



Curriculum Vitae

Personal information Emer Cooke

Work experience

Emer Cooke has been the Executive Director of the European Medicines Agency, based in Amsterdam, since November 2020. She also holds the role of Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA).

Between November 2016 and November 2020, she was the Director responsible for all medical product related regulatory activities at the World Health Organization in Geneva.

Ms. Cooke is a pharmacist with Master's degrees in Science and Business Administration from Trinity College Dublin. She has over 30 years' experience in international regulatory affairs and held management positions at the EMA as Head of Inspections and Head of International Affairs respectively from 2002 until 2016.

She has also worked in the Pharmaceuticals unit of the European Commission, where intra-alia, she was responsible for international collaboration, EU enlargement and the orphan medicines regulation for the European Pharmaceutical Industry Association (EFPIA) and in various industry and regulatory positions in Ireland.

In 2021 she received the Muckross (her alma mater) Woman of the Year award. In 2022 she received European Movement Ireland's "European of the Year" award. In 2023 she was awarded an honorary doctorate by the Royal College of Surgeons Ireland (RCSI) University of Medicines and Health Sciences.

Education and training

- Master's degree in Business Administration, Trinity College Dublin, Ireland (1991)
- Master of Science, Trinity College Dublin, Ireland (1985)
- Bachelor in Science (Pharmacy), Trinity College Dublin, Ireland (1982)
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Additional information

Publications

Annex 1 – Extract of relevant publications in the last 10 years

1. Clinical Evidence 2030

Arlett P, Umuhire D, Verpillat P, Foggi P, Wändel Liminga U, Sepodes B, Lunzer M, Aylward B, Vamvakas S, Roes K, Pétavy F, Thirstrup S, Lamas M, Cooke E, Broich K.

Clin Pharmacol Ther. 2025 Feb 14. doi: 10.1002/cpt.3596. PMID: 39949283

2. COVID-19 vaccines- The way forward

Klimek L, Agache I, Cooke E, Jutel M, Akdis CA, O'Hehir R.

Allergy. 2022 Jan;77(1):15-16. doi: 10.1111/all.14995.PMID: 34191300

3. Scientific considerations for global drug development

*Wilson JL, Cheung KWK, Lin L, Green EAE, Porrás AI, Zou L, Mukanga D, Akpa PA, Darko DM, Yuan R, Ding S, Johnson WCN, Lee HA, **Cooke E**, Peck CC, Kern SE, Hartman D, Hayashi Y, Marks PW, Altman RB, Lumpkin MM, Giacomini KM, Blaschke TF.*
Sci Transl Med. 2020 Jul 29;12(554):eaax2550. doi: 10.1126/scitranslmed.aax2550.PMID: 32727913

4. Global regularoty agility during covid-19 and other health emergencies

*Mak TK, Lim JC, Thanaphollert P, Mahlangu GN, **Cooke E**, Lumpkin MM*
BMJ. 2020 Apr 27;369:m1575. doi: 10.1136/bmj.m1575.PMID: 32340997

5. Evidence generation and reproducibility in cell and gene therapy research: A call to action

*Abou-El-Enein M, Angelis A, Appelbaum FR, Andrews NC, Bates SE, Bierman AS, Brenner MK, Cavazzana M, Caligiuri MA, Clevers H, **Cooke E**, Daley GQ, Dzau VJ, Ellis LM, Fineberg HV, Goldstein LSB, Gottschalk S, Hamburg MA, Inqber DE, Kohn DB, Krainer AR, Maus MV, Marks P, Mummery CL, Pettigrew RI, Rutter JL, Teichmann SA, Terzic A, Urnov FD, Williams DA, Wolchok JD, Lawler M, Turtle CJ, Bauer G, Ioannidis JPA*
Mol Ther Methods Clin Dev. 2021 Jul 21;22:11-14. doi: 10.1016/j.omtm.2021.06.012. eCollection 2021 Sep 10.PMID: 34377737

6. Optimizing the East African Community's Medicines Regularoty harmonization initiative in 2020-2022: A Roadmap for the Future

*Arik M, Bamenyekanye E, Fimbo A, Kabatende J, Kijo AS, Simai B, Siyoi F, Azatyan S, Ambali A, **Cooke E**, Mashingia JH, Mwesiye JP, Ndomondo-Sigonda M, Sillo H, Sonoiya S, Tanui P, Ward M, Delano T.*
PLoS Med. 2020 Aug 12;17(8):e1003129. doi: 10.1371/journal.pmed.1003129. eCollection 2020 Aug.PMID: 32785229

7. Preparing Europe for future health threats and crises – the European Medicines Agency; ensuring safe and effective medicines and medical devices

Emer Cooke

PMID: 36268739 PMCID: [PMC9585881](https://pubmed.ncbi.nlm.nih.gov/36268739/) DOI: [10.2807/1560-7917.ES.2022.27.42.2200798](https://doi.org/10.2807/1560-7917.ES.2022.27.42.2200798)

8. Expanding global access to essential medicines: investment priorities for sustainably strengthening medical product regulatory systems

*Roth L, Bempong D, Babigumira JB, Banoo S, **Cooke E**, Jeffreys D, Kasonde L, Leufkens HGM, Lim JCW, Lumpkin M, Mahlangu G, Peeling RW, Rees H, Ndomondo-Sigonda M, Stergachis A, Ward M, Nwokike J.*
Global Health. 2018 Nov 1;14(1):102. doi: 10.1186/s12992-018-0421-2.PMID: 30382856

9. Real-World Evidence in EU Medicines Regulation: Enabling Use and Establishing Value

*[Peter Arlett](#), [Jesper Kjær](#), [Karl Broich](#), **Cooke E***

ASCPT – 19 November 2021

<https://doi.org/10.1002/cpt.2479>

10. Evidence generation and reproducibility in cell and gene therapy

research: A call to action.

Abou-El-Enein M, Angelis A, Appelbaum FR, Andrews NC, Bates SE, Bierman AS, Brenner MK, Cavazzana M, Caligiuri MA, Clevers H, **Cooke E**, Daley GQ, Dzau VJ, Ellis LM, Fineberg HV, Goldstein LSB, Gottschalk S, Hamburg MA, Ingber DE, Kohn DB, Krainer AR, Maus MV, Marks P, Mummery CL, Pettigrew RI, Rutter JL, Teichmann SA, Terzic A, Urnov FD, Williams DA, Wolchok JD, Lawler M, Turtle CJ, Bauer G, Ioannidis JPA

Mol Ther Methods Clin Dev. 2021 Jul 21;22:11-14. doi:

10.1016/j.omtm.2021.06.012. PMID: 34377737; PMCID: PMC8322039.

[COVID - 19 vaccines—The way forward - Klimek - 2022 - Allergy - Wiley Online Library](#)

11. The European Medicines Agency's EU conditional marketing authorisations for COVID-19 vaccines

[Marco Cavaleri 1](#), [Harald Enzmann 2](#), [Sabine Straus 3](#), [Emer Cooke 4](#)

PMID: 33453149, PMCID: [PMC7833511](#), DOI: [10.1016/S0140-6736\(21\)00085-4](#)

Lancet 2021 Jan 30;397(10272):355-357

12. Emerging next-generation gene therapies: the need for high quality evidence and research reproducibility

Under review

13. The quest for more effective vaccine markets – Opportunities, challenges, and what has changed with the SARS-CoV-2 pandemic

Tania Cernuschi¹, Stefano Malvolti², Shanelle Hall³, Luc Debruyne⁴, Hanne Bak Pedersen⁵, Helen

Rees⁶, **Emer Cooke**⁷

14. COVID-19 vaccines - the way forward

Ludger Klimek, Ioana Agache; Anthony Fauci, **Emer Cooke**, Marek Jutel, Cezmi A. Akdis, Robyn E

O´Hehir

15. Scientific considerations for global drug development

[Jennifer L Wilson 1](#), [Kit Wun Kathy Cheung 1](#), [Lawrence Lin 1](#), [Elizabeth A E Green 1](#), [Analia I Porrás 2](#), [Ling Zou 1](#), [David Mukanga 3](#), [Paul A Akpa 4](#), [Delese Mimi Darko 5](#), [Rae Yuan 6](#), [Sheng Ding 7 8](#), [Wiltshire C N Johnson 9](#), [Howard A Lee 10 11](#), [Emer Cooke 12](#), [Carl C Peck 1 13](#), [Steven E Kern 3](#), [Dan Hartman 3](#), [Yoshikazu Hayashi 14](#), [Peter W Marks 15](#), [Russ B Altman 16](#), [Murray M Lumpkin 3](#), [Kathleen M Giacomini 17](#), [Terrence F Blaschke 18](#)

PMID: 32727913, DOI: [10.1126/scitranslmed.aax2550](#)

Sci Transl Med 2020 Jul 29;12(554):eaax2550

16. Global regulatory agility during covid-19 and other health emergencies

[Tippi K Mak 1 2 3](#), [John Cw Lim 4 2](#), [Prapassorn Thanaphollert 5](#), [Gugu N Mahlangu 6](#), [Emer Cooke 7](#), [Murray M Lumpkin 8](#)

PMID: 32340997, DOI: [10.1136/bmj.m1575](#)

BMJ 2020 Apr 27;369:m1575

17. WHO's Snakebite Envenoming Strategy for prevention and control

[Ren Minghui 1](#), [Mwelecele Ntuli Malecela 1](#), [Emer Cooke 1](#), [Bernadette Abela-Ridder 2](#)

PMID: 31129124, DOI: [10.1016/S2214-109X\(19\)30225-6](#)

18. A new approach to an old problem: Overview of the East African Community's Medicines Regulatory Harmonization initiative

[Margareth Ndomondo-Sigonda 1](#), [Gugu Mahlangu 2](#), [Margaret Agama-Anyetei 3](#), [Emer Cooke 4](#)

PMID: 32785223, PMCID: [PMC7423057](#), DOI: [10.1371/journal.pmed.1003099](#)
PLoS Med 2020 Aug 12;17(8): e1003099

19. Expanding global access to essential medicines: investment priorities for sustainably strengthening medical product regulatory systems

[Lukas Roth 1](#), [Daniel Bempong 1](#), [Joseph B Babigumira 2](#), [Shabir Banoo 3](#), [Emer Cooke 4](#), [David Jeffreys 5](#), [Lombe Kasonde 6](#), [Hubert G M Leufkens 7](#), [John C W Lim 8](#), [Murray Lumpkin 9](#), [Gugu Mahlangu 10](#), [Rosanna W Peeling 11](#), [Helen Rees 12](#), [Margareth Ndomondo-Sigonda 13](#), [Andy Stergachis 2](#), [Mike Ward 4](#), [Jude Nwokike 14](#)

PMID: 30382856, PMCID: [PMC6211488](#), DOI: [10.1186/s12992-018-0421-2](#)
Global Health 2018 Nov 1;14(1):102

21. GMP Oversight of Medicines Manufacturers in the European Union. European Commission

Luigetti R, Cooke E, Cuddy B, Goux S
PDA, 2016

22. Regulatory Science for Paediatric Medicines in Low- and Middle-Income Countries

Saint-Raymond, A. & Cooke E

MacLeod S., Hill S., Koren G., Rane A. (Eds) *Optimizing Treatment for Children in the Developing World*. (2015). Adis Cham, Switzerland

Book Chapters

Cooke, E. The European regulation on orphan medicinal products. *Pharmaceuticals Policy and Law*: 3 (2001), 11-17.

Projects

Memberships

Honorary Doctorate Award - November 2023
European of the Year `2022 - February 2023
Muckroos Woman of the Year - April 2021

Other Relevant Information