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HEALTHCARE NEWSLETTER

RECENT LEGAL DEVELOPMENTS IN INDIA

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INTRODUCTION

This newsletter highlights the key developments and measures as well as other major developments in the Indian healthcare and pharma sector for the months of April-May 2023.

RECENT LEGAL & REGULATORY DEVELOPMENTS

Draft rules published to amend the New Drugs and Clinical Trials Rules, 2019

On May 11, 2023, the Government of India ("**GOI**") published draft amendment rules to amend the New Drugs and Clinical Trials Rules, 2019 ("**Draft NDCT Rules**").[1] The Draft NDCT Rules intend to introduce provisions to govern registration and functioning of clinical research organisations ("**CRO**"). The proposed definition of CROs states that they are either commercial or academic bodies that can be delegated or transferred tasks, duties, or obligations by sponsors[2] to conduct clinical trials. Currently, the Draft NDCT Rules are subject to ongoing public consultation.

Some of the noteworthy amendments proposed by the GOI, under the Draft NDCT Rules are as follows:

a. CROs shall be required to obtain registration from the Central Licensing Authority ("**CLA**") to conduct any clinical trial or bioavailability or bioequivalence study of new drugs or investigational new drugs in human subjects;

b. the registration granted to CROs will be valid for a period of 5 years from the date of its issuance; and

c. CLA will have the power to take certain punitive actions against CROs such as: (i) to suspend or cancel the license granted to CROs; (ii) to issue written warning to CROs describing the deficiency or defect observed by CLA; (iii) to reject the results of the clinical trial or the bioavailability or bioequivalence study; or (iv) to debar the CRO from conducting any clinical trial study or bioavailability or bioequivalence study in future.

Draft rules published to amend the Cosmetics Rules, 2020

On May 15, 2023, the GOI published draft amendment to the Cosmetics Rules, 2020 ("**Draft Amendment Rules**").[3] The Draft Amendment Rules propose to grant extensive powers upon the State Licensing Authority ("**SLA**") to cancel or suspend the license issued under the Cosmetics Rules, 2020. The SLA can take such action if the licensee fails to adhere to any of the conditions of the licence or fails to comply with any of the provisions of the Drugs and Cosmetics Act, 1940 or the Cosmetics Rules, 2020. Before the SLA passes an order of suspension or cancellation of the license, the licensee will be provided with an opportunity to present their case and show cause. Additionally, if the SLA does pass an order of suspension or cancellation, the licensee will have the opportunity to make an appeal to the appropriate state government against that order.

The Ministry of Chemical and Fertilizers published the National Medical Devices Policy, 2023

On May 2, 2023, the Ministry of Chemical and Fertilizers, Department of Pharmaceuticals ("**DoP**") released the National Medical Devices Policy, 2023 ("**Policy**").[4] This Policy recognises the following areas of intervention for promoting the medical devices sector: (a) regulatory streamlining such as setting up a single window clearance system for licensing of medical devices; (b) enabling infrastructure such as establishment of large medical device parks and testing facilities; (c) facilitating research and development and innovation through collaboration between medical device industry and educational institutions, for the development of indigenous medical technology; (d) attracting investment in the domestic medical sector by encouraging public and private partnerships; (e) training and development of personnel skilled in MedTech; and (f) brand positioning and awareness creation by increasing global competitiveness of domestic companies.

Indian government successfully conducted a trial run of blood bag delivery using a drone

The Indian Council of Medical Research ("**ICMR**") has successfully conducted a trial run of blood bag delivery using a drone.[5] This trial was carried out as part of the ICMR's Drone Response and Outreach for Northeast ("**i-DRONE**") program.[6] The trial drone flight carried 10 units of whole blood samples, and the required temperature was maintained until reaching the destination. This trial conducted by the ICMR aims to reduce the time required for last-mile delivery of essential medicines and blood bags.

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1. https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTAxNDI=
2. As per section 2(hh) of the Draft NDCT Rules, a 'sponsor' includes a person, a company or an institution or an organisation responsible for initiation and management of a clinical trial.
3. https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTAxNTU=
4. https://pharmaceuticals.gov.in/sites/default/files/Gazette%20Notification%20%20National%20Medical%20Devices%20Policy%202023.pdf
5. https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1923159#:~:text=The%20drone%2Dbased%20delivery%20of,distributing%20vaccines%20to%20unreachable%20areas
6. https://www.icmr.gov.in/idrone.html

The ICMR had previously used drones for distributing Covid-19 vaccines in remote areas of India.[7] The ICMR will further conduct studies and trials to assess the quality of red blood cells, fresh frozen plasma, and platelets delivered using drones vis-à-vis standard methods of transportation.

Draft cabinet note on the new scheme of Promotion of Research and Innovation in the Pharmaceuticals MedTech Sector

The DoP has submitted a proposal to the Economic Finance Committee ("**EFC**") for a new scheme, namely, the Promotion of Research and Innovation in Pharma MedTech Sector ("**PRIP**"). The PRIP scheme had an outlay of INR 7,150 crores and was in line with the announcements made in the union budget for the financial year 2023-24.[8] However, in its meeting held on March 15, 2023, the EFC approved the PRIP scheme with an overall outlay of INR 5,000 crores for a period of 5 years (i.e., from 2023-24 to 2027-28).[9] Following this, a draft cabinet note on the PRIP scheme has been prepared and sent to the empowered technology group for approval.

The PRIP scheme consists of two components. The first component focuses on strengthening the research infrastructure by establishing 7 centres of excellence at different National Institutes of Pharmaceuticals Education and Research. The second component aims to promote research in the pharmaceutical sector by encouraging research in 6 areas, including new chemical entities, complex generics (including biosimilars), medical devices, stem cell therapy, orphan drugs, and antimicrobial resistance. Financial assistance will be provided to companies working with government institutes and for in-house research and development.

Amendment to the operational guidelines of the Scheme for Promotion of Medical Device Parks

The GOI has amended the operational guidelines of the Scheme for Promotion of Medical Device Parks ("**Medical Device Scheme**") through a corrigendum dated May 19, 2023 ("**Amended Scheme**").[10] These amendments have been introduced in response to an office memorandum dated March 9, 2022, issued by the GOI. The memorandum advised that funds disbursed by the central government under central schemes should be released in a 'just-in-time' manner.[11]

The Medical Device Scheme was initially introduced in 2020[12] with the objective of providing aid to states for establishing a total of 4 medical device parks in India. These parks would serve as centralized locations for common testing and laboratory facilities. A comparison of the fund disbursement schedule between the Medical Device Scheme and the Amended Scheme is set out below:

Instalment and % of the funds to be disbursed	Conditions under the Medical Device Scheme	Conditions under the Amended Scheme
1st instalment 30% of the funds	• final approval of the project by the Scheme Steering Committee ("**SSC**"). • deposit of 30% of the project cost by the State Implementing Agency ("**SIA**") in the trust and retention account, escrow or no lien account. • receipt of all relevant environment clearances.	No change.

7. https://www.who.int/india/news/feature-stories/detail/india-deploys-drones-to-deliver-covid-19-vaccines
8. Report on Demands for Grants, Department of Pharmaceuticals, 42nd Report, Standing Committee on Chemicals and Fertilizers (2023-24) (https://loksabhadocs.nic.in/lsscommittee/Chemicals%20&%20Fertilizers/17_Chemicals_And_Fertilizers_42.pdf)
9. https://www.livemint.com/news/india/rs-5-000-crore-r-d-scheme-for-pharma-medtech-soon-11682101603193.html
10. https://pharmaceuticals.gov.in/sites/default/files/Final%20DoP%20Corrigendum%20Dated%2019.05.2015%20reg%20Amendment%20in%20the%20Operational%20Guidelines%20for%20the%20Scheme%20Promotion%20of%20Medical%20Device%20Parks_0.pdf
11. https://cga.nic.in//writereaddata/file/GuidelinesCentralSectorSchemesDt09032022.pdf
12. https://pharmaceuticals.gov.in/sites/default/files/Guidelines%20of%20the%20Scheme%20Promotion%20of%20Medical%20Devices%20Parks_1.pdf

Instalment and % of the funds to be disbursed	Conditions under the Medical Device Scheme	Conditions under the Amended Scheme
2nd instalment 30% of the funds	• 60% utilisation of the 1st instalment. • proportionate expenditure has been incurred by the SIA. • proportionate physical progress of the medical device park as reflected in the Detailed Project Report ("**DPR**"). • against production of bills.	• 75% utilisation of the 1st instalment. • proportionate expenditure has been incurred by the SIA. • proportionate physical progress of the medical device park as reflected in the DPR. • against production of bills.
3rd instalment 30% of the funds	• 100% utilisation of 1st instalment. • at least 60% utilization of 2nd instalment. • proportionate expenditure has been incurred by the SIA. • proportionate physical progress of the medical device park as per the DPR. • against production of bills.	• 100% utilisation of 1st instalment. • at least 75% utilization of 2nd instalment. • proportionate expenditure has been incurred by the SIA. • proportionate physical progress of the medical device park as per the DPR. • against production of bills.
4th instalment 10% of the funds	• 100% utilisation of 2nd and 3rd instalments. • SIA has mobilized and spent its entire share in proportion to the grant and completed the project in all respects.	• 100% utilisation of 2nd and 3rd instalments. • SIA has mobilized and spent its 100% share proportion to the first 3 grants.

Prices of 651 essential medicines reduced as the government caps prices

The National Pharmaceutical Pricing Authority ("**NPPA**") has reduced the cost of 651 essential medicines by implementing a cap on the drug prices. As a result, the prices of 651 essential medicines listed under the National List of Essential Medicines ("**NLEM**") have been reduced by an average of 6.7%.

The pricing of the drugs listed in the NLEM is subject to annual adjustments based on the Wholesale Price Index ("**WPI**"). For instance, let's consider the case of a 500mg tablet of paracetamol. Its ceiling price under NLEM in 2015 was INR 1.01, but the revised ceiling price after refixation under NLEM 2022 was INR 0.9. The ceiling price after WPI as on April 1, 2023, is INR 0.89. This represents an 11.88% net reduction from NLEM 2015 price, despite the increase in the WPI. Similarly, the price for a 2mg tablet of glimepiride, used for treating type 2 diabetes mellitus, has reduced by 8.68% from the NLEM 2015. Additionally, the price for metformin, another medication for type 2 diabetes mellitus, has decreased by 5.63%.[13]

DoP to fix retail prices for new drugs with components going off patent

On May 11, 2023, the DoP notified amendments to the Drugs (Prices Control) Order, 2013 ("**Price Control Order**") to fix the retail prices of new drugs with ingredients that have become off-patent or are about to become off-patent. According to the notification, the retail prices of such new drugs will be arrived at by reducing 50% of the price calculated as per the provisions of the Price Control Order. It further adds that, after 1 year of such reduction in the retail prices of such drugs, the ceiling price shall be revised again as per the provisions of the Price Control Order, based on the market data of the preceding month.[14]

13. https://www.thepharmaletter.com/article/india-sees-6-73-reduction-in-the-cost-of-651-essential-medicines

14. http://www.pharmabiz.com/NewsDetails.aspx?aid=158106&sid=1

Indian Drug Manufacturers' Association has urged DoP to revisit paragraph 18(1) and paragraph 13(2) of the Price Control Order

The Indian Drug Manufacturers' Association ("**IDMA**") has urged DoP to consider two alternatives regarding pricing of scheduled formulations. The IDMA has suggested to either not re-average prices every 5 years or allow companies with a maximum retail price ("**MRP**") lower than the notified ceiling price to raise their MRP to the ceiling price, in order to ensure a level playing field.

As per paragraph 18(1) of the Price Control Order, the prices of scheduled formulations are re-averaged every 5 years. This leads to severe erosion in the ceiling prices every 5 years despite the yearly revisions. Further, paragraph 13(2) of the Price Control Order specifies that if the MRP of a scheduled formulation is less than the price notified by the DoP then the lower MRP should be maintained and that its MRP cannot be raised to the notified ceiling price. The IDMA has requested the NPPA to delete paragraph 13(2) as it is unfair and deprives existing manufacturers from selling at the notified ceiling price.[15]

Cough syrup exporters to undertake product testing before exporting of products

The Directorate General of Foreign Trade, GOI issued a notification dated May 22, 2023, to apply additional conditions on the cough syrup exporters. The notification states that the export of cough syrup will now require mandatory testing of product samples in government laboratories.[16] Effective from June 1, 2023, exporters of cough syrup must have their products tested at specified government labs and obtain a certificate of analysis from any of the specified government laboratories before obtaining permission for outbound shipments.

This decision was made in response to allegations raised by several countries, including Marshall Islands, Micronesia, Gambia, and Uzbekistan, regarding cough syrups manufactured in India.[17] The mandatory testing and certification aim to ensure the quality and safety of cough syrup exports and address concerns raised by these countries.

The Cabinet Committee on Economic Affairs approves the establishment of 157 new nursing colleges

The Cabinet Committee on Economic Affairs has approved the establishment of 157 nursing colleges in co-location with existing medical colleges. This initiative aims to create a cadre of skilled professionals and is expected to contribute approximately 15,700 nursing graduates annually.[18] The objective is to ensure quality, affordable, and equitable nursing education in India, particularly in underserved districts and states/union territories. The government has set a target to complete the project within the next 2 years and has laid out detailed timelines for planning and execution stages of the project.[19]

Ministry of Ayush and Ministry of Minority Affairs collaborate for the development of Unani medicine system

On May 25, 2023, the Ministry of Ayush and the Ministry of Minority Affairs announced their collaboration for development and promotion of Unani system of medicine.[20] Under the Pradhan Mantri Jan Vikas Karyakram Scheme, the Ministry of Minority Affairs has approved a grant of INR 45.34 crores. This funding will be utilized to upgrade the Unani research and development facilities in Hyderabad, Chennai, Lucknow, Silchar, and Bengaluru.

15. http://www.pharmabiz.com/ArticleDetails.aspx?aid=158248&sid=1

16. The specified central government laboratories include Indian Pharmacopoeia Commission, regional drug testing lab (RDTL – Chandigarh), central drugs lab (CDL – Kolkata), central drug testing lab (CDTL – Chennai Hyderabad, Mumbai), RDTL (Guwahati) and the NABL (National Accreditation Board for Testing and Calibration Laboratories) accredited drug testing labs of state governments.

17. https://www.firstpost.com/india/india-imposes-conditions-for-export-of-cough-syrup-exporters-need-to-undertake-product-testing-at-govt-labs-from-june-1-12634342.html

18. https://www.thehindu.com/news/national/cabinet-approves-establishment-of-157-new-nursing-colleges/article66782122.ece

19. https://www.expresshealthcare.in/news/cabinet-approves-establishment-of-157-new-nursing-colleges/439050/

20. https://pib.gov.in/PressReleasePage.aspx?PRID=1927151

MAJOR DEALS IN INDIA IN THE PHARMA AND HEALTHCARE INDUSTRY

The following are the key deals announced during the months of April-May 2023, in the pharma and healthcare industry:

UCare Health, a Mumbai based digital health and financial wellness platform has been acquired by Thriwe, a technology focused business to business marketplace, in an all-cash deal. UCare Health's platform provides real time monitoring health parameters by offering emergency assist services, including first responder and ambulance facilities as well as hospitalization. As part of the acquisition, Ucare Health's 100 plus employees along with its founders will join Thriwe as part of its worldwide expansion plan. Thriwe has evolved to offer a host of lifestyle and wellness benefits via its flagship subscription-based digital program called We-Live.[21]

Serum Institute of Life Sciences, a unit of Adar Poonawalla led Serum Institute of India, has agreed to invest an additional amount of USD 150 million in Biocon Biologics Limited after converting a loan provided to Biocon Pharma Limited into equity. As a part of the aforesaid arrangement, Biocon Biologics Limited will receive access to 100 million doses of vaccines annually which will significantly add to its product portfolio for global markets and will also gain distribution rights to Serum's vaccine portfolio.[22]

Fortis Healthcare Limited ("Fortis"), a chain of hospitals controlled by Malaysian hospital chain IHH Healthcare, has executed definitive agreements with VPS Group to acquire Medeor Hospital in Manesar, Haryana for a consideration of USD 27.4 million. The deal is likely to be closed by end of July 2023. Medeor Hospital has a potential bed capacity of 350 beds which is to be operationalized in a phased manner. This acquisition comes just days after Fortis unit SRL Diagnostics bought Lifeline Laboratory to expand its reach in the Indian pathology market. Post this acquisition, Fortis will become the second largest healthcare service provider in Gurugram. This acquisition will also enable it to expand its services in the upcoming areas of Dwarka Expressway, New Gurugram etc.[23]

Emil Pharmaceutical Limited, a Mumbai based pharmaceuticals contract manufacturer, has raised INR 150 crores from Somerset Indus Capital Partners, a health care focused private equity firm, through a mix of primary and secondary sale of shares. The aforesaid funds will primarily be used by the company for rapid expansion and modernization of its pharmaceutical formulation capacities and for increasing its footprints globally.[24]

EarKart, a hearing aid technology start-up firm has raised an undisclosed amount in a pre-series A funding round led by Agility Ventures with participation from Blume Ventures and certain other investors. EarKart focuses on providing smart diagnosis and remote management of hearing aids and it aims to use the funds raised to build its technology infrastructure and expand its team to support its growing customer base. With this funding, EarKart has raised a total of INR 7.6 crores so far.[25]

Dozee, a startup providing contactless remote patient monitoring and AI-based early warning system has raised USD 6 million in its series A2 funding round. The round saw infusion of funds from existing investors such as Prime Venture Partners, 3one4 Capital, YourNest VC as well as new investors, including State Bank of India, J&A Partners Family office and Dinesh Mody Ventures. Dozee plans to further tap over 2,000 hospitals in more than 100 districts in the next 2 years to improve the quality of critical care facilities in India. The current series A2 fundraising is a part of the company's aim to expand in the Indian market, and to begin the era of 'Made in India' products in the global market.[26]

Health Care at Home India Private Limited, ("Health Care at Home") an out-of-hospital healthcare provider has acquired Nightingales Home Health Services, an entity engaged in providing specialty home healthcare services in a share swap deal. This is the fourth deal closed by Health Care at Home. Previously, it acquired a 100% stake in Seniority, which is reportedly India's largest geriatric-centric digital platform. Through the aforesaid acquisition, Health Care at Home aims to increase its geographic footprint and have a strong presence throughout India and lead the 'out-of-hospital' vertical in the Indian healthcare delivery sector.[27]

21. https://www.vccircle.com/yournestbacked-thriwe-buys-healthcare-platform-ucare-health
22. https://www.vccircle.com/serumto-double-investment-in-pe-backed-biocon-biologics-to-300-mn
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25. https://www.financialexpress.com/healthcare/healthtech/earkart-raises-undisclosed-pre-series-a-funding-led-by-agility-ventures-blume-ventures/3084636/
26. https://www.thehindubusinessline.com/info-tech/dozee-raises-6-million-in-series-a2-funding-round/article66698760.ece
27. https://www.vccircle.com/quadriabacked-hcah-marks-third-acquisition

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