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synapse

A quarterly update on the pharma, life sciences and healthcare industry

Volume V | Issue IV | July 2022 - September 2022

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Dear Readers,

We hope that all of you and your families are safe and healthy.

With the return to normalcy becoming a reality after two-and-a-half years of Covid-19 pandemic, a gradual bounce-back in the economy is clearly visible as businesses pick up steam. The onset of the festive season in India heralds a new hope, and expectations are running high that lower incidents of Covid-19 infections would permit restriction-free celebrations. The continuous advancement in the development and administration of vaccines has made us reasonably resistant to current strains of Omicron variant of Covid-19, as per clinical and epidemiological analyses. We hope that our nation continues to tread on this road while we cross over to the pandemic-safe zone, and may it extend the gains seen in the pharmaceutical, healthcare, life sciences and medical devices sector in recent times.

Like the previous few quarters, the sector witnessed important regulatory updates even in the last quarter, which we have covered in this edition of Synapse. Of particular note is the notification of new New Drugs, Medical Devices, and Cosmetics Bill, 2022, which seeks to amend and consolidate the laws relating to import, manufacture, distribution and sale of drugs, medical devices and cosmetics into a single legislation. This quarter also saw the notification of new National List of Essential Medicines - 2022, which will promote the rational use of medicines based on cost, safety and efficacy. In another news, the grace period to enter the licensing regime has been extended by another six months for all non-notified Medical Devices of Class A and B categories. Also, the provisions of the Cigarettes and other Tobacco Products (Packaging and Labelling) Amendment Rules, 2008 have been amended to include a printed 'Textual Health Warning' along with images on cigarettes and other tobacco products w.e.f. December 1, 2022.

In the litigation space, the Hon'ble Supreme Court, in a landmark judgment held that all women, including unmarried women, are entitled to seek abortion of unwanted pregnancy in the term of 20-24 weeks, occurring out of a consensual relationship. The Court noted that denying unmarried women the access to abortion while allowing married women the same for an identical pregnancy term would fall foul of the spirit guiding Article 14, The Court reminded that the rights of reproductive autonomy, dignity, and privacy under Article 21 grant unmarried women the same right of choice as married women in deciding whether or not to bear a child. In another matter, the Supreme Court issued notice on a petition challenging various provisions of the Assisted Reproductive Technology (Regulation) Act, 2021, the ART (Regulation) Rules, 2022, the Surrogacy (Regulation) Act, 2021 and the Surrogacy (regulation) Rules, 2022. The petition has been filed *inter alia* seeking recognition of rights of women other than married women above

thirty - five years of age to avail surrogacy and striking down the definition of couple under Section 2(1)(h) of the Surrogacy Act, 2021 and of commissioning couple in Section 2(1)(e) of the ART Act, 2021.

We also witnessed some significant transactions and investments in the sector and have endeavoured to cover the same in this edition of *Synapse*.

Cyril Amarchand Mangaldas, India's premier full-service law firm, has an industry leading and dedicated Pharmaceuticals, Healthcare and Life Sciences practice. Our class-leading practice specialists are always on top tracking the latest developments in the sector. In our endeavour to keep you abreast of the latest developments in this dynamic sector, we present to you the latest issue of Synapse. We hope you find this issue of interest. As always, your feedback makes us improve our efforts. Please feel free to send your comments, feedback and suggestions to cam.publications@cyrilshroff.com.

We also encourage you to visit our blog at https://corporate.cyrilamarchandblogs.com for more articles on the Indian pharmaceutical and healthcare sector.

We hope that you enjoy reading our newsletter as much as we have enjoyed preparing it. Your comments and feedback are most welcome. In the meanwhile, please stay safe and stay healthy.

Regards,
CYRIL SHROFF

Managing Partner
Cyril Amarchand Mangaldas

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Regulatory Updates

1. Notification of New Drugs, Medical Devices, and Cosmetics Bill, 2022[1]

The Ministry of Health and Family Welfare (**MoHFW**) *vide* notification no. X.11012/2/2021- DRS, dated July 8, 2022, has notified the draft of Drugs, Medical Devices, and Cosmetics Bill, 2022 (**DMC Bill**) with the aim of updating the pre-independence legislation of the Drugs and Cosmetics Act, 1940 and for keeping up with the changing needs, times, and technology. The new DMC Bill seeks to amend and consolidate the law relating to the import, manufacture, distribution & sale of drugs, medical devices and cosmetics to ensure their quality, safety, efficacy, performance, to warrant clinical trial of new drugs as well as clinical investigation of investigational medical devices and for matters connected therewith or incidental thereto.

2. Notification on Classification of Medical Devices pertaining to rehabilitation under the provisions of the MD Rules[2]

The Central Drugs Standard Control Organisation (**CDSCO**) *vide* Gazette Notification no. F. 29/Misc./03/2020-DC (160), dated July 6, 2022, has issued the classification of medical devices with respect to the import, manufacture, clinical investigation, sale and distribution based on the intended use, associated risks and other parameters linked to devices.

3. Notification on Cigarettes and other Tobacco Products (Packaging and Labelling) Amendment Rules, 2022[3]

The MoHFW *vide* Gazette Notification no. G.S.R. 592(E), dated July 21, 2022, has notified regarding amendments in the provisions of the Cigarettes and other Tobacco Products (Packaging and Labelling) Amendment Rules, 2008 regarding *'Textual Health Warning' and images* to be printed on the Cigarettes and other Tobacco Products. These rules shall come into force on December 1, 2022.

4. Notification on mandatory medical prescription on e-commerce sites for Ayurveda, Siddha and Unani Drugs[4]

The Central Consumer Protection Authority (**CCPA**) *vide* notification no. J-25/64/2022-CCPA, dated July 14, 2022, has advised all e-commerce platforms that are selling or facilitating the sale of Ayurveda, Siddha and Unani Drugs if made up of a substance as specified in the list of Schedule E(1) of the Drugs and Cosmetics Rules, 1945 (**D&C Rules**) shall be done only after a valid prescription from a registered medical practitioner is uploaded.

5. Notice on clarification regarding import of non-drug / lab kits shipments related to clinical trial / clinical research purposes[5]

The CDSCO *vide* Public Notice under file no. 12-01/22-DC (Pt-142), dated July 7, 2022, has issued a clarification regarding import of non-drug / lab kits shipments related to clinical trial / clinical research purposes to encourage research and clinical development along accompanying a an undertaking with intended purpose.

6. Draft on Guidance Document: Stability Studies of InVitro Diagnostic Medical Device[6]

The CDSCO *vide* document no. CDSCO/ IVD/ GD/ Stability/ 01/2022, dated July 7, 2022, has issued the draft of a document titled *"Guidance on Stability Studies of InVitro Diagnostic Medical Device (IVDMD)"* with the aim of creating public awareness about in Vitro Diagnostic Device regulation. The same was open for 30 days from its upload.

7. Draft on Guidance Document: Performance Evaluation / External Evaluation of In vitro Diagnostic Medical Device[7]

The CDSCO *vide* document no. CDSCO/IVD/GD/PER/01/2022, dated July 7, 2022, has issued the draft of a guidance document titled *"Performance Evaluation / External Evaluation of In vitro Diagnostic Medical Device (IVDMD)"* with the aim of creating public awareness about in Vitro Diagnostic Device regulation . The same is open to comment.

8. Draft on Guidance Document: Post Market Surveillance of In vitro Diagnostic Medical Device[8]

The CDSCO *vide* document no. CDSCO/IVD/GD/PMS/ 01/2022 dated July 7, 2022 has issued the draft of a guidance document titled *"Post Market Surveillance of In vitro*

1 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODc5Mw
2 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODc1Mg
3 https://ntcp.nhp.gov.in/assets/document/Cigarettes_and_other_Tobacco_Products_Packaging_and_Labelling_%202022.pdf
4 https://consumeraffairs.nic.in/sites/default/files/file-uploads/latestnews/ADVISORY-Conserning%20sale%20of%20Ayurvedic%2C%20Siddha%20and%20Unani%20Drugs.pdf
5 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODc5NA
6 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODc2OA
7 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODc2Ng==

Diagnostic Medical Device (IVDMD)" with the aim of creating public awareness about in Vitro Diagnostic Device regulation. The same is open to comment.

9. Notification issued by ICMR on Third Volume of Standard Treatment Guidelines[9]

World Health Organisation, the National Health Authority, and the Indian Council of Medical Research (**ICMR**) have released the third volume of Standard Treatment Workflows (STWs), which covers 54 diseases on July 12, 2022. It has been published as well as released through a mobile application to empower the primary, secondary and tertiary care physicians/surgeons towards achieving the overall goal of Universal Health Coverage with disease management protocols and pre-defined referral mechanisms by decoding complex guidelines.

10. Notification on National Standards for Blood Centres and Blood Transfusion[10]

The MoHFW, with the National Blood Transfusion Council (**NBTC**), has released the National Standards for Blood Centres and Blood Transfusion Services (2nd Edition) for quality, safety and efficacy of blood and blood products on July 29, 2022.

11. Extension of TMR Notification on 5 Medical Devices[11]

The National Pharmaceutical Pricing Authority (**NPPA**) *vide* Gazette Notification S.O. 3534(E) dated July 29, 2022, has extended TMR Notification on 5 Medical Devices regarding capping of trade margins of these devices and the same shall continue till further notice.

12. Notification on Reconstitution of National Medical Device Promotion Council[12]

The Department of Pharmaceuticals under the Ministry of Chemicals and Fertilisers (**MoC&F**) *vide* notification no. 31026/26/2018-MD, dated August 5, 2022, has notified regarding the reconstitution of National Medical Device Promotion Council under the Chairpersonship of Secretary, Department of Pharmaceuticals.

13. NPPA Order fixing Retail Prices of 45 Formulations[13]

The NPPA *vide* an Order dated August 24, 2022, has fixed Retail Prices of 45 Formulations under the Drugs (Prices Control) Order, 2013 based on the decision of 100th authority meeting dated August 5, 2022.

14. Comptroller and Auditor General of India Audit Report on Procurement and Supply of Drugs under CGHS[14]

The Office of the Comptroller and Auditor General of India (**CAG**) on August 8, 2022, via a press release, announced its Performance Audit Report on Procurement and Supply of Drugs in the Central Government Health Scheme (**CGHS**) for the period 2016-17 to 2020-21. The CAG Audit Report highlights the lapses in procurement, supply chain of drugs under the CGHS scheme.

15. Parliamentary Panel asks Government to exempt basic customs duty & GST on drugs and medical devices to combat Covid-19[15]

The Department Related Parliamentary Standing Committee (**DRPSC**) on Chemicals and Fertilisers, in a report submitted in the Lok Sabha on August 8, 2022, has recommended the Central Government to exempt the basic customs duty as well as Goods and Services Tax (**GST**) on medicines and medical devices used to combat Covid-19. The report seeks such exemption until the pandemic is over.

16. Notice on list of Certified Medical Device Testing[16]

The CDSCO *vide* Public Notice under file no. 29/Misc./03/2019-DC (211), dated August 17, 2022, has notified the list of certified medical device testing laboratory under the MD Rules to carry out the test or evaluation of medical devices.

17. Notification on Drugs (Seventh Amendment) Rules, 2022[17]

The MoHFW *vide* Gazette Notification G.S.R. 654(E), dated August 24, 2022, has issued an amendment pertaining to Rule 75 of D&C Rules allowing parallel submissions in Form 28-D.

[8] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODc2Nw==
[9] https://stw.icmr.org.in/stws
[10] https://main.mohfw.gov.in/sites/default/files/National%20Standards%20for%20Blood%20Centres.pdf
[11] https://www.nppaindia.nic.in/wp-content/uploads/2022/08/Gazett-Notification.pdf
[12] OM dated 5-8-2022_Reconstitution of NMDPC under chairpersonship of Secretary, DoP_0.pdf (pharmaceuticals.gov.in)
[13] https://www.nppaindia.nic.in/wp-content/uploads/2022/08/Retail_English.pdf
[14] https://cag.gov.in/uploads/PressRelease/PR-PRESS-RELEASE-ON-REPORT-NO-17-ENGLISH-062f0fd6eea9987-57223030.pdf
[15] http://164.100.47.193/lsscommittee/Chemicals%20&%20Fertilizers/17_Chemicals_And_Fertilizers_35.pdf
[16] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODg4Mg

18. Notice on list of Notified bodies registered with CDSCO under MDR, 2017[18]

The CDSCO *vide* Public Notice under file no. 29/Misc./3/2017-DC (288), dated August 25, 2022, has notified the list of certified medical device testing laboratory under the MD Rules to carry out audit of manufacturing sites.

19. New National List of Essential Medicines - 2022 released by MoHFW[19]

The MoHFW *vide* notification no. X.11035/346/2021-DRS, dated September 13, 2022, has released an updated national list of essential medicines (**NLEM**), i.e. NLEM 2022, which includes 384 drugs across different therapies. The new NLEM 2022 has been released after a gap of seven years, i.e. after NLEM 2015. The primary purpose of NLEM is to promote the rational use of medicines based on cost, safety and efficacy. NLEM 2022 is the fourth revision after the original list was formulated in the year 1996.[20]

20. Extension of grace period on all non-notified Medical Devices of Class A and B categories to enter licencing regime[21]

The CDSCO *vide* Circular File No. 29/Misc/03/2022-DC (257), dated September 30, 2022, has issued that all existing importer/manufacturer who are already importing /manufacturing any of the non-regulated Class A or Class B Medical Devices, having submitted application to Central Licensing Authority or State Licensing Authority on or before September 30, 2022, which shall be deemed valid, can continue to import /manufacture the said device(s) up to six (6) months from the date of issuance of the CDSCO order or until the time their applications are reviewed, whichever is earlier.

21. Notification on Medical Devices (Fifth Amendment) Rules, 2022[22]

The MoHFW *vide* Gazette Notification no. G.S.R. 754(E) dated, September 30, 2022, has notified the draft Medical Devices (Fifth Amendment) Rules, 2022 with the aim of adding in Rule 87 of the Medical Devices Rules, 2017 (**MD Rules**), a new sub-rule as "87A. Registration certificate to sell, stock, exhibit or offer for sale or distribute a medical device including in vitro

diagnostic medical device." In addition to the above, in sub-rule (1) of rule 34, the words, letters and figure "or registration certificate in Form MD-42" after the words "wholesale licence for sale or distribution" have been inserted vide the amendment rules.

22. Notification on draft of Medical Devices (..... Amendment) Rules, 2022[23]

The MoHFW *vide* Gazette Notification no. G.S.R. 710(E), dated September 20, 2022, has notified the draft Medical Devices (.....Amendment) Rules, 2022 with the aim of Exemption of certain Class A medical device from licensing regime under the MD Rules. For seven (7) days since the date of notification, the draft was open for comments by the public.

23. Notifications by the Food Safety and Standards Authority of India (FSSAI)

a) Order of FSSAI related to Referral Food Laboratories notified by FSSAI under section 43 (2) of FSSAI Act, 2006[24]

The FSSAI *vide* Order no. File No. QA-12013/7/2021-QA-FSSAI, dated July 1, 2022, has notified a list of 20 FSSAI-notified Referral Food Laboratories under Section 43(2) of the Food Safety and Standards Act, 2006 (**FSSAI Act**) to carry out the functions entrusted to the referral food laboratory.

[17] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODg5NQ
[18] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODkwMQ
[19] https://main.mohfw.gov.in/sites/default/files/Notification%20and%20Report%20on%20National%20List%20of%20Essential%20Medicines%2C%202022.pdf
[20] https://pib.gov.in/PressReleasePage.aspx?PRID=1858931
[21] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTA1Nw
[22] https://egazette.nic.in/WriteReadData/2022/239316.pdf
[23] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTA0MQ==

b) Order of FSSAI recognising Food Testing Laboratories[25]

The FSSAI *vide* Order no. File No. QA-12/1/2021-RARD-FSSAI, dated July 4, 2022, has notified a list of FSSAI recognised laboratories along with the validity of their NABL accreditation scope of testing as on June 30, 2022 for the purpose of carrying out the analysis of food samples taken under the FSSAI Act and Rules and Regulations.

c) FSSAI Notice for applicability of GST on all services[26]

The FSSAI *vide* Notice no. FA-11023/1/2022-FA-FSSAI/43, dated July 20, 2022, has notified that GST will be applicable on all services provided by FSSAI like issue of central licence, product approval fee, food safety mitra fee, import licence fee etc.

d) Notification on Guidelines for submission of applications for endorsement of vegan logo and formats thereof [27]

The FSSAI *vide* Notification no. File No. STD/SP-18/T dated July 25, 2022, has notified the Guidelines for submission of applications for endorsement of vegan logo and formats thereof as required under the Food Safety and Standards (Vegan Foods) Regulations, 2022.

e) FSSAI Order mandating health certificate for food consignment imports[28]

The FSSAI *vide* Order no. File No. 1829/Health Certificate/FSSAI/Imports- 2021, dated August 3, 2022, has notified that imported consignments of milk, milk products, pork, fish, and fish products will require health certificates issued by the competent authority of the exporting country. The certificates will be valid till 90 days from the date of issuance.

f) Notification on Food Safety and Standards (Advertising and Claims) First Amendment Regulations, 2022[29]

The FSSAI *vide* Gazette Notification no. F. No. Stds/SP(L&C/A)/Oil Claims/FSSAI-2018, dated August 30, 2022, has notified the Food Safety and Standards (Advertising and Claims) First Amendment Regulations, 2022. This amendment provides for a substitution of the table for Schedule II A in Food Safety and Standards (Advertising and Claims) Regulations, 2018, dealing with List of Claims for Edible Vegetable Oils. These amendments shall come into force on March 1, 2023.

g) Notification on Food Safety and Standards (Packaging) Second Amendment Regulations, 2022[30]

The FSSAI *vide* Gazette Notification no. F. No. Std/SP-20/T(Migration-N) dated August 30, 2022, has notified the Food Safety and Standards (Packaging) Second Amendment Regulations, 2022. This amendment provides for a change in regulation 4 by adding entries in Table 1 of the Food Safety and Standards (Packaging) Regulations, 2018, which relates to migration limit for Antimony and DEHP in plastic materials.

h) Notification on Food Safety and Standards (Foods for Infant Nutrition) First Amendment Regulations, 2022[31]

The FSSAI *vide* Gazette Notification no. F. No. Std./SP-05/T(IFR-01) dated August 30, 2022, has notified the Food Safety and Standards (Foods for Infant Nutrition) First Amendment Regulations, 2022. This amendment provides for a change in various regulations of the Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020. These amendments shall come into force on October 1, 2022.

i) Notification on Food Safety and Standards (Prohibition and Restrictions on Sales) First Amendment Regulations, 2022[32]

The FSSAI *vide* Gazette Notification no. F. No. Stds./03/Notification(IFR)/FSSAI-2017(part-3), dated August 31, 2022, has notified the Food Safety and Standards (Prohibition and Restrictions on Sales) First Amendment Regulations, 2022. This amendment provides for a change in regulation 2.3 of the regulation to state that ""No person shall manufacture, sell, store or exhibit for sale food for infant nutrition, except under Bureau of Indian Standards (BIS) Certification Mark, wherever BIS standards available". These amendments shall come into force on April 1, 2023.

j) Notification on Food Safety and Standards (Prohibition and Restrictions on sales) Second Amendment Regulations, 2022[33]

The FSSAI *vide* Gazette Notification No. F.No. REG/Representation-MSEO/FSSAI-2021, dated September 5, 2022, has notified the Food Safety and Standards (Prohibition and Restrictions on sales) Second Amendment Regulations, 2022. This amendment

[24] https://fssai.gov.in/upload/advisories/2022/07/62bebe65c62ccOrder_Referral_Labs_01_07_2022.pdf
[25] https://fssai.gov.in/upload/advisories/2022/07/62c29cda76d56Order_Lab_Validity_04_07_2022.pdf
[26] https://fssai.gov.in/upload/advisories/2022/07/62d7f34e747ceNotice_GST_20_07_2022.pdf
[27] https://www.fssai.gov.in/upload/advisories/2022/07/62df709761476Guidelines_Vegan_Food_26_07_2022.pdf
[28] https://fssai.gov.in/upload/advisories/2022/08/62eb545fc190aOrder_Import_Certificate_03_08_2022.pdf
[29] https://www.fssai.gov.in/upload/notifications/2022/09/63106ab314c26Gazette_Notification_Advertisement_01_09_2022.pdf
[30] https://www.fssai.gov.in/upload/notifications/2022/09/631067fe88a44Gazette_Notification_Plastic_01_09_2022.pdf
[31] https://egazette.nic.in/WriteReadData/2022/238485.pdf
[32] https://egazette.nic.in/WriteReadData/2022/238516.pdf

provides for substitution of the words "Multi source Edible Vegetable Oil" with the words "Multi-source edible oil" in sub-regulation 2.3.14 under regulation 2.3, in clause (11), in the Food Safety and Standards (Prohibition and Restrictions on sales) Regulations, 2011.

k) Notification on Food Safety and Standards (Labelling and Display) First Amendment Regulations, 2022[34]

The FSSAI *vide* Gazette Notification no. F. No. Std/SP-08/A-1.2021/N-01, dated September 9, 2022, has notified the Food Safety and Standards (Labelling and Display) First Amendment Regulations, 2022. This amendment provides for a change in font size, exemptions, etc., in the Food Safety and Standards (Labelling and Display) Regulations, 2020.

l) FSSAI draft Notification on Food Safety and Standards (Labelling & Display) Amendment Regulations, 2022[35]

The FSSAI *vide* Gazette Notification no. F. No. Std./SP-08/T(FoPNL-N-01), dated September 13, 2022, has notified the draft of Food Safety and Standards (Labelling & Display) Amendment Regulations, 2022. This amendment provides for a change in relation to Front of Pack Nutritional Labelling (FOPNL) and High fat, sugar, salt (HFSS) etc. The draft is open for comments by the public for 60 days since the date of notification.

m) Draft Notification on Food Safety and Standards Authority of India (Transaction of Business at its meetings) Amendment Regulations, 2022[36]

The FSSAI *vide* Gazette Notification no. F. No. GA-18012/2/2022-Gr.Admin-FSSAI, dated September 13, 2022, has notified the draft of Food Safety and Standards Authority of India (Transaction of Business at its meetings) Amendment Regulations, 2022. This amendment provides for a change in the Food Safety and Standards Authority of India (Transaction of Business at its meetings) Regulations, 2010 related to reimbursement of expenses. The public can give their opinion on the draft, which is open for comments for 60 days since the date of notification.

n) Notification on Food Safety and Standards (Food Products Standards and Food Additives) First Amendment Regulations, 2022[37]

The FSSAI *vide* Gazette Notification no. F. No. 1-116/Scientific Committee/Notif.28.4/2010-FSSAI (2), dated September 13, 2022, has notified the Food Safety and Standards (Food Products Standards and Food Additives) First Amendment Regulations, 2022. This amendment provides for inclusion of Fermented Soybean Curd and Fermented Soybean Curd (made with s. thermophillus + L. bulgaricus) in sub-regulation 2.4.38 relating to 'Mixed Millet Flour' in Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011. These amendments shall come into force on April 1, 2023.

o) FSSAI Order regarding graphic specifications of the Vegan logo[38]

The FSSAI *vide* File No. STD/SP-18/T(Vegan Foods), dated September 14, 2022, has specified the graphic representation of the vegan logo as stipulated under sub-regulation 4(2) of the FSS (Vegan Foods) Regulations, 2022.

p) FSSAI clarification on the requirement of health certificate with import of food consignment[39]

The FSSAI *vide* Order no. File No. 1829/Health Certificate/FSSAI/Imports- 2021, dated September 26, 2022, has clarified that an integrated/single certificate incorporating food safety related requirements/ attestations is also accepted by FSSAI at the time of import clearance of imported consignments of milk, milk products, pork, fish, and fish products. Adherence to the format notified *vide* order dated August 3, 2022 must be ensured by the importers.

[33] https://egazette.nic.in/WriteReadData/2022/238617.pdf
[34] https://www.fssai.gov.in/upload/notifications/2022/09/631f1f96efc35Gazette_Notification_FSS_Label_12_09_2022.pdf
[35] https://www.fssai.gov.in/upload/uploadfiles/files/Draft_Notification_HFSS_20_09_2022.pdf
[36] https://www.fssai.gov.in/upload/uploadfiles/files/Draft_Notification_Business_20_09_2022.pdf
[37] https://egazette.nic.in/WriteReadData/2022/238836.pdf
[38] https://www.fssai.gov.in/upload/advisories/2022/09/6321bea9ece61Direction_Vegan_Food_14_09_2022.pdf
[39] https://www.fssai.gov.in/upload/advisories/2022/09/63319d965a303Order_Import_Certificate_26_09_2022.pdf

News Updates

1. First Nasal Vaccine against COVID- 19 supported by DBT-BIRAC gets emergency use authorization from DCGI[40]

The Department of Biotechnology (**DBT**) and Biotechnology Industry Research Assistance Council (**BIRAC**) has announced the grant of approval from the Drugs Controller General of India (**DCGI**) for emergency use authorisation of first-of-its-kind intranasal COVID-19 Vaccine to Bharat Biotech (**BBIL**). This marks the fourth success story for the COVID-19 vaccine under the aegis of Mission COVID Suraksha, to together reinforce and accelerate COVID-19 vaccine development efforts as part of Aatmanirbhar 3.0. The BBV154 is an intranasal replication-deficient chimpanzee adenovirus SARS-CoV-2 vectored vaccine.

2. BBIL's intranasal vaccine 'iNCOVACC' received emergency approval[41]

BBIL's interanasal vaccine iNCOVACC (BBV154) received approval under Restricted Use in Emergency Situation for ages 18 and above. It was developed in partnership with Washington University St. Louis, which had designed and developed the recombinant adenoviral vectored constructs and evaluated them in preclinical studies for efficacy.

3. Max Super Speciality Hospitals and Pfizer India sign MoU to gather real-world evidence on drug efficacy and proven therapies[42]

Pfizer India has signed a Memorandum of Understanding (**MoU**) with Max Super Specialty Hospitals to give fellowships to young doctors in Max Hospitals to gather real-world evidence on drug efficacy and proven therapies from the existing Electronic Patient Records (**EPRs**). This evidence generation will focus on prevention, treatment and management of diseases that are of public health priority in India, such as cancer and cardiovascular disease. Pfizer sees this as a long-term, academic collaboration to promote high-quality medical research in the country, and through this collaboration, both parties also intend to build centres of excellence in rare diseases.

4. Johnson & Johnson new consumer health company to be named 'Kenvue'[43]

Johnson & Johnson (**J&J**) has announced that its planned new consumer health arm would be called 'Kenvue'. As per J&J's official statement, Kenvue's visual identity represents the company's timelessness, while allowing space for its

[40] https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1857433
[41] https://www.thehindubusinessline.com/companies/bharat-bio-gets-cdscos-nod-for-intranasal-covid-vaccine/article65856758.ece
[42] https://www.expresspharma.in/pfizer-india-partners-with-max-super-speciality-hospitals/
[43] https://www.jnj.com/johnson-johnson-announces-kenvue-as-the-name-for-planned-new-consumer-health-company

iconic brands to also have a home. The Kenvue logo centers on the "K" symbol, embodying the company's strengths – the geometry of the rectangle representing scientific precision and the round edges evoking the warmth of care.

5. Setting up of Export Promotion Council for Medical Devices[44]

In order to promote export of medical devices from India, the Ministry of Commerce and Industry has decided to set up an Export Promotion Council for Medical Devices (**EPCMD**). The EPCMD will function under the auspices of the Department of Pharmaceuticals and will be headquartered in Yamuna Expressway Industrial Development Authority (**YEIDA**), Greater Noida with regional offices in Andhra Pradesh and Telangana.

6. Zenara Pharma gets CDSCO nod to launch Paxlovid[45]

Zenara Pharma, a Hyderabad-based drug maker owned by Biophore India Pharmaceuticals, has received approval from the CDSCO to manufacture and market generic version of Pfizer's Covid antiviral drug Paxlovid in India. The approval by the CDSCO has been granted under the emergency authorisation route considering the unmet medical need. With this approval, Zenara will become the second company after Hetero Drugs to receive approval from CDSCO for Paxlovid.

7. 9th Edition of The Indian Pharmacopoeia (IP) out[46]

The Indian Pharmacopoeia Commission (**IPC**), on behalf of MoHFW, has published the 9th Edition of The Indian Pharmacopoeia (**IP**) on July 1, 2022, which prescribes the official standards for drugs produced and/or marketed in India and thus contributes to the control and assurance of the quality of the medicines. The standards set up by the IP are authoritative and legally enforceable. It intends to help in the licensing of manufacturing, inspection, and distribution of medicines in our country. Four countries- Afghanistan, Ghana, Nepal, and Mauritius have accepted IP as the book of standards.

8. Pharmacopoeia Commission for Indian Medicine[47]

The Government of India has established Pharmacopoeia Commission for Indian Medicine & Homoeopathy (**PCIM&H**), as a subordinate office under Ministry of AYUSH by merging PCIM&H and the two central laboratories namely Pharmacopoeia Laboratory for Indian Medicine, Ghaziabad and Homoeopathic Pharmacopoeia Laboratory vide Gazette notification dated July 6, 2020.

9. MoC&F launched three initiatives for pharma MSMEs[48]

In order to support Micro, Small and Medium Enterprises (**MSMEs**) in pharma industry, the Department of Pharmaceuticals under the MoC&F has rolled out the schemes under the banner of 'Strengthening Pharmaceuticals Industry' on July 21, 2022. The schemes provide for credit linked capital and interest subsidy for technology upgrade of MSME units in pharmaceutical sector, as well as support of up to INR 20 crore each for common facilities, including research centre, testing labs and ETPs, in pharma clusters.[49]

10. NITI Aayog releases 'Mitigation and Management of COVID-19'[50]

On July 2, 2022, NITI Aayog released a compendium 'Mitigation and Management of COVID-19' of Ayush-based practices from States and Union territories detailing information about various Ayush-based initiatives and practices adopted by the States and Union territories in India for containing and managing the COVID-19 outbreak.

11. Medtronic launches AI powered GI Genius module for colonoscopy for detection of colorectal cancer in India[51]

India Medtronic, a wholly owned subsidiary of Medtronic Plc. announced the launch of innovative computer-aided polyps detection system powered by artificial intelligence (AI), the GI Genius intelligent endoscopy module for detection of colorectal cancer in India.

[44] https://health.economictimes.indiatimes.com/news/medical-devices/to-increase-medical-device-exports-centre-sets-up-dedicated-export-promotion-council/94370783
[45] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/zenara-pharma-gets-cdsco-nod-to-launch-covid-antiviral-paxlovid-in-india/articleshow/93190132.cms
[46] https://pib.gov.in/PressReleasePage.aspx?PRID=1838570
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[49] https://www.business-standard.com/article/economy-policy/govt-launches-3-schemes-to-strengthen-msmes-in-pharmaceutical-sector-122072101388_1.html
[50] https://www.pib.gov.in/PressReleasePage.aspx?PRID=1838781
[51] https://health.economictimes.indiatimes.com/news/medical-devices/medtronic-india-launches-ai-powered-module-for-colonoscopy-of-colorectal-cancer/93450500

12. MoU between Ministry of AYUSH and MeitY[52]

IOn August 12, 2022, a MoU was signed between Ministry of AYUSH and Ministry of Electronics and Information Technology (**MeitY**) for providing technical support to Ministry of Ayush for digitalisation of Ayush Sector under the Ayush Grid project for a period of three (3) years. From a user's perspective, Ayush Grid is the proposed central IT platform offering multiple IT services for all systems of medicines under AYUSH across functional areas, namely, healthcare delivery, education, research, capacity building, drug licensing and standardisation along with media outreach.

13. Silver Jubilee[53] of NPPA

A programme was organised on August 29, 2022, to celebrate the silver jubilee of the NPPA. Dr. Mansukh Mandaviya, Union Minister for Chemicals & Fertilisers and Health & Family Welfare joined as the Chief Guest. On this occasion, Integrated Pharmaceutical Database Management System 2.0 (IPDMS 2.0), an integrated responsive cloud-based application developed by NPPA with technical support from Centre for Advance Computing (C-DAC) was launched. A book titled *An Overview of Drug Pricing @ NPPA 25 Year Odyssey was also published*.

14. MoU between PCIM&H and IPC for 'One Herb, One Standard'[54]

A MoU was signed between Pharmacopoeia Commission for Indian Medicine and Homoeopathy (Ministry of AYUSH) and Indian Pharmacopoeia Commission (MoHFW) on August 30, 2022, for Inter-Ministerial cooperation for promotion and facilitation of 'One Herb, One Standard'.

15. NPPA engages Policy Think Tank to study global drug pricing policies[55]

The NPPA has roped in Bridge Policy Think Tank, a Delhi-based policy think tank to do a comparative study of drug pricing policies of various countries and regions, chief among them being the UK, US, Australia, Brazil, Sri Lanka Bangladesh, European Union, Thailand, China and South Africa. The aim of this endeavour is to collate information on access to

medicines at affordable prices and find out various methods including trade margin rationalisation for reduction of prices of drugs.

16. All 23 AIIMS to be named after local heroes, monuments and other historic events[56]

The Government has firmed up a proposal to give specific names to 23 All India Institute of Medical Sciences (**AIIMS**), based on regional heroes, freedom fighters, historical events or monuments of the area or their distinct geographical identity.

17. 'Swasth Sabal Bharat' Conclave held[57]

Dr Mansukh Mandaviya, Union Minister for Health and Family Welfare, virtually inaugurated the 'Swasth Sabal Bharat' Conclave on September 3, 2022. The purpose of the conclave was to discuss the present situation of body-organ-eye donation in India and find solutions to the challenges ahead in future.

18. Pradhan Mantri Tuberculosis (TB) Mukt Bharat Abhiyaan[58]

Hon'ble President of India, Smt. Droupadi Murmu, virtually launched the Pradhan Mantri TB Mukt Bharat Abhiyaan on

[52] https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1851293
[53] https://pib.gov.in/PressReleasePage.aspx?PRID=1855005
[54] https://www.pib.gov.in/PressReleasePage.aspx?PRID=1855452
[55] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/nppa-ropes-in-delhi-based-think-tank-to-study-global-drug-pricing-policies/articleshow/93487087.cms
[56] https://economictimes.indiatimes.com/news/india/all-23-aiims-to-be-named-after-local-heroes-monuments/articleshow/93694223.cms
[57] https://www.pib.gov.in/PressReleasePage.aspx?PRID=1856518
[58] https://www.pib.gov.in/PressReleasePage.aspx?PRID=1857394

September 9, 2022, to reinvigorate the mission of Tuberculosis elimination from the country by 2025. The Ni-kshay Mitra portal which provides a platform for donors to provide various forms of support to those undergoing TB treatment will also be launched.

19. Declaration of Data results of National Family Health Survey (NFHS)[59]

The MoHFW conducts one integrated survey namely NFHS at an interval of about three years and so far, completed five (5) rounds of survey. As per the fifth round of NFHS conducted by MoHFW during the year 2019-21, the Total Fertility Rate has declined to 2.0 children per woman from 2.2 children per woman as per the fourth round of NFHS conducted during the year 2015-16, resulting in the achievement of the replacement level of fertility, which is 2.1 children per woman.

20. NHA collaboration with QCI[60]

The National Health Authority (**NHA**) has onboarded the Quality Council of India (**QCI**) for six months to accredit and rate HMIS (Health Management Information System)/ LMIS (Laboratory Information Management System) solutions that have integrated with Ayushman Bharat Digital Mission (**ABDM**). The National Accreditation Board for Hospitals and Healthcare Providers (**NABH**), the constituent board of QCI is responsible for national accreditation in the domain of healthcare. NABH will undertake the responsibility of accrediting and rating the ABDM compliant solutions on various parameters, including the ease of usage, user interface, pricing, number of modules/features and value for money/pricing so that prospective purchasers may get credible information.

20. MoU between NHA and Department of Social Justice and Empowerment to provide a composite health package for Transgender Persons[61]

A MoU was signed between the NHA under MoHFW and Department of Social Justice and Empowerment to provide an inclusive and composite health package for Transgender Persons under Ayushman Bharat (AB)-PMJAY. It is one of its kind in the country which will give impetus to ensuring rightful and respectable place for transgender community by accessing healthcare services under AB-PMJAY.

21. Creation of 22,97,64,327 ABHA numbers[62]

Government of India launched ABDM with an aim to establish National Digital Health ecosystem by creating an online platform, enabling interoperability of health data to create longitudinal electronic health record (**EHR**) of citizens. The ABHA Number generated is permanently assigned to the person as its Unique ID. Until July 15, 2022, a total of 22,97,64,327 ABHA numbers have been created. ABHA number can be populated across existing digital health interventions to create longitudinal EHR of the citizen.

22. MoU signed between ICMR and IISc to ink pact to create high-quality medical datasets[63]

The ICMR and the Indian Institute of Science have signed an MoU to collaborate on a national initiative toward the creation of high-quality medical datasets representing India's diversity.

23. CCRAS 'SPARK' program to support innovative research in Ayurveda initiated[64]

The Central Council for Research in Ayurvedic Sciences (**CCRAS**), has taken a unique initiative to support the research efforts of bright young minds of the Country by developing the Studentship Program for Ayurveda Research Ken (SPARK) for Ayurveda (BAMS) students studying in recognised Ayurveda colleges.

24. Patent awarded for use of advanced automated system or instrument for Therapeutic Emesis[65]

An advanced automated system or instrument for Therapeutic Emesis has been developed, which will make this therapy simple and convenient. This advanced automated system will help the Ayurveda fraternity in teaching and practicing Ayurveda with the use of technology. Going forward commercialisation of this invention is also being looked into, so that it can be used across hospitals in the country.

[59] https://www.pib.gov.in/PressReleasePage.aspx?PRID=1847431
[60] https://www.pib.gov.in/PressReleasePage.aspx?PRID=1848447
[61] https://www.pib.gov.in/PressReleasePage.aspx?PRID=1854076
[62] https://www.pib.gov.in/PressReleasePage.aspx?PRID=1845076
[63] https://health.economictimes.indiatimes.com/news/mergers-and-aquisitions/icmr-iisc-ink-pact-to-create-high-quality-medical-datasets/94376113
[64] https://www.pib.gov.in/PressReleasePage.aspx?PRID=1856321
[65] https://www.pib.gov.in/PressReleasePage.aspx?PRID=1843508

Major Litigation Updates

1. SC Judgment on all women are entitled to safe & legal abortion upto 24 weeks of pregnancy[66]

The Hon'ble Supreme Court (**SC**), in Civil Appeal No. 5802 of 2022, in a ground-breaking judgment declared that unmarried women are also entitled to seek abortion of pregnancy in the term of 20-24 weeks arising out of a consensual relationship. The issue at hand before the Hon'ble SC was the application of Rule 3B[67] of the Medical Termination of Pregnancy Rules, 2011 (**MTP Rules**) as being arbitrary and discriminatory in as much as it excludes unmarried women, whose pregnancy arises out a consensual relationship, from the application of the said Rule. The said Rule encapsulates the categories of women who are eligible for termination of their pregnancy in the duration of 20-24 weeks. The Court observed that the object of Section 3(2)(b) of the Medical Termination of Pregnancy Act, 2003 read with Rule 3B of the MTP Rules is to provide for abortions between 20 and 24 weeks, rendered unwanted due to a change in the material circumstances of women. In view of the object, there is no rationale for excluding unmarried or single women (who face a change in their material circumstances) from the ambit of Rule 3B. The three-judge Bench of the SC observed that *"Prohibiting unmarried or single pregnant women (whose pregnancies are between twenty and twenty-four weeks) from accessing abortion while allowing married women to access them during the same period would fall foul of the spirit guiding Article 14."* The Hon'ble SC in its judgment also observed that the rights of reproductive autonomy, dignity, and privacy under Article 21 give an unmarried woman the right of choice on whether or not to bear a child, on a similar footing of a married woman.

2. SC issues notice on petition challenging provisions of Surrogacy (Regulation) Act & Assisted Reproductive Technology (Regulation) Act, 2021[68]

The Hon'ble SC, in the matter of *Arun Muthuvel vs. Union of India & Ors.* has issued notice on the petition challenging various provisions of the Assisted Reproductive Technology (Regulation) Act, 2021 (**ART Act**), the ART (Regulation) Rules, 2022, the Surrogacy (Regulation) Act, 2021 (**Surrogacy Act**) and the Surrogacy (regulation) Rules, 2022. The petition has been filed on behalf of Arun Muthuvel, an IVF healthcare practitioner *inter alia* seeking the following[69]; (a) Recognition of rights of women other than married women above 35 years of age to avail surrogacy; (b) to strike down the definition of couple under Section 2(1)(h) of the

[66] X vs. The Principal Secretary, Health and Family Welfare Department, Govt. of NCT of Delhi & Anr., Judgement dated September 29, 2022 in Civil Appeal No. 5802 of 2022.
[67] Rule 3B : Women eligible for termination of pregnancy up to twenty-four weeks.
[68] Arun Muthuvel vs. Union of India & Ors., Order dated September 26, 2022 in W.P. (C) No.756/2022.

Surrogacy Act, 2021 and of commissioning couple under Section 2(1)(e) of the ART Act, 2021 or include couples other than the married man and woman in these definitions; (c) to rephrase the definitions of gestational surrogacy and surrogate mother in order to align them with each other; (d) issue direction to the respondents prescribing a time limit for issuance of essentiality certificate by the District Medical Board and further come up with a provision for appeal/review; (e) to strike down Section 27(6) of the ART Act which mandates a donor bank to obtain Aadhaar details of each donor; (f) to declare Section 4(iii)(b)(III) to be in violation of Article 14 and 21 of the Constitution; (g) to strike down the provisions of the ART Act imposing rigorous penalties for medical practitioners and; (h) to reduce the onerous requirements for registration of ART Clinics including the exorbitant registration fees.

3. NCDRC awards INR 1 crore compensation to parents for death of the child due to gross medical negligence[70]

The Hon'ble National Consumer Disputes Redressal Commission (**NCDRC**) awarded an exemplary compensation of INR 1 crore to the parents of a 6-year-old child, who met with an untimely death due to the gross medical negligence and deficiency in service during a squint eye conducted at Sankara Nethralaya, Chennai. The question for examination before the NDCRC was whether the doctors treating the child patient at the hospital committed breach in their duty of care, which was the proximate cause of death of the child.

The parents of deceased listed down a series of lethargic approaches and negligent behaviour on behalf of the medical staff leading to the death of their child in their Complaint. The Hon'ble NCDRC relying on a catena of judgments of the SC on medical negligence in its order observed that "*...having medical negligence conclusively attributed to the treating doctor at the hospital and having regard to that the complainants lost their only son, in the ends of justice, we are of the considered view the compensation of ₹1 crore is just and fair in the instant case.*" The NCDRC directed the Hospital to pay a sum of INR 85 lakh; the Anaesthetist, a sum of INR 10 lakh and the operating Ophthalmologist, a sum of INR 5 lakh to the Complainants within six weeks from the date of its order.

4. Delhi High Court gives a clarification on Para 20 of the DPCO 2013

The Hon'ble High Court of Delhi, in the batch matter of *Bharat Serums and Vaccines Ltd. vs. Union of India & Ors.*[71] has stated that in case of non-scheduled formulations, a manufacturer's right to 10 percent increase, every twelve months cannot be denied due to overcharging a particular year and must be considered while computing any overcharging liability. The Hon'ble High Court held that the stand taken by the respondents, i.e. NPPA to the effect that the right to seek such increase would stand lost until such time as the price is revised and brought down, would not only amount to recasting of Para 20 of the DPCO 2013, it would also and on more fundamental terms, result in the introduction of a penal consequence which neither flows from a plain reading of that provision nor can be inferred.

[69] Dr. Reba Modak & Anr. v. Sakara Nethralaya & Ors., Judgement dated August 26, 2022 in Consumer Case No. 155 of 2001.
[71] Judgement dated September 22, 2022 in W.P. (C) 7946/2018, W.P. (C) 8190, 2018, and W.P. (C) 8190, 2018.

Major Transactions

1. Piramal Enterprises' (PEL) demerger approved by NCLT[72]

The National Company Law Tribunal (**NCLT**) has approved the demerger of Piramal Enterprises' (**PEL**) Pharma business and the simplification of the company's corporate structure. The NCLT order paves the way towards the creation of two separate listed entities viz. Piramal Enterprises Limited (NBFC) and Piramal Pharma Limited[73].

2. Cipla Health acquires Endura Mass[74]

Cipla Health Ltd., an arm of Cipla Ltd. announced that it has entered into definitive agreements to acquire Endura Mass, a nutritional supplement brand from Medinnbelle Herbalcare for an undisclosed sum. The acquisition is in line with Cipla's critical strategic move to augment its wellness portfolio for bringing about a shift from an illness to a wellness mindset. The agreements include Endura and all other associated trademarks to form the part of the transaction.

3. Torrent Pharma all set to acquire Curatio Healthcare[75]

Torrent Pharmaceuticals Limited, a leading Gujarat based pharmaceuticals company promoted by the Torrent Group, has announced that they have entered into definitive agreements to acquire 100 percent stake in Curatio Healthcare. Curatio Halthcare has a strong presence in the cosmetic dermatology segment with a portfolio of over 50 brands, marketed in India. Curatio's portfolio consists of leading brands such as Tedibar, Atogla, Spoo, B4 Nappi, and Permite, which are ranked amongst top 5 brands in their covered market. This acquisition will mark the entry of Torrent Pharma in the league of top 10 players in the dermatology segment.

4. Medi Assist to acquire Medvantage Insurance TPA Pvt Limited[76]

Medi Assist, India's leading health insurance third party administrator, is ready to acquire 100% stake in Mumbai-based Medvantage Insurance TPA Pvt. Ltd. which is one of the oldest Third-Party Administrators in the country. The proposed combination of the two players will allow Medi Assist to service over INR 10,000 crore of health insurance premiums as part of its corporate portfolio and also command a market share of close to 30% in this segment.

5. MediBuddy acquires telehealth platform Clinix[77]

MediBuddy, a leading Indian tech-health startup has acquired rural India-focused online consultation platform, Clinix for an undisclosed amount. The acquisition will enable

[72] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/nclt-approves-demerger-of-pharma-business-from-piramal-enterprises/articleshow/93527356.cms
[73] https://www.piramal.com/wp-content/uploads/2022/07/NCLT-Order-dated-July-19-2022.pdf
[74] https://www.cipla.com/press-releases-statements/cipla-health-signs-agreement-acquire-endura-mass
[75] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/torrent-pharmaceuticals-to-acquire-100-of-curatio-healthcare-for-rs-2000-crores/articleshow/94481136.cms
[76] https://www.financialexpress.com/money/insurance/medi-assist-signs-definitive-agreement-to-acquire-medvantage-insurance-tpa/2691956

MediBuddy to further expand its reach in non-metro areas of the country. MediBuddy will leverage Clinix's network across 20 Tier-2, 3 cities to increase its user base and further scale their operations.

6. Tata 1mg partners with Seekho.ai[78]

Tata 1mg, a technology enabled healthcare service provider, has partnered with Seekho.ai, an AI-powered platform, to roll out industry-certified programs in healthcare and other sectors. The two companies believe this partnership of complementary missions will lead to a skilled India, and a healthier India.

7. MFine merges with Lifecell International[79]

Healthtech startup MFine has announced its merger with Chennai-based LifeCell International's diagnostic business to create a new entity called LifeWell. Mfine will be the digital arm of Lifewell, which will build a nationwide lab network. Mfine will remain the app and consumer brand for digital healthcare services like tele-consultations, care plans, diagnostic tests, IP concierge, e-pharmacy and corporate subscriptions.

8. Dr. Reddy's Laboratories signs licensing deal with Slayback Pharma[80]

Dr. Reddy's Laboratories, a leading Indian multinational pharmaceutical company announced a licencing agreement with US based Slayback Pharma to obtain rights to Brimonidine Tartrate Ophthalmic Solution 0.025 percent that reduces eye redness.

9. Sonde Health inks multi-year partnership with Koye Pharma[81]

Sonde Health, a leading enterprise vocal biomarker company, has signed a multi-year agreement with Koye Pharmaceuticals, a specialty pharma company focused on the Indian Pharmaceutical market, to develop a new vocal biomarker detection and monitoring capability for chronic obstructive pulmonary disease in India. This deal represents Sonde's first partnership with a pharmaceutical company as per the official statement released by Sonde Health.

10. Pfizer to Acquire Global Blood Therapeutics for $5.4 Billion to Enhance Presence in Rare Hematology[82]

Pfizer Inc., on August 8, 2022, announced that it will acquire GBT, a biopharmaceutical company dedicated to the discovery, development and delivery of life-changing treatments that provide hope to underserved patient communities, starting with sickle cell disease (**SCD**). SCD is a lifelong, devastating inherited blood disorder impacting millions of people worldwide, predominantly in populations of African, Middle Eastern and South Asian descent.

11. GlaxoSmithKline acquires Sierra Oncology[83]

GlaxoSmithKline, after receiving shareholder approval, has fully acquired Sierra Oncology, a California-based biopharmaceutical company focused on targeted therapies for the treatment of rare forms of cancer. Momelotinib, a late-stage asset to treat anaemia in myelofibrosis patients, is made available to GSK as a result of the acquisition.

[77] https://inc42.com/buzz/medibuddy-acquires-healthtech-startup-clinix-to-expand-reach-in-rural-india/
[78] https://health.economictimes.indiatimes.com/news/mergers-and-aquisitions/tata-1mg-partners-with-seekho-ai-to-upskill-healthcare-and-allied-sectors-/94394441
[79] https://ehealth.eletsonline.com/2022/07/healthtech-company-mfine-merges-with-lifecells-diagnostics-business-raises-80-mn/
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