$~61 to 65

* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

Date of decision: **21.04.2026.**

\+ **W.P.(C) 6845/2025 and CM APPL. 31030/2025**

MAXFORD HEALTHCARE & ORS. .....Petitioners

Through: Mr. Aman Saroha, Ms. Kushi Sharma, Mr. Gourav Garg and Mr.Sachin, Advocates.

versus

UNION OF INDIA & ANR. .....Respondents

Through: Mr. Nishant Gautam CGSC Ms.Kavya Shukla, Mr. Vineet Negi, Mr. Vibhav V. Nath and Ms. Theresa Advocates.

62

\+ **W.P.(C) 6846/2025 and CM APPL. 31032/2025**

AJANTA PHARMA LTD. & ORS. .....Petitioners

Through: Mr. Aman Saroha, Ms. Kushi Sharma, Mr. Gourav Garg and Mr.Sachin, Advocates.

versus

UNION OF INDIA & ANR. .....Respondents

Through: Mr. Nishant Gautam CGSC Ms.Kavya Shukla, Mr. Vineet Negi, Mr. Vibhav V. Nath and Ms. Theresa Advocates.

63

\+ **W.P.(C) 7495/2025 and CM APPL. 33532/2025**

RICA ENTERPRISES & ORS. .....Petitioners

Through: Mr. Aman Saroha, Ms. Kushi Sharma, Mr. Gourav Garg and Mr.Sachin, Advocates.

versus

UNION OF INDIA & ANR. .....Respondents

Through: Mr. Nishant Gautam CGSC Ms.Kavya Shukla, Mr. Vineet Negi, Mr. Vibhav V. Nath and Ms. Theresa Advocates.

64

\+ **W.P.(C) 7509/2025 and CM APPL. 33563/2025**

DOLPHIN LIFE SCIENCES & ORS. .....Petitioners

Through: Mr. Aman Saroha, Ms. Kushi Sharma, Mr. Gourav Garg and Mr.Sachin, Advocates.

versus

UNION OF INDIA & ANR. .....Respondents

Through: Mr. Nishant Gautam CGSC Ms.Kavya Shukla, Mr. Vineet Negi, Mr. Vibhav V. Nath and Ms. Theresa Advocates.

65

\+ **W.P.(C) 7581/2025 and CM APPL. 33807/2025**

CAFOLI LIFECARE PVT. LTD. & ORS. .....Petitioners

Through: Mr. Aman Saroha, Ms. Kushi Sharma, Mr. Gourav Garg and Mr.Sachin, Advocates.

versus

UNION OF INDIA & ANR. .....Respondents

Through: Mr. Nishant Gautam CGSC
Ms.Kavya Shukla, Mr. Vineet Negi, Mr. Vibhav V. Nath and Ms. Theresa Advocates.

CORAM:
HON'BLE MR. JUSTICE PURUSHAINDRA KUMAR KAURAV

J U D G E M E N T

PURUSHAINDRA KUMAR KAURAV, J. (ORAL)

1. The petitioners are private limited companies and firms engaged in the business of research and development, manufacture and marketing of drugs, cosmetics and other pharmaceutical products. The present petition assails the order dated 11.04.2025 bearing File No.4-01/2023-DC(Misc. 3) passed by the Directorate General of Health Services, Central Drugs Standard Control Organisation (FDC division) ***[hereinafter referred to as 'FDC division']***.

2. By way of the impugned communication, the FDC division has requested the respective State and Union Territory Drug Controller(s) to review the approval process for Fixed Dose Combination drugs (FDCs) falling within the category of a "New Drug". The record indicates that the said communication was issued in the interest of patient safety and public welfare; concerns were raised regarding premature approvals of new drugs without evaluating the safety and efficacy of the same.

3. The regulatory framework governing such approvals is contained in the **New Drugs and Clinical Trials Rules, 2019** *(hereinafter referred to as*

'the NDCT Rules'), framed under Sections 12(1) and 33 of **the Drugs and Cosmetics Act, 1940**. The said framework applies to all new drugs for human use, clinical trials, etc., and governs the approvals for the same. Rule 2(1)(w)(iii) of the NDCT Rules expressly states that a fixed dose combination of two or more drugs which were approved separately, when proposed to be combined for the first time, would fall within the definition of a "new drug".

4. A perusal of the said Rules indicates that the scheme includes a centralised regulatory scrutiny before initiating clinical testing or market authorisation. Rule 3 designates the respondent, Drug Controller General of India *(hereinafter referred to as the ' drug controller')*, as the licensing authority. No clinical trial is to be conducted without permission of the respondent[1], along with the approval of the ethics committee. This framework is also supplemented by additional statutes like the **Good Clinical Practise Guidelines** that ensure assessment safety, scientific validity (through pre-clinical supporting data), ethical considerations, and the periodic reporting of adverse drug reactions.

5. The respondent submits that a practice has been developed, whereby, licenses have been granted by State Licensing Authorities for the manufacture and sale of FDCs without adhering to the aforementioned statutory requirements. It is contended that such approvals granted without evaluation of safety and efficacy in terms of the NDCT Rules have resulted in the availability of unapproved FDCs in the market, posing a risk to patient safety and public health at large.

6. In view of the aforementioned reasons, the impugned order dated 11.04.2025 does not warrant any interference. The impugned communication merely requires the concerned State and Union Territory Drug Controllers to undertake a review of the approval process followed in respect of FDCs falling within the category of a "new drug". It further calls upon the authorities to examine the licences granted for the manufacture, sale and distribution of such FDCs, as identified in their annexure. Concerned authorities were instructed to take appropriate action, including revocation of licenses (to manufacture, sell, and distribute) where warranted, in accordance with the provisions of the NDCT Rules, 2019, and to submit a report thereon.

7. Some of the licenses were voluntarily surrendered by respective manufacturers following the show-cause notice. The unapproved FDCs compromise patient safety and may lead to adverse drug reactions and cause other health hazards due to the absence of scientific validation.

8. The respondent-authority, therefore, has rightly sensitised all concern by way of the impugned advisory.

9. The petitioners are unable to satisfy the Court as to on what ground the impugned advisory deserves to be set aside. There does not seem to be any valid permission being granted by the respondent authorizing the petitioners to sell in the market the drugs in question.

10. Therefore, finding no justification to interfere into the impugned

[1] Rule 19 of the New Drugs And clinical Trials Rules, 2019

order, the instant petitions stand dismissed. Pending applications also stand disposed of.

(PURUSHAINDRA KUMAR KAURAV)
JUDGE

APRIL 21, 2026
Nc