20 November 2020

EMA/628963/2020

Biological Health Threats and Vaccines strategy (HTV)

Agenda for ETF meeting on vaccines against COVID-19

26th November 2020 @ 11:00 CET time – ROOM 07/A at EMA

**Chair:** Marco Cavaleri

Connection details are attached to the Outlook invitation

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| --- | --- | --- | --- |
| Order | Topics | Speaker | Time |
| 1 | *Teleconference opening*Welcome and declarations of interest of expertsPre-meeting list of participants with identified restrictions in relation to declarations of interests applicable to the items of the agenda for the TC to be held on 26th November 2020 is attached to this agenda. |  |  |
| 2 | Ad26.COV2.S vaccine (Janssen-Cilag International NV) - start of the Rolling Review | CHMP Rapporteur: Christophe Focke (BE)CHMP CoRapporteur: Sol Ruiz (ES)EMA: Maribel Gonzalez Tome Maribel | 10’ |
| 3 | COVID-19 vaccine (recombinant, adjuvanted) (Sanofi) - EMA/SA/0000047681 - recombinant protein derived from the SARS-CoV-2 prefusion Spike delta TM protein for the prevention of COVID-19 disease – Rapid Scientific Advice | SAWP: Dr Walter Janssens (BE); Dr Mário Miguel Coelho da Silva Rosa (PT) EMA: Efthymios Manolis | 40’ |
| 4 | BNT162 (mRNA1273 vaccine) Biontech/Pfizer -Rolling Review (CMC wave 1) | CHMP Rapp: Filip JosephsonCHMP Co-Rapp: Jean-Michel Race, acting on behalf of Alexandre MoreauCHMP Peer Reviewer: Ingrid WangEMA: Vanessa Seguin | 40’ |
| 5 | BNT162 (mRNA1273 vaccine) – (002861-PIP02-20) - Biontech – update on the PIP discussion | EMA: Laura Fregonese | 20’ |
| 6 | A.O.B. |  |  |
|  | *Teleconference closing* |  |  |

SAP HR code for this meeting: 19.06

**ETF:** Harald Enzmann (CHMP Chair), Bruno Sepodes (CHMP Vice-chair), Sabine Straus (PRAC Chair), Koenraad Norga (PDCO Chair), Anja Schiel (SAWP Chair), Maria Cortizo (IDWP Chair), Filip Josephson (IDWP), Regine Lehnert (IDWP), Nathalie Morgensztejn (IDWP), Mair Powell (VWP Chair), Eleonora Wijnans (VWP), Mikael Andersson (VWP), Sol Ruiz (BWP Chair), Ralf Wagner (CMC/NC assessor), Blanka Hirshlerova (QWP Chair), Sven-Erik Hillver (QWP), Jean-Michel Dogne (PRAC and GACVS), Ann Marie Janson Lang (CTFG), Jacqueline Kerr (BPWP), Ita Walsh (BPWP), Agustin Portela (VWP member), Isabelle Bekeredjian- Ding (VWP member), Dagmar Stara (EC), Ulla Wändel Liminga (PRAC), Martin Huber (PRAC Vice-chair), Daniel Morales (PRAC), Kora Doorduyn - van der Stoep (CMDh Vice-chair), Rui Pedro da Costa Vilar (CMDh alternate), Cesar Hernandez Garcia (CMDh expert), Jan Müller-Berghaus (SAWP and CAT member), Sara Galluzzo (PDCO member), Sabine Mayrhofer (expert), Ingrid Schellens (SAWP Alternate), Charlotta Bergquist (VWP – member), Kaisa Immonen (Civil society – observer), Leire Solis (Civil society - observer alternate), Anita Simond (Civil society – observer), Tiago Villanueva (Civil society - observer alternate)

**EMA Responsive team**: Marco Cavaleri (Scientific Lead, Biological Health Threats and Vaccines Strategy Office (HTV)), Agnès Saint-Raymond (Head of International Affairs Division, AF-IA), Monika Benstetter (Head of Office of Media and Public Relations S-CO-MPR), Marie-Agnes Heine (Head of Communication Department S-CO), Veronika Jekerle (Head of Pharmaceutical Quality H-QS-QUA), Iordanis Gravanis (Head of Scientific Advice Office, D-DS-SCA), Jane Moseley (Head of Inspections, H-QS-ISP), Xavier Kurz (Head of Data Analytics, TDA-DAT), Peter Arlett (Head of Data Analytics and Methods Task Force (TDA)), Fergus Sweeney (Head of Clinical Studies and Manufacturing Task Force (TCS)), Alexis Nolte (Head of Human Medicines Division (H), Irene Rager (Head of Vaccines and therapies for infectious diseases Office (H-INF)), Spiridon Vamvakas (Scientific Adviser on Human Medicines), Morgane de Verdiere (Head of Medical and Health Information Office (S-PH-MHI)), Georgy Genov (Head of Pharmacovigilance Office (H-QS-PHV)), Jordi Llinares Garcia (Regulatory Science and Innovation- Research and Innovation – Head of Workstream)

**EMA operational staff**: Monica Dias (WS on supply), Manuela Mura (Scientific Coordination Officer, SCO, HTV office), Radu Botgros (HTV Office), Ragini Shivji (Pharmaceutical Quality Office), Eric Pelfrene (Vaccines and Therapeutics for Infectious Diseases INF Office), Laura Fregonese (Paediatric Medicines Office, H-EG-PME), Jaime Oliva Peñas (INF Office), Maribel Gonzalez (INF Office), Efthymios Manolis (Scientific Advice Office, D-DS-SCA), Zigmars Sebris (Reg Affairs Office, H-QA-REG), Monika Mayr (GMP Inspection Office), Palle Valentiner-Branth (INF Office), Brendan Cuddy (WS supply), Margarida Guimaraes (H-QS-PHV), Andrew Thomson (TDA-MET), Sophie Labbe (S-CO-MPR), Richard Vesely (H-IMM), Francesca Scotti (TCS-CTS), Nacho Mbaeliachi (S-PH-MHI), Evangelos Kotzagiorgis (H-QS-QUA)

Annex II – List of participants

including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the ETF meeting on 26th November 2020.

| **Name** | **Role** | **Member state or affiliation** | **Outcome restriction following evaluation of e-DoI** | **Topics on agenda for which restrictions apply** |
| --- | --- | --- | --- | --- |
| Harald Enzmann  | Member  | CHMP - chair | No interests declared | Full involvement |
| Bruno Sepodes  | Member | CHMP – vice-chair | No interests declared | Full involvement |
| Sabine Straus  | Member | PRAC - chair | No interests declared | Full involvement |
| Koenraad Norga  | Member | PDCO - chair | No restrictions applicable to this meeting | Full involvement |
| Anja Schiel  | Member | SAWP - chair | No interests declared | Full involvement |
| Maria Cortizo | Member | IDWP - chair | No interests declared | Full involvement |
| Filip Josephson | Member | IDWP - member | No interests declared | Full involvement |
| Regine Lehnert | Member | IDWP - member | No interests declared | Full involvement |
| Nathalie Morgensztejn  | Member | IDWP - member | No interests declared | Full involvement |
| Mair Powell | Member | VWP - chair | No interests declared | Full involvement |
| Mikael Andersson | Member | VWP - member | No interests declared | Full involvement |
| Sol Ruiz | Member | BWP - chair | No interests declared | Full involvement |
| Ralf Wagner | Member | BWP - assessor | No interests declared | Full involvement |
| Blanka Hirschlerova | Member | QWP - chair | No interests declared | Full involvement |
| Sven-Erik Hillver | Member | QWP - member | No interests declared | Full involvement |
| Jean-Michel Dogne | Member | PRAC, WHO GACVS - member | No interests declared | Full involvement |
| Ann Marie Janson Lang (MPA SE) | Member | CTFG | No interests declared | Full involvement |
| Eleonora Wijnans | Member | VWP - member | No interests declared | Full involvement |
| Jacqueline Kerr | Member | BPWP - member | No interests declared | Full involvement |
| Ita Walsh | Member | BPWP - member | No interests declared | Full involvement |
| Agustin Portela | Member | VWP - member | No interests declared | Full involvement |
| Isabelle Bekeredjian- Ding | Member | VWP - member | No interests declared | Full involvement |
| Ulla Wändel Liminga | Member | PRAC - member | No interests declared | Full involvement |
| Martin Huber | Member | PRAC – vice-chair | No interests declared | Full involvement |
| Daniel Morales | Member  | PRAC - member | No interests declared | Full involvement |
| Kora Doorduyn - van der Stoep | Member | CMDh -chair | No interests declared | Full involvement |
| Rui Pedro da Costa Vilar | Member  | CMDh - alternate | No interests declared | Full involvement |
| Jan Müller-Berghaus | Member | SAWP and CAT member | No interests declared | Full involvement |
| Sara Galluzzo | Member | PDCO - member | No interests declared | Full involvement |
| Sabine Mayrhofer | Member | CHMP - Expert | No interests declared | Full involvement |
| Ingrid Schellens | Member | SAWP Alternate | No interests declared | Full involvement |
| Charlotta Bergquist | Member | VWP - member | No interests declared | Full involvement |
| Dagmar Stara | Member | EC | No interests declared | Full involvement |
| Edit Szepessy | Expert | EC | No interests declared | Full involvement |
| Kristof Bonnarens | Expert | EC | No interests declared | Full involvement |
| Laurence O'Dwyer | Expert | EU IN | No interests declared | Full involvement |
| Kaisa Immonen | Observer | Civil society - observer | No restrictions applicable to this meeting | Full involvement |
| Leire Solis | Alternate | Civil society - observer alternate | No restrictions applicable to this meeting | Full involvement |
| Anita Simond | Observer | Civil society - observer | No restrictions applicable to this meeting | Full involvement |
| Tiago Villanueva | Alternate | Civil society - observer alternate | No interests declared | Full involvement |
| Marco Cavaleri | ETF - chair | EMA | No interests declared | Full involvement |
| Manuela Mura (or relevant back -up) | ETF Secretariat (vaccines) | EMA | No interests declared | Full involvement |
| Radu Botgros (or relevant back -up) | ETF Secretariat (therapeutics) | EMA | No interests declared | Full involvement |
| Katarzyna Turobos (or relevant back -up) | ETF Secretariat | EMA | No interests declared | Full involvement |