



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

7 September 2022  
EMA/661919/2022

## Draft agenda – Fifth EMA-Medicines for Europe Bilateral meeting

15 September 2022, 14:00-16:30

Virtual Meeting

Chair: Juan Garcia Burgos, EMA

| Item | Preliminary draft agenda   | Time |
|------|--|------|
| 1.   | <b>Welcome and introductions</b><br><i>EMA</i><br><br><b>Introductory Remarks</b><br><i>Medicines for Europe</i>   | 10'  |
| 2.   | <b>Transparency and stakeholders relations</b><br><i>Medicines for Europe</i><br><i>EMA</i>  | 15'  |
| 3.   | <b>Accelerating and tailoring Centralised Marketing Authorisation (MA) procedures for off patent medicines</b><br><i>Medicines for Europe</i><br><i>EMA</i><br><i>Discussion</i> | 25'  |
| 4.   | <b>Improving Article 10 to support off-patent medicines</b><br><i>Medicines for Europe</i><br><i>EMA</i><br><i>Discussion</i>  | 50'  |

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| 5.   | <b>Modernise maintenance procedures to foster medicines availability</b><br><i>Medicines for Europe</i><br><i>EMA</i><br><i>Discussion</i> | 25'  |
| 6.   | <b>Oversight of manufacturing and Supply chain</b><br><i>Medicines for Europe</i><br><i>EMA</i><br><i>Discussion</i>                       | 20'  |
| 7.   | <b>A.O.B</b>   | 5'   |
| 8.   | <b>Summary of follow-up items</b><br><b>Close of meeting</b>   | 5'   |