News from here and there

Uniform code for pharmaceutical marketing practices (UCPMP) 2024

On 12 March 2024, the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, issued the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024 (*https://pharmaceuticals.gov.in/sites/default/files/UCPMP%202024%20for%20website.pdf*). The UCPMP 2024 is intended to curb unethical behaviour and includes drug promotion, endorsement, ethical conduct for medical representatives (MRs; sales representatives including personnel retained by way of contract with third parties), and maintaining relationships with a healthcare professional (HCP). The term 'promotion' as per the *'Ethical criteria for medicinal drug promotion'* endorsed by the World Health Assembly (1988) refers to all informational and persuasive activities by manufacturers and distributors, which are intended to induce the prescription, supply, purchase and/or use of medical drugs.

The UCPMP 2024 mandates that a drug can only be promoted after obtaining marketing approval from the competent authority; also, promotion of a drug must be consistent with the terms of its marketing approval. The Code states that MRs must not employ any inducement or subterfuge to gain an interview and should not pay, under any guise, for securing access to HCPs. It also holds companies responsible for the actions of their MRs.

Claims for the usefulness of a drug must be based on up-to-date evaluation of all available evidence. The word 'safe' must not be used without qualification; it must to be categorically stated that a drug has 'no side effects, toxic hazards, or risk of addiction'. The UCPMP 2024 states that any drug that has been available and any intervention that has been promoted in India for more than a year should not be described as 'new'.

The UCPMP 2024 stipulates that all text and promotional material issued by an authorized holder must comply with the requirements specified in this Code. Brand reminders are permitted for informational and educational items, as also free samples provided by the companies to HCP. Informational and educational items include books, calendars, diaries, print and electronic journals, among others, the value of which does not exceed ₹1000 per item. Free samples of drugs (marked 'Free medical sample, not for sale') are only to be supplied to the HCP qualified to prescribe the same and must be handed over directly by the MRs. The pharmaceutical companies are mandated to maintain details such as doctor's name, name of the product, date and quantity of samples distributed. The UCPMP 2024 also states that the monetary value of samples distributed should not exceed 2% of the domestic sales of the company annually.

The UCPMP 2024 allows the engagement of pharmaceutical industry with the conduct of continuing medical education (CME) or continuing professional development (CPD) programmes, seminars, workshops, through a well-defined, transparent and verifiable set of guidelines. Such events are permitted to be conducted by engaging the pharmaceutical industry with medical colleges/teaching institutions/universities/hospitals; professional associations of doctors/specialists; National Institute of Pharmaceutical Education and Research (NIPER), laboratories of Indian Council of Medical Research (ICMR), Department of Biotechnology (DBT), Council for Scientific and Industrial Research (CSIR), pharmaceutical colleges/other academic and research institutions, etc.

The UCPMP 2024 also provides guidelines regarding industry–academia linkage, interaction between pharmaceutical companies and HCPs in the conduct of research, and engagement of HCPs in consultant-advisory capacity.

The UCPMP states that no gift should be offered or provided for personal benefit of any HCP or their family members (both immediate and extended) by any pharmaceutical company or its agent. Unless the HCP is a speaker at conference, seminar, workshop, CME or CPD programmes, the code prohibits HCP from accepting paid travel, hotel stays, gifts from pharmaceutical companies or agents, among others. The code also prohibits pharmaceutical companies or their representatives from paying cash or monetary grant to any HCP or their family members (both immediate and extended).

Regarding deductions and reporting of income, both the giver and recipient of brand reminders should comply with the relevant provisions of the Income Tax Act, 1961. All pharmaceutical associations were asked to take further necessary steps towards implementation of UCPMP 2024 including constituting an ethics committee for pharmaceutical marketing practices (ECPMP) and setting up a dedicated UCPMP portal on their website along with the detailed procedure for lodging of complaints, which will be linked to the UCPMP portal of the Department of Pharmaceuticals.

ALLADI MOHAN, *Tirupati, Andhra Pradesh*
ORCID iD: 0000-0002-3214-9884

All age groups to be offered health insurance: Decision by the IRDAI

Effective 1 April 2024, the Insurance Regulatory and Development Authority of India (IRDAI) has abolished the age cap for purchasing health insurance policies, as per an official Gazette notification of 20 March 2024.

The new regulations state that health insurance companies must offer health insurance products to all individuals, irrespective of their age. With this, a major constraint that was previously placed on senior citizens—the age eligibility for purchasing health insurance was 65 years—has been removed.

These regulations were implemented based on the recommendations of the Health Insurance Consultative Committee, set up by IRDAI. The Committee was headed by IRDAI member, Mr Rakesh Joshi. The other members were Dr Alexander Thomas, the national president of the Association of Healthcare Providers India (AHPI) and Dr Devi Shetty, Chairman of Narayana Health.

The Committee focused on the hardships faced by senior citizens in purchasing health insurance policies. One of their recommendations was that there should be no age cap for the

purchase of affordable insurance policies. Another recommendation was the removal of goods and services tax (GST) for senior citizens, and that all senior citizens should be covered by the Pradhan Mantri Jan Arogya Yojana (PM-JAY).

The IRDAI Gazette notification has also stated that health insurance companies should endeavour to offer coverage for all types of existing medical conditions. As a result, serious medical conditions such as cancer will be covered henceforth.

In addition, the health insurance waiting period has been reduced from a period of 48 months to 36 months. This ensures that health insurance companies will be obliged to cover all pre-existing conditions after a period of 3 years, irrespective of the fact whether the policyholder disclosed such a condition initially.

The IRDAI has also mandated the provision of benefit-based policies and prohibited health insurance companies from introducing indemnity-based health policies. This change will streamline the claims process and ensure clarity to the policy holders by offering fixed costs upon the occurrence of a covered disease.

The IRDAI is a statutory body formed for the overall supervision and development of the Indian insurance sector. It was formed under an Act of Parliament, namely, the Insurance Regulatory and Development Authority Act of 1999 (IRDAI Act 1999). The IRDAI head office is located in Hyderabad, with regional offices in Mumbai and New Delhi.

One of the key objectives of IRDAI is the promotion of competition among health insurance companies so that customer satisfaction is enhanced via increased choice and proper premiums, while, at the same time ensuring financial security of the insurance companies.

P.M. NISCHAL, *Mysuru, Karnataka*
ORCID iD: 0000-0003-3491-5500

Memorandum signed in Barcelona on openness and inclusivity in science research data-sharing

16th April 2024 saw the Barcelona Declaration on Open Research Information come into effect, via an official launch webinar. The agreement, which seeks to expand access to metadata related to the conduct and communication of science-related research, was initially conceptualized by more than 25 experts from various organizations, in a workshop in Barcelona hosted by the SIRIS Foundation. SIRIS Foundation is a 100% not-for-profit entity which supports open access to science and government-run decision making and public investments, in endeavours related to research, education and innovation. The experts have been involved in funding, implementation and evaluation of research infrastructure. Current signatories of the Barcelona Declaration include universities performing research, across Europe, South America, Turkey and Ukraine, government-funded and private-funded research organizations including Austrian Science Fund, French National Research agency, Bill and Melinda Gates Foundation, Sage Bionetworks (US) and supporting institutions such as Directory of Open Access Books and Journals, PLOS (Public Library of Science), Confederation of Open Access Repositories and Research Data Alliance, amongst others.

The need for laying down such agreements for impartial access to metadata was highlighted as a large volume of data is under restricted access with lock-in agreements in proprietary infrastructures. Subsequently, there is scope for influencing the extent of raw data used by the said infrastructures to draw conclusions from the raw data, and in the translation of the raw data into metrics, which then effects how science and practices based on the science are decided. Most of the eminent, influential mainstream sources of metadata are situated in North America and Western Europe with less visibility and more biases against information and research originating in the Global South. A large proportion of open science monitoring and incentivization is thus actually based on closed data with inherent geographical, regional and language-related biases and lack of transparency. This has direct repercussions on career trajectories of researchers and research organizations situated in different parts of the world as well.

The Barcelona Declaration uses as its foundation, four pillars of commitment—openness as the default setting for research information being produced and used, joint enterprises with services and systems that support and enable open research, support for longevity of infrastructures that cater to open research information, and creation of coalitions to ease transition to open research information in all organizations. Platforms such as Crossref and Directory of Open Access Journals (DOAJ), which are efforts to move away from the dominant closed-data models of research infrastructure, are some of the transparency movements that the Barcelona Declaration on Open Research Information hopes to consolidate into a cohesive community.

Although no protocols were laid down in the inaugural session, a proposal to establish standards and specific recommendations to expand the linguistic, topical and diversity of perspectives and to secure inclusivity in unbiased analyses of transparent research, that will be reproducible using the latest technological tools available, was recognized as the next step to implement this change.

MAHARRA HUSSAIN, *United Arab Emirates*
ORCID iD: 0000-0001-7632-0631