



Brussels, 26 Sep 2024

11TH MEETING

SUBGROUP FOR JOINT SCIENTIFIC CONSULTATIONS

10 OCTOBER 2024

Location

The meeting is organised online on Webex

DRAFT AGENDA

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|----------------------|--|
| 09.45 – 10.00 | <i>Opening of the online connection</i> |
| 10.00 – 10.10 | Opening of the meeting <ul style="list-style-type: none">○ <i>Welcome by Chair and co-Chair</i>○ <i>Approval of the agenda</i>○ <i>Approval of minutes from 10th meeting on 09 September 2024</i>○ <i>Declarations of interests for the JSC subgroup</i>○ <i>Action points' status</i> |
| 10.10 – 10.25 | Updates - Information points <ul style="list-style-type: none">○ HTACG Meeting○ Parallel Advice for the interim period○ Update Implementing Acts on JSC○ IT Platform○ Financing: Tender proposal |
| 10.25 – 10.55 | Procedural guidance JSC MP
Feedback on 2 nd review by SG and discussion |
| 10.55 – 11.10 | Standard Operating Procedure JSC MP
Feedback on 1 st review by SG and discussion |
| 11.10 – 11.40 | Guidance on JSC Selection MP
Feedback on 2 nd review by SG and discussion |
| 11.40 – 11.50 | Submission Request Templates MP
Conditional validation by SG |
| 11.50 – 12.00 | Briefing Document Templates MP
Conditional validation by SG |
| 12.00 – 12.15 | <i>Break</i> |
| 12.15 – 12.30 | Outcome document MP
Feedback on 2 nd review by SG and discussion |

- 12.30 – 12.45** **Guidance on appointment of assessor and co-assessor**
Update during 2nd review by SG and discussion
- 12.45 – 13.05** **Submission Request Templates MD/IVD**
Feedback on 1st review by SG and discussion
- 13.05 – 13.30** **Outcome document MD/IVD**
Feedback on 2nd review by SG and discussion
- 13.30 – 13.40** **Briefing Document Templates MD/IVD**
Update during 1st review by SG and discussion
- 13.40 – 13.45** **Observer participation in the 3rd pilot phase on scientific advice to
manufacturers from Expert Panels on MD**
For information
- 13.45 – 14.00** **Closing of the meeting**
AOB and concluding remarks by Chair and co-Chair