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European Confederation of
Pharmaceutical Entrepreneurs AISBL

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Rue Marie de Bourgogne
58 – 1000 Brussels
Virtual meeting via TEAMS

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REGULATORY WORKING GROUP MEETING

21 February 2023, 11am – 2pm CET

Agenda

1. **Welcome / Past and Next Events**
2. **Strategic Priorities and Goals for 2023** – Summary (Axel Korth, EUCOPE & Jörg Plessl, Norgine, Co-Chair of the Regulatory Working Group)
3. **MDR/IVDR Implementation** – the [EU Commission Proposal](#) dated 6 January 2023 (Alexandre Regniault & David Caumartin, France Biotech)
4. **EU Policy Update** – Revision of the GPL and the OMP/Paediatric Regulation – Current State of Affairs (Stefano Romanelli, EUCOPE)
5. **CTR Implementation** – Mandatory Use of CTIS (Bertrand Fournier, Shionogi – Chair of the CTR/CTIS Focus Group)
6. **Update from the Pharmacovigilance Focus Group** (Peter de Veene – Chair of the PV Focus Group)
7. **Update from the Quality Innovation Focus Group** (Marcello Milano, BioMarin – Chair of the Quality Innovation Focus Group)
8. **AOB / End of meeting**