**PBAC CONSIDERATION OF THE REPORT OF THE DRUG UTILISATION SUB-COMMITTEE**

The PBAC noted utilisation reports with associated stakeholder responses from the June 2019 Drug Utilisation Sub-Committee (DUSC) meeting, which were provided in Items 10.03 to 10.05 of the PBAC Agenda. DUSC minutes relating to these items were provided to the PBAC as the [June 2019 DUSC outcome statement](http://www.pbs.gov.au/info/industry/listing/elements/dusc-meetings/dos).

**Armodafinil for the treatment of narcolepsy**

This report considered the predicted and actual utilisation of armodafinil for narcolepsy since it was PBS listed for this indication.

*Outcome*

The PBAC noted the number of patients on PBS-subsidised therapy for narcolepsy had increased over the last four years. The listing of armodafinil had increased the total narcolepsy market.

The PBAC recalled when recommending the listing of armodafinil, the committee considered armodafinil may cease to be cost-effective over time due to a decrease in the price of modafinil as a result of patent expiry and the introduction of generic versions of modafinil. The PBAC noted multiple generic brands of modafinil are now available on the market.

The PBAC noted modafinil and armodafinil are listed on the PBS as second line therapy when treatment with dexamfetamine sulfate poses an unacceptable medical risk or intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal.

**GnRH agonists for the treatment of carcinoma of the prostate, central precocious puberty, breast cancer, endometriosis, and anticipated premature ovarian failure**

This report considered the utilisation of gonadotrophin-releasing hormone (GnRH) agonists for the treatment of carcinoma of the prostate, central precocious puberty, breast cancer, endometriosis, and anticipated premature ovarian failure.

*Outcome*

The PBAC noted the total number of prescriptions dispensed for GnRH agonists was growing and goserelin is dominating the GnRH market.

The PBAC noted that the review incorrectly stated that goserelin had a TGA registered indication for premature ovarian failure (POF). The PBAC requested for this to be amended in the public release version of the review report. The PBAC recalled its July 2017 recommendation to extend the listing of goserelin 3.6 mg for the prevention of POF. The PBAC noted that the recommendation was made in the absence of a TGA registered indication as a pragmatic approach to ensure equity of access for an area of clinical need.

The PBAC noted the number of new patients treated with GnRH agonists appeared to be stable but the number of prevalent treated patients was growing.

The PBAC noted there were more male patients initiating and being treated with GnRH agonists compared to females.

The PBAC noted, overall the review indicated that GnRH agonists were generally being used within the PBS restrictions.

**Sapropterin for hyperphenylalaninaemia due to BH4 deficiency**

This report considered the predicted versus actual utilisation of sapropterin since PBS listing on 1 May 2014. In recommending sapropterin for listing, the PBAC requested that the Department review the utilisation of sapropterin after five years of its first listing to examine the number of patients continuing on this therapy.

*Outcome*

The PBAC noted the findings of the report. In particular that:

* + - the majority of patients initiated on sapropterin are continuing treatment;
    - the number of actual patients treated with sapropterin in the first two years of listing was similar to predicted and exceeded predicted levels from year 3 onwards; and
    - the higher than predicted number of patients in the later years did not translate to a greater than predicted expenditure for sapropterin.

The PBAC noted the Metabolic Dietary Disorders Association advice on the utilisation report for sapropterin.