



Drug Information Bulletin

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Regulatory Affairs Division (RAD), IPA

Volume: 17

Number: 18 & 19

28th January 2024

Content

- *Appeal of Director General of Health Services (DGHS), MOH, Govt. of India to Pharmacists dispensing antibiotics only on prescription of a qualified doctor*
- *New Drug Approved: Abrocitinib Tablets 50mg, 100mg & 200mg*
- *WHO calls for safe and ethical AI for health*
- *WHO urges Global Pact to Tackle "Disease X" Threat*
- *Zinc acetate Risk of gastric ulcer*
- *Photographs of recent Event*

Editorial



Greetings from Drug Information Bulletin!

Antimicrobial resistance is a serious threat to the public health having its impact on health round the world. In order to combat this menace several international agencies including WHO and several countries have adopted policies and framed several legislations. India also adopted well thought strategies and recently Director General of Health Services (DGHS), Govt. of India has issued an appeal to the pharmacists vide No. Z. 18025/27/1/2023-AMR dtd. 1st January 2024 for following Schedule H & H1 in case of dispensing of antimicrobials for containment of antimicrobials. DGHS appealed to the Pharmacists "...to strictly implement schedule H and H1 of the Drugs & Cosmetics Rules and stop over the counter sale of antibiotics and sale them only on prescription of a qualified doctor".

It is a fact that a good percentage of medicines are being dispensed from the community pharmacy with or without prescriptions of a registered medical practitioner. Additionally in some cases dispensing of medicines are being conducted without supervision of pharmacist due to several reasons. Though this practice is prevailing since long back, it could not be resolved. Therefore regulators required to implement provision of dispensing of a prescription by a registered Medical Practitioner under supervision of a registered pharmacist as per Drugs and Cosmetics Rules. Moreover it is an opportunity for the Indian pharmacists to serve as one of the health care personnel in this crisis.

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Appeal of Director General of Health Services (DGHS), MOH, Govt. of India to Pharmacists dispensing antibiotics only on prescription of a qualified doctor



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स्वास्थ्य सेवा महानिदेशालय
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services

No. Z. 18025/27/1/2023-AMR
1st January 2024

Subject: Urgent appeal to pharmacists dispense antibiotics only on prescription of a qualified doctor

Dear ~~++~~ Colleagues & Friends,

Antimicrobial resistance (AMR) is one of the top global public health threats facing humanity. It is estimated that bacterial AMR was directly responsible for 1.27 million global deaths in 2019 and 4.95 million deaths were associated with drug resistant infections. AMR threatens the effective prevention and treatment of infections caused by resistant microbes, resulting in prolonged illness and greater risk of death. Treatment failures also lead to longer periods of infectivity and the prohibitive high cost of the second-line drugs may result in failure to treat these diseases in many individuals.

Misuse and overuse of antimicrobials is one of the main drivers in the development of drug-resistant pathogens. With few new antibiotics in the Research & Development pipeline, prudent antibiotic use is the only option to delay the development of resistance.

Under Drugs & Cosmetics Rules 1945, antibiotics are included in the list of drugs specified under Schedule H, which are required to be sold by retail on the prescription of a Registered Medical Practitioner (RMP) only. Some high end antibiotics are included in list of HI drugs.

This is an urgent appeal to all the pharmacists in the country to strictly implement schedule H and HI of the Drugs & Cosmetics Rules and stop over the counter sale of antibiotics and sell them only on prescription of a qualified doctor.

Looking forward to your support to promote judicious use of antimicrobials to reduce emergence of AMR.

With warm regards, & best wishes for a healthy new year.

Yours truly,

(Atul Goel)

To

All Pharmacist Associations in India

New Drug Approved: Abrocitinib Tablets 50mg, 100mg & 200mg
Abrocitinib Tablets 50mg, 100mg & 200mg has been approved by CDSCO Indicated for the treatment of adults with refractory, moderate-to-

severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable on 29.11.2023.

WHO calls for safe and ethical AI for health

The World Health Organization (WHO) is calling for caution to be exercised in using artificial intelligence (AI) generated large language model tools (LLMs) to protect and promote human well-being, human safety, and autonomy, and preserve public health.

LLMs include some of the most rapidly expanding platforms such as ChatGPT, Bard, Bert and many others that imitate understanding, processing, and producing human communication. Their meteoric public diffusion and growing experimental use for health-related purposes is generating significant excitement around the potential to support people's health needs.

It is imperative that the risks be examined carefully when using LLMs to improve access to health information, as a decision-support tool, or even to enhance diagnostic capacity in under-resourced settings to protect people's health and reduce inequity.

While WHO is enthusiastic about the appropriate use of technologies, including LLMs, to support health-care professionals, patients, researchers and scientists, there is concern that caution that would normally be exercised for any new technology is not being exercised consistently with LLMs. This includes widespread adherence to key values of transparency, inclusion, public engagement, expert supervision, and rigorous evaluation.

Precipitous adoption of untested systems could lead to errors by health-care workers, cause harm to patients, erode trust in AI and thereby undermine (or delay) the potential long-term benefits and uses of such technologies around the world.

Concerns that call for rigorous oversight needed for the technologies to be used in safe, effective, and ethical ways include:

- the data used to train AI may be biased, generating misleading or inaccurate information that could pose risks to health, equity and inclusiveness;
- LLMs generate responses that can appear authoritative and plausible to an end user; however, these responses may be completely incorrect or contain serious

errors, especially for health-related responses;

- LLMs may be trained on data for which consent may not have been previously provided for such use, and LLMs may not protect sensitive data (including health data) that a user provides to an application to generate a response;
- LLMs can be misused to generate and disseminate highly convincing disinformation in the form of text, audio or video content that is difficult for the public to differentiate from reliable health content; and
- while committed to harnessing new technologies, including AI and digital health to improve human health, WHO recommends that policy-makers ensure patient safety and protection while technology firms work to commercialize LLMs.

WHO proposes that these concerns be addressed, and clear evidence of benefit be measured before their widespread use in routine health care and medicine – whether by individuals, care providers or health system administrators and policy-makers.

WHO reiterates the importance of applying ethical principles and appropriate governance, as enumerated in [the WHO guidance on the ethics and governance of AI for health](#), when designing, developing, and deploying AI for health. The 6 core principles identified by WHO are: (1) protect autonomy; (2) promote human well-being, human safety, and the public interest; (3) ensure transparency, explainability, and intelligibility; (4) foster responsibility and accountability; (5) ensure inclusiveness and equity; (6) promote AI that is responsive and sustainable.

For details: <https://www.who.int/news/item/16-05-2023-who-calls-for-safe-and-ethical-ai-for-health>

WHO Urges Global Pact to Tackle "Disease X" Threat

World Health Organization (WHO) Director-General Dr. Tedros Ghebreyesus has issued a compelling call for nations to endorse the health organization's pandemic treaty to fortify global

readiness against the looming threat of "Disease X."

Addressing a gathering at the World Economic Forum (WEF) in Davos recently, Dr. Ghebreyesus expressed his optimism that countries would finalize a pandemic agreement by May this year.

The WHO has identified "Disease X" as a potential catalyst for the next pandemic, emphasizing that it may already be in transit. Scientists have warned that this hypothetical pathogen could be 20 times deadlier than COVID-19. Added to the WHO's roster of pathogens for research in 2017, "Disease X" poses the potential for a "serious

international epidemic," as highlighted in a 2022 WHO press statement.

Responding to inquiries about future pandemic preparedness, he underscored ongoing initiatives, including establishing a pandemic fund dedicated to readiness. He acknowledged the existing challenges of vaccine hoarding by high-income countries and emphasized the need for global equity.

(Source: <https://www.indiatoday.in/world/story/disease-x-who-chief-tedros-calls-for-world-pandemic-treaty-to-prepare-for-another-possible-virus-outbreak-2491574-2024-01-21>)

Zinc acetate Risk of gastric ulcer

The MHLW and the PMDA have announced that the product information for zinc acetate will be updated to include the risk of gastric ulcer. Zinc acetate is indicated for the treatment of Wilson's disease and hypozincaemia. The MHLW and the PMDA assessed a total of 13 reported cases involving zinc acetate and peptic ulcer, and in the seven cases a causal relationship between the

medicine and event was reasonably possible. Based on the sites of ulceration in the reports, gastric ulcer, rather than peptic ulcer, was considered as more appropriate term for precaution and added in the product information as clinically significant adverse reaction.

Reference: Safety Information, MHLW/PMDA, 30 May 2023 (link to the source within www.pmda.go.jp/english/)



Gangasagar Health Camp 2024: organized jointly by Indian Pharmaceutical Association, Bengal Branch & IPA Bengal Pharma & Healthcare Trust, Kolkata

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