Luthra and Luthra
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INSIDE

It gives us immense pleasure to circulate the October 2024 edition of the Luthra and Luthra Law Offices India's Pharmaceutical Bulletin. In this edition, we have primarily focused on the recent and major legal developments in the Pharmaceutical Sector for the month of September 2024. We hope you enjoy reading the Bulletin.

WHO releases guidance to improve the design, conduct and oversight of clinical trials

The World Health Organization (WHO) released guidance[1] to improve the design, conduct, and oversight of clinical trials in countries with all income levels. This guidance aims to support stronger country-led research and development (R&D) ecosystems to advance health science so that new, safe and effective health interventions can be made more accessible and affordable globally for people everywhere, faster.

For the first time, WHO offers recommendations for national health authorities, regulatory authorities, funders and others on how they can best facilitate clinical trials to generate evidence on health interventions. It addresses challenges such as poor trial design, limited diversity of participants, insufficient infrastructure, and bureaucratic efficiencies, that cost time, money and lives.

The guidance includes practical considerations for setting up trials to include pregnant and lactating women, given they have unique healthcare needs. In general, at-risk populations should be involved from the earliest stages. To facilitate this, safety should be assessed as an initial priority, for instance, by reviewing comparable interventions or expediting pre-clinical studies for these groups. Appropriate procedures for consent and assent are key, particularly for children. The guidance recommends putting patient, participant and community engagement at the heart of organising clinical trials, to ensure that research planning, delivery and dissemination meets public needs and maintains trust.

The guidance was developed in response to World Health Assembly resolution WHA 75.8 in an extensive and inclusive process, involving nearly 3000 stakeholders from various sectors across 48 countries. The guidance covers trials for any health intervention, including, but not limited to pharmaceutical medicines; vaccines; diagnostics; nutritional measures; cognitive, behavioural and psychological interventions; preventive care; digital and public health approaches; and traditional or herbal measures.

[1] 9 Sept 24049 GCTF Guidance for best practices for clinical trials (who.int).

Punjab & Haryana High Court directs CBI to enquire into large-scale manufacture of Alprasafe tablets by Pharma firms in Himachal Pradesh

The Punjab & Haryana High Court in a recent order has directed the CBI to carry out a preliminary inquiry into a possible inter-state drug racket pumping huge quantities of drug in the state of Punjab.

The order comes in light of a Civil Writ Petition[2] demanding a thorough independent investigation of the inter-state drug production and supply by mega pharmaceutical companies who are the alleged kingpins of the drug trade in Punjab, after the petitioner, as a member of the Special Task Force, seized huge quantities of *Alprasafe* tablets and traced them to a pharmaceutical firm in Himachal Pradesh. The Court noted the gravity of the situation and opined that there is a possibility of people with clout and presence at different levels of administration being involved in the inter-state racket.

Bombay High Court restrains Indian Pharma Company from using 'deceptively similar' trademark stating stricter approach is required for adjudicating on possibility of confusion in medical products[3]

The Bombay High Court has restrained an Indian pharmaceutical company from using a trademark that is 'deceptively similar' to that of an international pharmaceutical company. The plaintiffs alleged infringement of their renowned trademark 'SEFIER' by the defendants through their trademark "SERVIER'.

The decision came in an interim application filed by the applicants with a plea to restrain the defendants from using the trademark 'SERVIER' in any manner whatsoever. Granting the ad-interim relief, the High Court found that from a bare perusal of the two trademarks, it is clear that both are phonetically, aurally, visually and structurally similar, leading to higher chances of confusion and deception among the public. Advocating for a stricter approach to be adopted while adjudicating the possibility of confusion of one medicinal product for another, the Court clarified that similarity and confusion between the products should be examined from the point of view of an ordinary common man of average intelligence instead of that of a specialized medicinal practitioner.

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[2] *Vavinder Mahajan v. State of Punjab and Others,* Civil Writ Petition No. 26062 of 2024.
[3] *Les Laboratories Servier v. Sefier Life Science Private Ltd.,* Com IPR Suit (L) No. 18086 of 2024.

Delhi High Court refuses to restrain Zydus 'Sigrima' clarifying the importance 'claim-mapping' in biosimilar patent infringement suits[4]

The Hon'ble Delhi High Court has refused to grant ad-interim injunction to the F-Hoffmann-La Roche (Plaintiff) against Indian pharmaceutical giant Zydus from marketing and selling of its drug 'Sigrima' which is a biological similar of the plaintiff's 'Perjeta'.

The Hon'ble High Court, while dismissing the injunction application, highlighted that since the plaintiffs have failed to 'claim-map' qua their two patents with the impugned drug 'Sigrima', the court will not be able to restrain the impugned biosimilar merely because the composition of the two products is similar as biosimilars are designed to be highly similar to the reference product though not identical. Acknowledging the dual aspect of intellectual property concerning biological medicine which encompasses not only the molecular structure of the biologic but also the sophisticated processes required for its reliable, safe, and consistent large-scale manufacturing, the Court said the plaintiff ought to have claim-mapped because only when the biosimilar or similar biologic utilizes or embodies any aspect that is patented by the reference biologic, can there be a case for patent infringement. Accordingly, they have been asked to undertake such claim-mapping expeditiously and present before the Court.

US Biosecure Act may act as a fillip for the Indian Pharma Industry[5]

The US Senate House passed the US Biosecure Act, which stops the US pharma companies from dealing with the Chinese Counterparts. This gives an opportunity to the Indian Contract Development and Manufacturing Organisations (CDMOs) to replace the Chinese companies. India can be a suitable destination due to the availability of a skilled workforce, low costs, and government incentives. This Act will reap manifold benefits for Indian Companies like increased market share, improved capabilities, and global reach. By tapping on to this opportunity the Indian Companies can turn into major global players in the pharma sector. However, they may face stiff competition from other Asian players like Singapore, Korea, and local US CDMOs.

[4] *F-Hoffmann-La Roche AG & Anr. v. Zydus Lifesciences Limited,* CS(COMM) 159/2024.
[5] The US Biosecure Act: An impetus to strengthen India's pharma sector (orfonline.org).

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