



FIVE REASONS TO BECOME CERTIFIED IN MEDICINES DEVELOPMENT

Medicines Development is a complex and rapidly evolving field, with new drugs and therapies being developed all the time. As such, there is a growing need for professionals who are trained and certified in the various aspects of Medicines Development, including drug discovery, clinical trials, and regulatory affairs.

Click [here](#) for five reasons why becoming certified in Medicines Development can be a great career move.

TABLE OF CONTENTS

EMA addresses ongoing antibiotics shortage • P. 2

How Nature readers use ChatGPT • P. 2

News from FDA: CDER continues drug development efforts • P. 3

All-cause serious adverse events following immunization in • P. 3

News from the EMA: Bioequivalence guidelines • P. 4

US plan to shield science from "inappropriate influence" • P. 4

The right path toward polio eradication • P. 5

Drug safety news: pseudoephedrine • P. 5

Access to treatment for multiple sclerosis • P. 5

Eight successes against tropical diseases • P. 5

EMA NEWS: ADDRESSING THE ONGOING ANTIBIOTIC SHORTAGE

EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) met recently to discuss the progress made and to agree on the next steps in the coordinated response to the ongoing shortages of antibiotic medicines containing amoxicillin (alone and in combination with clavulanic acid) in the EU. The MSSG is made up of representatives from EMA, the European Commission and the Heads of Medicines Agencies (HMA).

A recent surge in respiratory infections has driven an increase in demand for amoxicillin which combined with other issues including manufacturing delays and production capacity challenges led to shortages affecting the majority of Member States.



The MSSG and its working party, the SPOC working party, have been closely monitoring the situation since November 2022 and have been engaging with key players in the supply chain of amoxicillin to take forward possible mitigating measures.

Click [here](#)¹ to read more about the EMA's response.

NEWS ON ARTIFICIAL INTELLIGENCE: HOW NATURE READERS ARE USING CHAT GPT



Researchers are keen to experiment with using generative AI tools such as the advanced chatbot ChatGPT to help with their work, according to a survey of Nature readers. But they are also concerned about the potential for errors and false information.

Of 672 readers who responded to an online questionnaire, around 80% have used ChatGPT or a similar AI tool at least once. More than one-fifth use such tools regularly — 8% said they use them every day, and 14% several times per week. Around 38% of respondents know of other researchers who use the tools for research or teaching.

Survey participants shared their thoughts on the potential of generative AI, and concerns about its use, through open-ended answers. Keep reading [here](#).²

NEWS FROM THE FDA: CDER CONTINUES RARE DISEASE DRUG DEVELOPMENT EFFORTS

A rare disease is any disease that affects fewer than 200,000 people in the U.S. There are approximately 25 to 30 million Americans living with a rare disease (about 1 in 10 people), and many rare diseases have few or no available treatment options. FDA's goal for this year's Rare Disease Day (February 28) is to explore ways to engage and collaborate with patients, patient advocates, and other stakeholders to support the development of safe and effective therapies.

CDER is committed to accelerating the development of treatments for patients with rare diseases.



In May 2022, CDER launched the Accelerating Rare disease Cures (ARC) Program. The ARC Program seeks to harness CDER's collective expertise and activities to drive scientific and regulatory innovation for rare diseases. It also builds upon CDER's existing capabilities to expand its interactions with the rare disease stakeholder community.³ Keep reading [here](#).

REPORTED RATES OF ALL-CAUSE SERIOUS ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH BNT-162B



The development of the vaccines against Covid-19 was a significant achievement, and a collaborative effort among scientists, regulators and pharmaceutical companies. However, much controversy surrounded the safety of these vaccines, especially among non-specialized opinion leaders, and especially regarding the use of vaccines in the pediatric population.

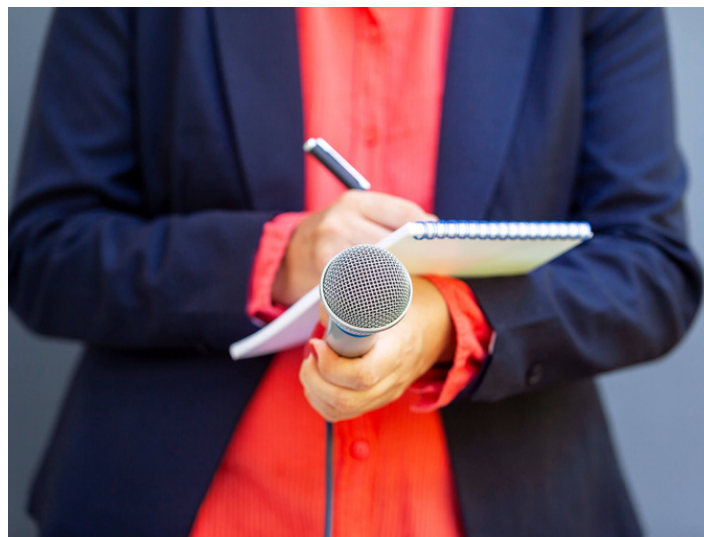
"Vaccine development against COVID-19 has mitigated severe disease. However, reports of rare but serious adverse events following immunization (sAEFI) in the young populations are fuelling parental anxiety and vaccine hesitancy. With a very early season of viral illnesses including COVID-19, respiratory syncytial virus (RSV), influenza, metapneumovirus and several others, children are facing a winter with significant respiratory illness burdens." ⁴

Continue reading [here](#).

NEWS FROM THE EMA: BIOEQUIVALENCE GUIDELINES ANNOUNCED FOR IMMEDIATE RELEASE SOLID ORAL DOSAGE FORMS

The European Medicines Agency has published for public consultation an ICH Guideline M13A on bioequivalence for immediate release solid oral dosage forms.

This guideline is intended to provide recommendations on conducting bioequivalence (BE) studies during both development and post-approval phases for orally administered immediate-release (IR) solid oral dosage forms designed to deliver drugs to the systemic circulation, such as tablets, capsules, and granules/powders for oral suspension.



Deviations from the recommendations in this guideline may be acceptable if appropriate scientific justification is provided. Applicants are encouraged to consult the regulatory authority(ies) when an alternate approach is proposed or taken. Comments should be provided using this template and sent to ich@ema.europa.eu by 26 May 2023.

US PLAN TO SHIELD SCIENCE FROM "INAPPROPRIATE INFLUENCE"



Science, like many other domains, is not immune to the influence of lobbyists in pursuit of results that further their agendas. Fortunately, as reported in the *Lancet*, the US government is taking steps to advance scientific integrity on a policy level.

“The Biden administration is launching a new initiative on scientific integrity in federal agencies following multiple lapses. Just a week after Joe Biden was sworn in as president in January, 2021, he created a multi-agency Task Force on Scientific Integrity to restore “trust in government through scientific integrity and evidence-based policy making”. The COVID-19 pandemic was entering its second year, and bizarre theories flourished on social media about how the virus spread and how to treat it. Last month, the White House Office of Science and Technology Policy (OSTP) released A Framework for Federal Scientific Integrity and Practice, a follow-up to the task force’s 2022 recommendations that provides a blueprint for implementation. “This first-of-its-kind framework will strengthen the ability of agencies and federal scientists to produce critical scientific information for evidence-based policy making that can help make our nation healthier, safer, more prosperous, and more secure.” Keep reading [here](#).

CHOOSING THE RIGHT PATH TOWARD POLIO ERADICATION

The Global Polio Eradication Initiative (GPEI), launched 34 years ago, aimed to eradicate poliomyelitis by 2000. The chosen strategy was to stop circulation of wild polioviruses, following the successful example of smallpox eradication. The task, however, turned out to be much more challenging than eradicating smallpox had been, since there are hundreds of asymptomatic poliovirus infections for each paralytic case that occurs, which substantially complicates critical surveillance. Aside from challenges inherent in vaccine delivery in some countries, another reason for the failure to eradicate polio were outbreaks caused by circulating vaccine-derived poliovirus (cVDPV) strains that emerged from viruses used in Oral Polio Vaccine (OPV). stopped.



Thus, to actually eradicate poliovirus, the use of OPV must also be stopped. The recent declaration of a public health emergency in New York State after a case of paralytic poliomyelitis caused by a cVDPV, along with cVDPV detection in wastewater both in New York and in London, is a sobering reminder that polio still represents a threat even in countries that have not seen it for decades.⁶ Continue reading [here](#).

DRUG SAFETY NEWS REGARDING PSEUDOEPHEDRINE



EMA's safety committee (PRAC) has started a review of medicines containing pseudoephedrine following concerns about the risk of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS), conditions affecting blood vessels in the brain.

Pseudoephedrine is taken by mouth and is used alone or in combination with other medicines to treat nasal congestion (a blocked nose) resulting from a cold, flu or allergy. PRES and RCVS can involve reduced blood supply (ischaemia) to the brain and may cause major and life-threatening complications in some cases. Common symptoms associated with PRES and RCVS include headache, nausea and seizures.

The review follows new data from a small number of cases of PRES and RCVS in people using pseudoephedrine-containing medicines which were reported in pharmacovigilance databases and the medical literature. Pseudoephedrine-containing medicines have a known risk of cardiovascular and cerebrovascular ischaemic events (side effects involving ischaemia in the heart and brain), including stroke and heart attack. Restrictions and warnings are already included in the medicines' product information to reduce these risks.⁷ Keep reading [here](#).

ACCESS TO TREATMENT FOR MULTIPLE SCLEROSIS

Access to treatments for neurological disorders is egregiously insufficient, particularly in low-income and middle-income countries (LMICs). The inclusion of therapeutic agents on the WHO Model List of Essential Medicines (referred to as the essential medicines list [EML]) is an initial step to potentially increase their availability worldwide, as the list serves as a guide for the development of national and institutional EMLs. The Intersectoral Global Action Plan On Epilepsy and Other Neurological Disorders promotes the inclusion and updating of essential and affordable medicines and health products for neurological disorders in national EMLs, as guided by the WHO list. However, neurological conditions remain poorly represented on the WHO EML, and multiple sclerosis is a case in point, as there are no treatments listed for the disease.



Neurology organisations are working hard to tackle this situation and, on Dec 11, 2022, the Multiple Sclerosis International Federation (MSIF) applied to WHO for the addition of disease-modifying treatments for multiple sclerosis to their EML.⁸

Click [here](#) to read more.

EIGHT SUCCESSES AGAINST TROPICAL DISEASES



Eight countries eliminated a neglected tropical disease last year, bringing the number of nations that have done so since the late 1990s to almost 50.

- The Democratic Republic of the Congo eliminated the parasitic guinea worm disease.
- Togo, Malawi, Saudi Arabia and Vanuatu got rid of the bacterial infection trachoma.
- Rwanda, Uganda and Equatorial Guinea eliminated a type of sleeping sickness.

More than one billion people, mostly living in impoverished communities, are affected by neglected tropical diseases. Despite this, the conditions are largely overlooked by global health agendas.⁹

The full report from the WHO is available [here](#).

REFERENCES

1. E. (2023a, February 6). EMA update on shortages of antibiotics in the EU – European Medicines Agency. European Medicines Agency. <https://www.ema.europa.eu/en/news/ema-update-shortages-antibiotics-eu>
2. Owens, B. (2023). How Nature readers are using ChatGPT. *Nature*, 615(7950), 20. <https://doi.org/10.1038/d41586-023-00500-8>
3. ResearchCDER Continues to Advance Rare Disease Drug Development with New Efforts, Including the Accelerating Rare Disease Cures (ARC) Program. U.S. Food And Drug Administration. <https://www.fda.gov/drugs/news-events-human-drugs/cder-continues-advance-rare-disease-drug-development-new-efforts-including-accelerating-rare-disease>
4. Mangat, H. S., Rippon, B., Reddy, N. T., Syed, A. A., Maruthanal, J. M., Luedtke, S., Puthumana, J. J., Srivatsa, A., Bosman, A., & Kostkova, P. (2022). Reported rates of all-cause serious adverse events following immunization with BNT-162b in 5–17-year-old children in the United States. *PLOS ONE*, 18(2), e0281993. <https://doi.org/10.1371/journal.pone.0281993>
5. Jaffe, S. (2023). US plan to shield science from “inappropriate influence.” *The Lancet*, 401(10375), 422–423. [https://doi.org/10.1016/s0140-6736\(23\)00289-1](https://doi.org/10.1016/s0140-6736(23)00289-1)
6. Chumakov, K., Brechot, C., Gallo, R. C., & Plotkin, S. (2023). Choosing the Right Path toward Polio Eradication. *The New England Journal of Medicine*, 388(7), 577–579. <https://doi.org/10.1056/nejmp2215257>
7. E. (2023, February 10). PRAC starts safety review of pseudoephedrine-containing medicines – European Medicines Agency. European Medicines Agency. <https://www.ema.europa.eu/en/news/prac-starts-safety-review-pseudoephedrine-containing-medicines>
8. Neurology, N. L. (2023). Towards equitable access to treatment for multiple sclerosis. *Lancet Neurology*, 22(3), 189. [https://doi.org/10.1016/s1474-4422\(23\)00041-8](https://doi.org/10.1016/s1474-4422(23)00041-8)
9. Control of Neglected Tropical Diseases. (2023, January 29). Global report on neglected tropical diseases 2023. https://www.who.int/publications/i/item/9789240067295?utm_source=Nature+Briefing&utm_campaign=91395db850-briefing-dy-20230213&utm_medium=email&utm_term=0_c9dfd39373-91395db850-47677880

Thanks for reading!

The GMDP Academy Newsletter is published bi-monthly and is compiled by the following:

Medical Editor: Domenico Criscuolo

Media Manager: Whitney English

Editorial Board: Pravin Chopra, Jacob Coots, Gustavo Kesselring, Honorio Silva, Peter Stonier

Operations Office: Amanda Schmitt, Gustavo Silva, Kiet Vo

CONTACT US:



420 Lexington Ave. Ste. 300
New York, NY 10170

(332) 333-2438