Pegloticase for the treatment of hyperuricaemia in people with symptomatic gout whose disease is refractory to conventional urate-lowering therapy, or in whom conventional urate-lowering therapy is contraindicated or not tolerated: Erratum

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Points of clarification following the manufacturer fact check of the Evidence Review Group (ERG) report

At several points in the ERG report (pages 6, 79, 87), we refer to the clinical continuation rule stated on page 75 of the manufacturer submission (MS): "Pegloticase should be discontinued if levels increase to above 360 μmol/L (6 mg/dL), particularly when 2 consecutive levels above 6 mg/dL are observed". When checking the ERG report for factual errors, the manufacturer noted that the wording for this definition of the clinical continuation rule was based on the draft SPC and the following text would more accurately reflect the wording in the final SPC and the continuation rule applied within the economic model: "Pegloticase should be discontinued if 2 consecutive levels above 6 mg/dL have been measured."

On page 68 of the ERG report, it is stated: "The data suggested that the rates of adverse events (all adverse events, gout flares, infusion-related reactions and serious CV adverse events) were not increased in long-term (apparently 2.5 years) compared with short-term (6 months) consistent treatment with pegloticase 8 mg every 2 weeks." The phrase 'apparently 2.5 years' was used by the ERG as it found the definition of 'long-term' within the abstract to be unclear. After checking the ERG report for factual errors, the manufacturer clarified that the treatment duration for long-term treatment was 2.5 years.

On page 79 in section 5.2.2 of the ERG report the following text is used to describe the non-completer group: "patients who are non-persistent to pegloticase treatment". This is the definition provided by the manufacturer on page 76 of the MS for the non-completer population within the economic model. However, it should be noted that further details regarding the definition of non-completers within the analysis of the trial data and the reasons for patients failing to complete the 6 month treatment course within the trials are discussed on page 83 of the ERG report.

Points of factual accuracy following the manufacturer fact check of the ERG report

On page 4 in section 1.2 and again on page 60 in section 4.2.2.6 of the ERG report, where the current text states '...[redacted],' this should be replaced by '...[redacted]'

On page 49, section 4.2.2.4 of the ERG report it is incorrectly stated that "non-responders had a higher mean body weight (kg) than non-responders." Instead, this text should read; "non-responders had a higher mean body weight (kg) than responders."

On page 67, section 4.2.2.7, of the ERG report the following text wrongly suggests that there was a placebo group in study C0407: "The briefing document also states that in the pegloticase 8 mg every 2 weeks treatment group in the OLE study (C0407) (N=59) there were 1 APTC and 7 non-APTC events (no data provided for the placebo group)". It should be replaced with: "The briefing document also states that in the pegloticase 8 mg every 2 weeks treatment group in the OLE study (C0407) (N=59) there were 1 APTC and 7 non-APTC events".

On page 68, section 4.2.2.7, the following text: "The manufacturer stated that, as UA response was not monitored during the trial to determine loss of pegloticase efficacy, non-responders continued to receive pegloticase treatment despite loss of response," should be replaced with, "The manufacturer stated that, non-responders continued to receive pegloticase treatment due to the double-blind design of the trial, despite loss of response."

On page 71, section 4.5.1, of the ERG report the following text: "[redacted]," should be replaced with, "[redacted]".

On pages 106 to 107, section 5.2.8 the statement: "The unit costs for A&E attendance and hospital admission in Table 7.15 are taken from PSSRU Unit Costs (Curtis, 2011) rather than from the Department Health reference costs for a specific HRG code and are therefore general estimates and not specific to patients with a diagnosis of gout", should be followed by, "The ERG noted that there isn't a specific HRG code for gout, but there are HRG codes covering inflammatory joint disorders which may be applied to patients with a diagnosis of gout."

On page 114, section 5.2.10, the statement: "The ICERs were increased to over £50,000 when assuming no benefits beyond 10 years", should be replaced with: "The ICERS were increased to over £50,000 when the time horizon was reduced to 10 years".