



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

20 November 2020

EMA/628963/2020

Biological Health Threats and Vaccines strategy (HTV)

## Agenda for ETF meeting on vaccines against COVID-19

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

**Chair:** Marco Cavaleri

Connection details are attached to the Outlook invitation

Order	Topics	Speaker	Time
1	<i>Teleconference opening</i>  Welcome and declarations of interest of experts  Pre-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 26 <sup>th</sup> November 2020 is attached to this agenda.		
2	Ad26.COVS 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	SAWP: Dr Walter Janssens (BE); Dr Mário Miguel Coelho da Silva Rosa (PT)  EMA: Efthymios Manolis	40'

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Order	Topics	Speaker	Time
	prevention of COVID-19 disease – Rapid Scientific Advice		
4	BNT162 (mRNA1273 vaccine) Biontech/Pfizer -Rolling Review (CMC wave 1)	CHMP Rapp: Filip Josephson  CHMP Co-Rapp: Jean- Michel Race, acting on behalf of Alexandre Moreau  CHMP Peer Reviewer: Ingrid Wang  EMA: Vanessa Seguin	40'
5	BNT162 (mRNA1273 vaccine) – (002861-PIP02-20) - Biontech – update on the PIP discussion	EMA: Laura Fregonese	20'
6	A.O.B.		
	<i>Teleconference closing</i>		

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 26<sup>th</sup> 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

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
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