

## 6.09 FOLLITROPIN ALFA

**Injection 75 I.U. in 0.125 mL pre-filled pen,  
Injection 150 I.U. in 0.25 mL pre-filled pen  
Injection 225 I.U. in 0.375 mL pre-filled pen  
Injection 300 I.U. in 0.5 mL pre-filled pen  
Injection 450 I.U. in 0.75 mL pre-filled pen  
Bemfola<sup>®</sup>, Gedeon Richter (Australia) Pty Ltd**

### 1 Purpose of Application

- 1.1 The minor submission requested a change to the prescribing authority for the biosimilar brand of follitropin alfa, Bemfola<sup>®</sup>, from Authority Required (STREAMLINED) to Restricted Benefit, for all PBS listings under the Section 100 IVF Program for Assisted Reproductive Technology.
- 1.2 The submission also requests the addition of an administrative note to the Gonal-f<sup>®</sup> PBS items under both the General Schedule and Section 100 IVF Program for Assisted Reproductive Technology to encourage biosimilar prescribing for treatment-naïve patients.
- 1.3 The Minister (delegate) has requested that the PBAC provide advice under section 101(3) of the National Health Act, 1953 (the Act) as to whether there would be any clinical or other concerns about appropriate use of medicines, if a policy decision were made to apply the biosimilar uptake measures agreed as part of the strategic agreement with Medicines Australia to follitropin alfa.

### 2 Background

#### ***Biosimilar brand of follitropin alfa***

- 2.1 At its March 2016 meeting, the PBAC recommended the listing of Bemfola<sup>®</sup> as a biosimilar of the reference brand of follitropin alfa (Gonal-f<sup>®</sup>), and recommended that the same indications that apply to Gonal-f<sup>®</sup> should apply to Bemfola. Gonal-f<sup>®</sup> and Bemfola<sup>®</sup> are both currently listed on the General Schedule for anovulatory infertility and hypogonadotropic hypogonadism, and on the Section 100 IVF Program for Assisted Reproductive Technology.
- 2.2 At its March 2016 meeting, the PBAC advised the Minister that it considered the Gonal-f<sup>®</sup> and Bemfola<sup>®</sup> brands of follitropin alfa could not be marked as equivalent (“a” flagged) for the purposes of substitution, primarily due to differences in the strengths, number of pens per pack and maximum quantities between the brands

which make substitution at the pharmacy level difficult from a practical perspective.

### ***Biosimilar uptake measures***

- 2.3 As part of the 2017-18 budget, the Government entered into a Strategic Agreement with Medicines Australia. Part of this agreement was to introduce biosimilar uptake drivers. Two biosimilar uptake drivers identified were to:
- allow a lower level of authority for the biosimilar than the reference biologic at commencement and/or continuation of therapy; and
  - identify the biosimilar brand as the preferred choice for treatment naïve patients.
- 2.4 With respect to these uptake measures, the Minister advised that the PBAC will be requested to provide case-by-case advice as to whether there would be any clinical or other concerns about appropriate use of medicines if a policy decision were made to apply the uptake measures mentioned above.

*For more detail on the PBAC's view, see section 4 PBAC outcome.*

## **3 Requested advice**

- 3.1 The submission requested that biosimilar uptake drivers in the form of lowering the category of authority be applied to all Bemfola® PBS items under the Section 100 IVF Program for Assisted Reproductive Technology, whilst maintaining the existing streamlined authority requirement for Gonal-f®. This change in prescribing authority for Bemfola Section 100 IVF items would see the current Authority Required (STREAMLINED), replaced with Restricted Benefit.
- 3.2 The Secretariat notes that while the intent of the lower level authority measure is to drive uptake of biosimilar brands, it is uncertain whether the change from streamlined authority to restricted benefit would result in a change in prescribing behaviour as this change is unlikely to present a considerable difference in convenience or time for the prescriber.
- 3.3 The submission requested the following administrative advice be added to all Gonal-f® PBS items: "Prescribing of the biosimilar brand, Bemfola, is encouraged for treatment naïve patients. Encouraging biosimilar prescribing for treatment naïve patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage ([www.health.gov.au/biosimilars](http://www.health.gov.au/biosimilars))."
- 3.4 The PBAC has previously stated it had no concerns over the inclusion of the aforementioned administrative advice to the Schedule to encourage prescribing of biosimilar brands for etanercept (PBAC Meeting August 2017).

*For more detail on the PBAC's view, see section 4 PBAC outcome*

### ***Sponsor hearing***

3.5 There was no hearing for this item as it was a minor submission.

### ***Consumer comments***

3.6 No consumer comments were received. The PBAC noted the input by Merck (sponsor of Gonal F) via the Consumer Comments facility on the PBS website.

## **4 PBAC Outcome**

4.1 The PBAC did not recommend lowering the category of prescribing authority for Bemfola<sup>®</sup>. In deciding not to recommend a change to the current Authority Required (STREAMLINED) category of prescribing authority for Bemfola<sup>®</sup> for Assisted Reproductive Technology, the PBAC considered;

- The potential for prescriber confusion surrounding Restricted Benefit listings for other infertility indications, which have differing maximum quantities and number of repeats;
- Changing the prescribing authority to Restricted Benefit would be inconsistent with other follitropins currently listed as Authority Required in the Section 100 IVF Program for Assisted Reproductive Technology; and
- No apparent benefit in terms of driving uptake of Bemfola<sup>®</sup>, given the current category of prescribing authority is STREAMLINED.

4.2 The PBAC recommended the addition of an administrative advice to the PBS listings for all Gonal-f<sup>®</sup> items to encourage prescribing of biosimilar brands for treatment naïve patients.

4.3 In deciding to recommend the addition of an administrative advice to Gonal-f<sup>®</sup> PBS listings, the PBAC recalled that it had previously stated that it had no concerns over the inclusion administrative advices to the Schedule to encourage prescribing of biosimilar brands as described above.

4.4 The PBAC noted the flow-on changes required for including an administrative advice to all Gonal-f<sup>®</sup> PBS listings.

4.5 The PBAC noted that this submission is not eligible for an Independent Review as it has received a positive recommendation.

### **Outcome:**

Recommended

## 5 Recommended listing

5.1 Add NOTE as follows:

All Gonal-f® PBS listings:

<b>Administrative Advice</b>	Prescribing of the biosimilar brand, Bemfola, is encouraged for treatment naïve patients. Encouraging biosimilar prescribing for treatment naïve patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage ( <a href="http://www.health.gov.au/biosimilars">www.health.gov.au/biosimilars</a> ).
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## 6 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

## 7 Sponsor's Comment

Gedeon Richter welcomes the PBAC's decision to recommend the addition of administrative advice to the PBS listing for all Gonal-f® items to encourage prescribing of biosimilar brands for treatment naïve patients.