Response to:

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85)

Prepared by:

Sandoz Ltd

6 May 2015

Response to the Assessment Report produced by Peninsula Technology Assessment Group (PenTAG): Immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85)

Commercial in confidence information is displayed as such [redacted]

Any reference to the Assessment Report is referred to in the format: [page X, Section X.X]

Medicinal product:	Tacrolimus monohydrate
Brand name:	Adoport®
Manufacturer:	Sandoz Ltd
Date:	6 May 2015

Letter of response

Dear Sirs,

We would like to take this opportunity to thank the National Institute for Health and Care Excellence for the time and consideration the research and technical teams have devoted to this submission process.

Upon reviewing the Assessment Report, Sandoz Ltd, overall, welcomes the conclusions made regarding the clinical and cost-effectiveness of immediate-release tacrolimus (TAC) products. There are two areas of the report, which Sandoz Ltd wishes to comment upon:

1. ***Inclusion criteria and study selection***

   As described within the Assessment Report **[page 81, Section 4.1.3.1]**, only randomised controlled trials (RCTs) or systematic reviews of RCTs were included as part of the study selection process to assess clinical effectiveness. Sandoz Ltd appreciates that this is a standard and well recognised approach of undertaking systematic reviews in the context of a health technology assessment. It is important to note, however, that as part of the European regulatory submission process, companies producing a generic medicine only need to provide information on the quality of that medicine and demonstrate that the generic formulation produces the same rate and extent of absorption of the active substance in the body as the reference product. As such, RCT data for generic medicines are not typically available as part of the market entry process. By only including RCTs within the analyses, the evidence appraised for immediate-release TAC products is, thus, biased towards the reference product. The majority of the included trials that assess the clinical effectiveness of immediate-release TAC were completed prior to 2010 and the analyses ignore the more recent TAC exposure reports from the UK that are predominantly in abstract format. As described within the original submission by Sandoz Ltd, generic TAC products have a substantial market share in the UK, with recent data indicating the proportions stand at: [redacted].[1]

   Hence, given the proportion of reference versus generic TAC formulations used in the UK, Sandoz Ltd anticipated the approach taken by the assessment group would have permitted analyses of studies more representative of the recent clinical use and exposure of immediate-release TAC products.

2. ***Cost-effectiveness conclusions***

   Overall, Sandoz Ltd welcomes the conclusions made regarding the cost-effectiveness of immediate-release TAC products. However, due to the structure of the cost-effectiveness model adopted within the Assessment Report – in which the drug acquisition costs for

immediate-release TAC products were grouped together to produce an average cost based on market share **[Table 194, page 456 Section 7.3.6.3]** – the analyses conducted fail to interrogate the potential differences in cost-effectiveness between the different immediate-release TAC products. As described within the original submission by Sandoz Ltd, [redacted] **[Table 194, page 456 Section 7.3.6.3]**. Sandoz Ltd would, therefore, like to note that the cost-effectiveness of immediate-release TAC products in the UK can only be expected to improve, when compared with the incremental cost-effectiveness ratio calculations of the Assessment Report, should there be a greater shift towards the use of the lower-priced immediate-release TAC products in the UK.

Yours faithfully,

[redacted]
[redacted] Transplant • Sandoz Limited

Reference

1. Sandoz Ltd. Data on file: February 2015 IMS data.