Curriculum Vitae

Personal information

Marco Cavaleri

Work experience

May 2022-present:

- **Head of Health Threats and Vaccines Strategy,** EMA, Amsterdam, NL.
- In addition to the role and responsibilities below, co-chair of the Emergency Task Force of the EMA working on preparedness and response for health threats
- Member of WHO PDVAC for development of new vaccines

March 2020-May 2022:

- **Head of Biological Health Threats and Vaccines Strategy,** Clinical trials and manufacturing Working Stream, EMA, Amsterdam, NL.
- Chair of the EMA COVID-19 Task Force for rapid evaluation of vaccines and therapeutics for COVID-19.
- EMA lead in the activities related to COVID-19 vaccines and therapeutics.
- Co-Chair of ICMRA Workshops on COVID-19 vaccines and therapeutics.
- Member of EC expert group on variant vaccines for COVID-19.
- Scientific contribution and coordination of the activities of the therapeutic area working parties, i.e. Vaccine Working Party and Infectious Diseases Working Party, including guideline development;
- Responsible for vaccines strategy of the EMA as per Regulatory Science Strategy and EU network strategy
- Responsible for the AMR Agency strategy on human medicines.
- EMA topic leader and scientific coordinator for activities related to public health emergencies of international concern
- Member of the WHO R&D Blueprint SAG.
- Member of the WHO WG on clinical trial design for emergent pathogens

2013-2020:

- **Head of Antiinfectives and Vaccines Office,** Scientific and Regulatory department, Human Medicines Evaluation Division, EMA, Amsterdam, NL.
- Responsible for scientific oversight and coordination of EU regulatory activities for antiinfectives and vaccines.
- Operational coordination and implementation of the Office activities and report regularly thereon to the Head of Department
- Supervision of work carried out by Office staff.
- Responsible for the Office's contributions with regard to safety, efficacy and risk management aspects related to medicinal products in the therapeutic areas, thereby ensuring that the Agency's role in the clinical and benefit/risk evaluation is performed with the highest possible quality.
- Developing the therapeutic area competencies to support research and development as well as pharmacovigilance activities, and to complement the competencies available in the network.
- Scientific contribution and coordination of the activities of the therapeutic area working parties, i.e. Vaccine Working Party and Infectious Diseases Working Party, including guideline development;
- Coordination of activities of scientific advisory groups (SAGs) for antivirals, antiinfectives and vaccines.
- EMA scientific leader for the AMR Agency strategy on human medicines and Chair of the EMA AMR Task Force.
- EMA topic leader and scientific coordinator for activities related to public health emergencies of international concern.
- EMA Chair of cluster meetings with FDA on vaccines, antibiotics and antivirals.
- Member of WHO R&D Roadmaps Task Force for diagnostics, vaccines and antivirals for several pathogens, e.g. Ebola/Marburg.
- Representative of EMA on the human medicines side in the context of Transatlantic Task Force on Antimicrobial Resistance (TATFAR) and in the context of the European Strategy on Antimicrobial Resistance.
- Chair of CPAS, Advisory group to CHMP and PRAC on classification of post-authorization studies.
- Member of several Scientific Advisory Board of EU funded projects.

2009-2013:

- **Head of Section Antiinfectives and vaccines**, Safety&Efficacy Sector, Human Medicines Development and Evaluation Unit, European Medicines Agency (EMEA), London, UK.
- Specific tasks include:
- Responsible for all pre- and post-authorization scientific, regulatory and procedural activities related to vaccines and antiinfectives, including management of Vaccine Working Party, Infectious Diseases Working Party and scientific advisory groups (SAGs) for antivirals, antiinfectives and ad-hoc groups for vaccines and tropical medicines.
- Operational coordination and implementation of the Section activities and report regularly thereon to the Head of Sector and supervision of work carried out by Office staff.
- EMA scientific coordinator of activities related to clinical and preclinical evaluation of vaccines during the 2009 H1N1 pandemic .
- Representation of EMA at various meetings and expert groups at WHO and at international scientific

meetings in the area of infectious diseases, especially in the areas of vaccines, influenza, TB and bacterial infections.
- Representation of EMA on the human medicines side in the context of Transatlantic Task Force on Antimicrobial Resistance (TATFAR) and in the context of the European Strategy on Antimicrobial Resistance.

2008- 2009:

- -**Specialised Group Leader Antiinfectives.** Safety&Efficacy Sector, Pre-Authorisation Human Unit, European Medicines Agency (EMEA), London, UK, managing the group within the EMEA secretariat in charge of initial MAA procedures for drugs in the areas of infectious diseases including vaccines, rheumatology, GI and autoimmune diseases.

2008:

- **Scientific Associate Director** at Cosmo Pharmaceuticals, Italy, acting as deputy of both Chief Scientific Officer and Chief Medical Officer. Main responsibilities included definition of regulatory, preclinical and clinical strategy for all products in full development

2005- 2007:

- **Scientific Administrator, Scientific Advice and Orphan Drugs Sector**, Pre-Authorisation Unit, European Medicines Agency (EMEA), London, UK acting as EMEA coordinator and project manager for both scientific advice and orphan drugs procedures.

2005:

- **Associate Director, Clinical Pharmacology** at Tibotec BVBA-Johnson & Johnson, Belgium, with global development responsibilities for clinical pharmacology for a new antitubercolosis drug.

2002- 2005:

- **European Project Leader and Senior Clinical Scientist**, at "Vicuron Pharmaceuticals Italy", Gerenzano.
- Responsible for clinical trials in Europe

2000-2002:

- **Head of Bioanalysis and Pharmacokinetics**, "Biosearch Italia S.p.A.", Gerenzano (VA)
- Project Leader for the early development candidates antibiotics
- Study Director of Bioanalysis, Pharmacokinetic and Toxicokinetic GLP studies with parenteral and topical antibiotics.
- Management of outsourced toxicology activities as Company representative and Study Monitor.

1997-2000:

- **PK specialist** at "Biosearch Italia S.p.A.", Gerenzano (VA) Italy.

Education and training

1995-1997:

- Degree in Pharmacology.

University of Milan, Italy.

1989-1995:

- Degree in Pharmaceutical Sciences.

University of Milan, Italy.

Additional information

Publications

Buoninfante, A., Andeweg, A., Baker, A.T. Mitesh Borad, Nigel Crawford, Jean-Michel Dogné, David Garcia-Azorin, Andreas Greinacher, Rita Helfand, Anders Hviid, Stefan Kochanek, Marta López-Fauqued, Ishac Nazy, Anand Padmanabhan, Sue Pavord, Daniel Prieto-Alhambra, Huyen Tran, Ulla Wandel Liminga & **Marco Cavaleri**

Understanding thrombosis with thrombocytopenia syndrome after COVID-19 vaccination. *npj Vaccines* **7**, 141 (2022). https://doi.org/10.1038/s41541-022-00569-8

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Building the concept for WHO Evidence Considerations for Vaccine Policy (ECVP): Tuberculosis vaccines intended for adults and adolescents as a test case

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Lienhardt C, Vernon AA, **Cavaleri M**, Nambiar S, Nahid P. Development of new TB regimens: Harmonizing trial design, product registration requirements, and public health guidance.

PLoS Med. 2019;16(9):e1002915. Published 2019 Sep 6. doi:10.1371/journal.pmed.1002915

Pelfrene E, Harvey Allchurch M, Ntamabyaliro N, Victoria Nambasa, Fátima V Ventura, Nithyanandan Nagercoil, **Marco Cavaleri**.

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P. Durbin, Tim Endy, Eva Harris, Bruce L. Innis, Leah C. Katzelnick, Peter G. Smith, Wellington Sun, Stephen J. Thomas, Joachim Hombach.

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Both L, Botgros R, **Cavaleri M.**

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Regulation of vaccines in Europe

Ehmann F, Kurz X., **Cavaleri M,** Arlett P.

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Elmgren L, Li X, Wilson C, Ball R, Wang J, Cichutek K, Pfleiderer M, Kato A, **Cavaleri M**, Southern J, Jivapaisarnpong T, Minor P, Griffiths E, Sohn Y, Wood D.

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Hatzakis A, Wait S, Bruix J, Buti M, Carballo M, **Cavaleri M**, Colombo M, Delarocque-Astagneau E, Dusheiko G, Esmat G, Esteban R, Goldberg D, Gore C, Lok AS, Manns M, Marcellin P, Papatheodoridis G, Peterle A, Prati D, Piorkowsky N, Rizzetto M, Roudot-Thoraval F, Soriano V, Thomas HC, Thursz M, Valla D, van Damme P, Veldhuijzen IK, Wedemeyer H, Wiessing L, Zanetti AR, Janssen HL.

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M.B. Dorr, D. Jabes, **M. Cavaleri**, J. Dowell, G. Mosconi, A. Malabarba, RJ White and T. Henkel,

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M. Cavaleri, S. Riva, A. Valagussa, M. Guanci, L. Colombo, J. Dowell and M. Stogniew

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D. Jabes, G. Candiani, G. Romanò, C. Brunati, S. Riva and **M. Cavaleri**

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M. Cavaleri, W. Pollini and L. Colombo.

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E. De Fabiani, D. Caruso, **M. Cavaleri**, M. Galli Kienle and G. Galli.

The Journal of Lipid Research (1996) ***37***, p.2280-2287.

Projects

Co-inventor of 3 EU and/or US registered patents.

Memberships

Other Relevant Information