Erratum: replaces page 11 of the ERG report

- empagliflozin used with regimens with multiple daily insulin injections (MDI)

The trials used two doses of empagliflozin, 10 mg and 25 mg daily.
Compared to placebo, empagliflozin reduced HbA1c;

- in dual therapy by 0.57% and 0.64% for 10 mg and 25 mg respectively, at 24 weeks
- in triple therapy, by 0.64% and 0.59% at 24 weeks
- in basal insulin regimens, by 0.46% and 0.62% at 78 weeks
- in MDI insulin regimens, by 0.38% and 0.46% at 52 weeks

In a trial in patients with renal impairment, HbA1c was reduced by 0.52% and 0.68% in those with mild renal impairment, and by 0.42% by the 25 mg dose in those with moderate renal impairment.

Empagliflozin was also associated with weight loss (via losing glucose and hence calories in the urine). Adjusted for placebo change;

- in dual therapy, by 1.6 kg for the 10mg dose and 2.0 kg for the 25 mg dose, compared to placebo
- in triple therapy, by 1.8 and 2.0 kg
- in basal insulin regimens, by 3.6 kg and 3.1 kg (i.e. those on the larger dose lost less)
- with MDI insulin, by 2.39 and 2.48 kg

There were reductions in systolic blood pressure (SBP) ranging from 1.4mm Hg in the MDI trial, to 4.8 mg Hg in the dual therapy trial. In a short-duration (12 weeks) trial in patients with hypertension, SBP reductions were 3.4 and 4.2mm Hg for the two doses.
There were only small differences between the two doses of empagliflozin, with the lower dose sometimes reported to have greater effects.

Because there were no head to head trials of empagliflozin against the gliptins or other flozins, the submission provided data for modelling from a series of network meta-analyses. In brief, the results showed roughly equal effectiveness in glycaemic control amongst the flozins and the gliptins.

ERG Commentary

The main weakness in the evidence base was that all but one of the trials compared empagliflozin with placebo rather than active comparators such as a gliptin. One trial