised (for example whether the PBS restriction is silent on which class of drugs should be used in which line of treatment), or whether the mechanism of action of the drug(s) is associated with a particular clinical outcome. The PBAC acknowledged that its view on the significance of the mechanism of action in this context has changed over time, and considered this reflects its growing knowledge and experience about groups of drugs that produce similar effects in the same condition.
- 4.15 The PBAC considered the concept of drugs being “pharmaceutically related” to be very broad and that the aspects of this phrase that are important to its consideration of whether drugs should be treated as interchangeable will be captured by its consideration of patient outcomes and, where relevant, mechanism of action.
- 4.16 Taking into account the above considerations, the PBAC reviewed its previous advices on the “biologics” that should be treated as interchangeable on an individual patient basis. It expressed the following revised views (which supersede the views it has previously expressed) in relation to biological therapies for MSUC and PsA. In doing this, PBAC acknowledged that some of its earlier advices grouped together drugs it had found were inferior (or superior) in terms of effectiveness or safety.

4.17 *For moderate to severe ulcerative colitis*

For MSUC, the drugs infliximab, vedolizumab and tofacitinib should be treated as interchangeable on an individual patient basis. That view was reached, in part, on the basis that, to date, none of these drugs has been demonstrated to provide better health outcomes than any other, and they are therefore considered to provide similar outcomes in terms of effectiveness and safety.

4.18 *For psoriatic arthritis*

For PsA, the drugs etanercept, adalimumab, infliximab, ixekizumab and golimumab should be treated as interchangeable on an individual patient basis. That view was reached, in part, on the basis that, to date, none of these drugs has been demonstrated to provide better health outcomes than any other, and they are therefore considered to provide similar outcomes in terms of effectiveness and safety.

In addition, for PsA the drugs certolizumab pegol, guselkinumab, ustekinumab, secukinumab and tofacitinib should be treated as interchangeable on an individual patient basis. That view was reached, in part, on the basis that, to date, none of these drugs has been demonstrated to provide better health outcomes than any other, and

they are therefore considered to provide similar outcomes in terms of effectiveness and safety.

Relevant to both rheumatoid arthritis and chronic plaque psoriasis

4.19 The PBAC clarified that its most recent advices on the “biologics” that should be treated as interchangeable on an individual patient basis for severe active RA (November 2019) and for severe CPP (July 2019) represented its current views (and had been intended to supersede earlier views that it had expressed on the same topics). The most recent advices were as follows:

4.20 *For severe active rheumatoid arthritis*

For RA, upadacitinib should be treated as interchangeable on an individual patient basis with abatacept, adalimumab, baricitinib, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab, sarilumab and tofacitinib. That view was reached, in part, on the basis that, to date, none of these drugs has been demonstrated to provide better health outcomes than another, and they are therefore considered to provide similar outcomes in terms of effectiveness and safety.

4.21 The PBAC noted its advice on biologicals in severe active RA has varied over time (for example in March 2015 PBAC advised that, on the basis of the material available to it at that time, tofacitinib should not be treated as interchangeable on an individual patient basis with any other drugs). The PBAC explained that its views on which biologics should be treated as interchangeable for severe active RA have changed as more evidence has become available. The PBAC noted that given the quality of evidence provided and the sequential nature of applications that it is not unexpected that its views may change over time. Furthermore, the PBAC noted that despite there now being eleven biologic therapies PBS subsidised for use in severe active RA, the comparative evidence base in the vast majority of applications has been based on indirect comparisons and the Committee has not been presented with high quality head-to-head evidence that demonstrates any one therapy is likely to *result* in clinically significant differences in long-term outcomes compared to the other PBS-subsidised therapies.

4.22 *For severe chronic plaque psoriasis* For CPP, risankizumab should be treated as interchangeable on an individual patient basis with adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab.

4.23 The PBAC noted its advice on biologicals in severe CPP has varied over time (for example ustekinumab was initially recommended for listing after PBAC advice that it was superior to etanercept). The PBAC explained its views as to superiority and inferiority have changed as more evidence has become available for this group of drugs.

4.24 In this context, the PBAC recalled that its most recent consideration of the biological treatments for severe CPP was triggered by the July 2019 submission for risankizumab

for severe CPP. This submission included an indirect comparison of risankizumab with other PBS-listed biologics for severe CPP via network meta-analyses (NMA): 60 randomised comparative trials for the short-term (10-16 weeks) outcomes and 23 trials for the long-term (44-60 weeks) outcomes. This provided PBAC with a contemporary overall analysis of the nine drugs when used in severe CPP.

- 4.25 The PBAC recalled that its overall conclusion in July 2019 was “based on extensive experience with biologics in clinical practice, its prior consideration of the relevant PBS-listed drugs for severe CPP and the data presented for risankizumab, there was unlikely to be any clinically significant difference in long-term outcomes between any of the PBS-listed biologic medicines available for use in CPP.”
- 4.26 The PBAC noted that it has not been provided with any more recent information that would cause it to change this view.
- 4.27 The PBAC noted the Pfizer submission also queried the absence of certolizumab from the most recent specification of drugs that should be treated as interchangeable on an individual patient basis for treatment of CPP. The PBAC advised that certolizumab was only excluded from the view because, despite the recommendation for listing in March 2019, it has not yet proceeded to listing for this indication.
- 4.28 The PBAC noted that this submission is not eligible for an Independent Review as the application does not relate to a submission for a new drug or seeking to change an existing listing.

**Outcome:**

Advice provided

## **5 Context for Decision**

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

## **6 Sponsor’s Comment**

Pfizer acknowledges the clarification provided by the PBAC about the current interchangeability determinations for these drugs. Pfizer looks forward to PBAC minutes and PSDs including a greater level of detail about the deliberations of the PBAC in determining whether drugs should be considered as interchangeable on an individual patient basis.