



PHARMACEUTICAL COMMITTEE

Agenda of the 100th meeting of the Pharmaceutical Committee

Friday, 21 October 2022

1. Adoption of the draft agenda

Key questions arising from the technical analysis of the revision of the general pharmaceutical legislation

2. Novel incentives for the development of antimicrobials addressing AMR and prudent use measures
3. Revised hospital exemption for ATMPs
4. Formal recognition of HMA network in legislation
5. Keynote address by SANTE Director General, Sandra GALLINA
6. Measures to improve access to medicines and market launch in all Member States
7. Strengthening the Environmental Risk Assessment of medicines
8. Active substance master file
9. Creation of a sandbox provision
10. Establishment of a mechanism to clarify the regulatory status of products
11. Points of information
 - a. Review of the variations Regulation in 2023
 - b. Conclusion of the market launch pilot
12. A.O.B.
