Comment form for the factual accuracy check by the HTD (Laborie) on JCAMD001 Optilume ®

The objective of this reviewer form is to standardise the process of the factual accuracy check of the Joint Clinical Assessment (JCA). The final version of the JCAMD001 on Optilume ® was open for a factual accuracy check by the health technology developer (HTD) Laborie between 22/05/2023 and 26/05/2023.

Comments received from: HTD, Laborie

All received comments are formally responded in this combined document, to be published on the EUnetHTA website, name of organisation/institution (or individual names of the reviewers/affiliations) disclosed.

Page number	Line/ section number	Comment and suggestion for rewording	Character of comment • 'major'[a] =1 • 'minor'[b] = 2 • 'linguistic'[c] =3	Authoring team response
13	218	This should stipulate 2023 EAU guidelines not 2022 given the reference leads to the recently updated in March 2023 EAU Urethral Stricture Guidelines. This should also consider inclusion of the specific guideline relative to drug coated balloon dilation (EAU Urethral Stricture Guidelines, Page 31, 6.2.3.4) to be factually correct and relevant. The summary of evidence states: Drug (paclitaxel)-coated balloon dilatation is associated with higher anatomic patency rates (at six months) and lower risk of retreatment (at one year) as compared to standard dilatation/DVIU in patients with short (< 3 cm), bulbar strictures that underwent at least two prior failed endoscopic treatments (LE 1b). The official guideline statement is as follows: Offer drug (paclitaxel)-coated balloon dilatation for a short (< 3 cm) bulbar stricture recurring after at least two prior endoscopic treatments, but only in patients for whom urethroplasty is not an option (weak recommendation).	1	Thanks for your comment. The 2022 EAU guideline was used in the JCA report as it was the available version during the drafting of the report. Thank you for spotting that the reference pointed to the 2023 version while we meant to refer to the 2022 version. The 2023 EAU update has introduced the drug-coated balloon dilation as one of the several strategies for post-dilation/direct vision internal urethrotomy. Therefore, the reference to the 2023 EAU guideline has been included in addition to the 2022 version into the report and the following sentence has been added to the report: "The 2023 EAU update has introduced the drug-coated balloon dilation as one of the several strategies for post-dilation/direct vision internal urethrotomy."
19	298	The JCAMD001 Assessment Report indicates that no study was provided specifically addressing PICO 1, PICO 2, or PICO 3. The ROBUST III trial included comparators for both PICO 1 and PICO 2. Although the primary analaysis evaluated these comparators in	1	Thank you for your comment. For clarification, the sentence "The HTD did not provide any study specifically addressing PICO 1, PICO 2 nor PICO 3 questions" has been

Page number	Line/ section number	Comment and suggestion for rewording	Character of comment • 'major'[a] =1 • 'minor'[b] = 2 • 'linguistic'[c] =3	Authoring team response
		a pooled fashion, sub-analyses evaluating Optilume against each individual comparator were consistent with the primary analysis and significant in favor of Optilume, see Response to Letter (Elliott SP, https://doi.org/10.1097/JU.0000000000002427). Stating that no study exists addressing these comparators is factually incorrect.		changed to "The HTD did not provide any study individually addressing the PICO 1, PICO 2 or PICO 3 question". Although the Response to Letter mentioning the sub-analyses is referenced in the JCA report, the corresponding detailed data were not provided nor referenced in the health technology developer submission dossier.
28	377 (Table 18)	Table 18 indicates that 'Drug-related adverse events' were not reported. This is factually incorrect. As a combination product, separating events due to the drug or the device aspect of the product is not practically feasible. Adverse events were independently adjudicated by a clinical events committee for relatedness to the treatment. A summary of relevant differences in treatment related event rates was described in the ROBUST III primary manuscript (Elliott SP, 2022) and a more detailed summary is included in RP1076-001	2	A footnote has been added to specify that the adverse events related solely to the drug are concerned in the line "Drug-related AEs". This footnote indicates "Refers to AEs related to the drug only (and not to the device)."
37	429 (Table 25)	Listed IPSS for Optilume DCB at 1 year is missing a decimal (90 should be 9.0)	1	Thanks for your comment. This has been amended.
37	429 (Table 25)	Listed PVR for Optilume DCB at 6 months – comma should be a decimal	2	Thanks for your comment. This has been amended.