**National Institute for Health and Care Excellence**

**Single Technology Appraisal (STA)**

**Pembrolizumab for previously treated oesophageal or gastro-oesophageal junction cancer ID1357**

**Response to consultee and commentator comments on the draft remit and draft scope (pre-referral)**

**Please note:** Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

**Comment 1: the draft remit**

| Section | Consultee/ Commentator | Comments [sic] | Action |
|---|---|---|---|
| Wording | Merck Sharp & Dohme Ltd | No comments. | No action required |
| Timing Issues | Merck Sharp & Dohme Ltd | At present, patients with locally advanced/ metastatic disease have limited treatment choice, i.e. best supportive care, and/or palliative chemotherapy.<br><br>We anticipate that the proposed appraisal should be scheduled to enable NICE to issue final guidance soon after regulatory approval. MSD has provided updated regulatory information in this document (below). This is also updated in PharmaScan on a regular basis. | Thank you for the updated information, which has been noted. |

**Comment 2: the draft scope**

| Section | Consultee/ Commentator | Comments [sic] | Action |
|---|---|---|---|
| Background information | Merck Sharp & Dohme Ltd | No comments. | No action required |
| The technology/ intervention | Merck Sharp & Dohme Ltd | Pembrolizumab is administered as a fixed dose for the proposed indication 200mg Q3W over a period of 30 minutes. | Comment noted. No action required. The technology section is intended as a brief overview only and does not include details of the dosing schedule. |
| Population | Merck Sharp & Dohme Ltd | Please note that the population enrolled in the clinical trial programme is described as “adenocarcinoma or squamous cell carcinoma of the esophagus or Siewert type I adenocarcinoma of the EGJ”. The study inclusion criteria describe eligible patients as those with “locally advanced/ metastatic, unresectable disease”. | Comment noted. No action required |
| Comparators | Merck Sharp & Dohme Ltd | No comments. | No action required |
| Outcomes | Merck Sharp & Dohme Ltd | No comments. | No action required |
| Economic analysis | Merck Sharp & Dohme Ltd | No comments. | No action required |

| Section | Consultee/ Commentator | Comments [sic] | Action |
|---|---|---|---|
| Equality and Diversity | Merck Sharp & Dohme Ltd | No comments. | No action required |
| Other considerations | Merck Sharp & Dohme Ltd | No comments. | No action required |
| Innovation | Merck Sharp & Dohme Ltd | MSD considers pembrolizumab to be innovative in its potential to make a significant and substantial positive impact on health-related benefits.<br><br>Pembrolizumab represents a novel mode of action for the treatment of patients with locally advanced/ metastatic unresectable disease and would represent a step-change in the management of these patients, which currently have limited treatment options. | Comment noted. No action required. |
| Questions for consultation | Merck Sharp & Dohme Ltd | No comments. | No action required |
| Additional comments on the draft scope | Merck Sharp & Dohme Ltd | No comments. | No action required |

**The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope**

Pfizer

Department of Health & Social Care