[2026] 10 S.C.R. 352 : 2026 INSC 1097

Federation of Medical & Sales Representatives Association of India & Ors.
v.
Union of India & Ors.

(Writ Petition (Civil) No. 323 of 2021)

08 October 2026

[Vikram Nath and Sandeep Mehta,* JJ.]

Issue for Consideration

The principal grievance of the petitioners is with regard to the alleged prevalence of unethical marketing and promotional practices adopted by pharmaceutical companies in their dealings with healthcare professionals. The petitioners have set up a case that such practices include, *inter alia*, direct or indirect monetary benefits, gifts, hospitality, sponsored travel, entertainment and other inducements extended to medical practitioners with a view to influencing their drug prescribing practices.

Headnotes†

Constitution of India – Arts.32, 21 – Unethical marketing practices in the pharmaceutical industry – Whether the existing framework adequately addresses the concerns relating to ethical practices, transparency and accountability in the pharmaceutical sector, while keeping in view the larger public interest in accessible and affordable healthcare.

Held: The material furnished by the petitioners and the intervenors, indicates that the existing framework has not proved entirely effective in preventing and curbing unethical practices in the pharmaceutical sector – In a sector which has a direct bearing upon the health and well-being of citizens, the efficacy of the regulatory framework cannot be assessed merely by the existence of prescribed norms; it must also be judged by their efficacy, implementation and enforcement – This aspect also finds reflection in the stand taken by the Union of India itself – The material placed on record demonstrates that the concerns arising in these proceedings have been engaging the attention of the involved departments and have been the subject of deliberations at the highest level – Significantly, the Union of India has proposed to

* Author

constitute a Committee to comprehensively examine the issues arising in the present proceedings and to make recommendations regarding the appropriate statutory and regulatory framework for regulating the conduct of pharmaceutical companies, particularly with a view to ensuring that pharmaceutical companies do not indulge in unethical practices in their dealings with medical practitioners. [Paras 17, 18]

Constitution of India – Arts.32, 21 – Unethical marketing practices in the pharmaceutical industry – Constitutional and institutional contours – Doctrine of separation of powers:

Held: The regulation of pharmaceutical marketing practices entails questions of legislative and executive policy, including the choice of the appropriate statutory framework, the nature and extent of regulatory oversight, the permissible contours of industry practices, and the mechanisms for monitoring and enforcement – These matters fall primarily within the domain of the Union of India and its authorities, who are better equipped, by virtue of their institutional expertise and access to relevant material, to assess the competing considerations and formulate an appropriate regulatory policy – This Court, while exercising its constitutional jurisdiction, must therefore remain mindful of the doctrine of separation of powers and cannot substitute its own policy determination for that of the executive – At the same time, the Court is required to ensure that the regulatory framework ultimately adopted is consistent with the constitutional guarantees and the larger public interest. [Para 20]

Constitution of India – Arts.32, 21 – Unethical marketing practices in the pharmaceutical industry – Whether the judicial restrain can be understood as requiring this Court to remain indifferent where the material before it discloses concerns having a direct bearing upon public health and the right to health:

Held: The judicial restraint cannot be understood as requiring this Court to remain indifferent where the material before it discloses concerns having a direct bearing upon public health and the right to health – The present proceedings have already resulted in a consultative exercise being undertaken by the Union of India, culminating in the proposal to constitute a Committee to examine the issues arising herein and to recommend an

appropriate statutory and regulatory framework – At this stage, therefore, the role of this Court is not to enter into the domain of policy formulation, but to facilitate a meaningful and effective consultative process, ensuring that the concerns raised and the suggestions placed before the Court receive due and objective consideration. [Para 21]

Constitution of India – Arts.32, 142 – Unethical marketing practices in the pharmaceutical industry – Having regard to the constitutional obligation to protect the right to health as well as the continuing need for an effective and enforceable framework to regulate pharmaceutical marketing practices – Directions issued u/Arts.32 and 142 of the Constitution of India:

Held: A) The Union of India shall, if not already constituted, constitute the Committee as proposed by it; B) The Committee so constituted shall undertake a holistic and comprehensive examination of all issues relating to unethical pharmaceutical marketing practices, including the adequacy of the existing statutory and regulatory framework, the efficacy of the mechanisms presently in place for monitoring, oversight and enforcement, and the measures required to ensure greater transparency, accountability and effective compliance, with a view to strengthening the regulatory framework and safeguarding the larger public interest; C) The Committee shall take into consideration the material already placed on record before this Court by the petitioners and the intervenors, and shall also afford them a reasonable opportunity to place before it their respective views, suggestions and concerns – The Committee shall also provide an appropriate opportunity to other stakeholders concerned with the subject matter to place their representations, so as to enable a comprehensive and informed consideration of all aspects of the issues under examination; D) The Committee shall duly consider the suggestions, representations and concerns placed before it by the petitioners, the intervenors and other stakeholders, and shall, upon an objective and comprehensive consideration thereof, make its recommendations to the Union of India regarding the appropriate regulatory and/or statutory framework for effectively regulating pharmaceutical marketing practices, keeping in view the need for transparency, accountability

and effective enforcement; E) For the purposes of undertaking an informed, comprehensive and objective examination of the issues, the Committee shall be at liberty to seek the assistance of such technical, professional and domain experts, institutions or bodies as it may consider necessary, and may obtain such expert inputs as may be required for a proper appreciation of the regulatory, medical, pharmaceutical and other relevant aspects arising for its consideration; F) The Committee shall endeavour to complete the entire exercise in a time-bound manner and submit its recommendations to the Union of India within a period of two months from the date of its first meeting, after duly undertaking the consultative process and considering the material and suggestions placed before it; G) The Union of India shall, upon receipt of the recommendations of the Committee, duly consider the same and take an appropriate and reasoned decision at the earliest, having regard to the constitutional mandate u/Art.21 of the Constitution of India and the larger public interest involved in ensuring ethical, transparent and accountable pharmaceutical marketing practices. [Para 23]

List of Acts

Constitution of India; Trade Unions Act, 1926; Uniform Code for Pharmaceutical Marketing Practices, 2015; Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002; Uniform Code for Pharmaceutical Marketing Practices, 2024; Essential Commodities Act, 1955; Drugs and Cosmetics Act, 1940.

List of Keywords

Right to health; Unethical pharmaceutical marketing practices; Statutory backing; Regulatory gap; Medical practitioners; Gifts; Hospitality; Travel facility; Monetary benefits; Doctrine of separation of powers; Judicial restraint; Legislative domain; Policy formation; Monitoring; Enforcement; Public interest; Healthcare.

Case Arising From

CIVIL ORIGINAL JURISDICTION: Writ Petition (Civil) No. 323 of 2021

Under Article 32 of the Constitution of India

Appearances for Parties

Advs. for the Petitioner(s):
Sanjay Parikh, Sr.Adv., Kishan Chand Jain, Rajesh Kumar, Sidhant Sahay, Ms. Neelam Tiwari, E. C. Agrawala, Ms. Kritika, Satwik Parikh, Rajat K. Mittal, Maitreya, Ritwik Parikh, Ms. Heena Khatun, Naresh Kumar Sharma.

Advs. for the Respondent(s):
Tushar Mehta, Solicitor General, K.M. Nataraj, A.S.G., Kapil Sibal, Kavin Gulati, Sr. Advs. Sudarshan Lamba, Madhav Sinhal, Mayank Pandey, Ms. Astha Singh,Vikash Sharma, Prateek Bhatia, Guntur Pramod Kumar, Ms. Prerna Singh, Dhruv Yadav, Arvind Kumar Sharma, Ms. Disha Singh, Ms. Eliza Barr, Ms. Akansha, Ms. Anjali Saxena, Govind Sharma, Aaditya Singh Rajawat, Praveen Khattar, Sumit R. Sharma, Mukul Kumar, Anando Mukherjee, Shwetank Singh, Utkarsh Anand, Ms. Jayasree Narasimhan, Aditya Bharat Manubarwala, Mrs. Shaila Arora, Mrs. Akriti Aditya Manubarwala, Mrs. Tanishka Grover, Mrs. Deepshikha Mishra, Mrs. Pradnya Sachin Matkar, Bharat Thakorlal Manubarwala, M/s Manubarwala and Partners Llp, Sravan Kumar Karanam, Ms. Harshini, Ms. Lakshita Yadav, Pradeep Sahu, Ms. Rupali Francesca Samuel, Ms. K V Vinaya, Zulfiker Ali P. S, Manish Sindwani, Ms. Lakshmi Sree P., Ms. Anna Oommen, Shifaz R Dheen, Ms. Lebina Baby, Surjendu Sankar Das, Ms. Annie Mittal, Ankit Roy, Ms. Mrinalini Ramesh, Ms. Jaya Pandey, Pukhrambam Ramesh Kumar, Karun Sharma, Ms. Anupama Ngangom, Ms. Rajkumari Divyasana, Avijit Mani Tripathi, T.K. Nayak, Daniel Stone Zyngdoh, Ms. Marbiang Khongwir, Upendra Mishra, Z.H. Isaac Haiding, Ashish Ranjan, Ms. K. Enatoli Sema, Amit Kumar Singh, Ms. Chubalemla Chang, Prang Newmai, Ms. Yanmi Phazang, Aniruddha Deshmukh, Siddharth Dharmadhikari, Aaditya Aniruddha Pande, Shrirang B. Varma, Shovan Mishra, Ms. Aneesha Rastogi, Saurabh Rajpal, Ms. Nidhi Jaswal, Gurmeet Singh Makker, Rajan Kumar Chourasia, Chitvan Singhal, Anuj Srinivas Udupa, Arun Kanwa, Purnendu Bajpai, Mrs. Madhulika Upadhyay, Yadav Narender Singh, Ms. Ruby Singh Ahuja, Ms. Kritika Sachdeva, Jappanpreet Hora, Ms. Aparajita Jamwal, Mohith, M/s Karanjawala & Co., Kaleeswaram Raj, Mohammed Sadique T.A., Ms. Thulasi K. Raj, Ms. Chinnu Mariya Antony, Ms. Athira Nandakumar, Ms. Rupali Francesca Samuel, Ms. K V Vinaya, Binay Kumar, Ms. Shriya Maini, Rajive Maini, Mohsin Alam, Ms. Aarti, Ms. Sowmya, Ms. Shobitha, Ms. Gayathri Singaraju, Ms. M. Sri Bhuvana,

Federation of Medical & Sales Representatives Association of India & Ors. v. Union of India & Ors.

Pranaya Kumar Mohapatra, Rajan Kumar Chourasia, Chitvan Singhal, Anuj Srinivas Udupa, Arun Kanwa, Purnendu Bajpai, Mrs. Madhulika Upadhyay, Gurmeet Singh Makker, Avijit Mani Tripathi, Upendra Mishra, P.S. Negi, Ashish Ranjan, Ms. Mirdula S. Dails, Dinesh Kumar Mudgal, Hitesh Kumar Sharma, Anupam Kumar, Amit Kumar Chawla, Akhileshwar Jha, Krishna Kumar Yadav, Ms. Sandhya Singh.

Petitioner-in-person

Judgment / Order of the Supreme Court

Order

Mehta, J.

1. The present writ petition under Article 32 of the Constitution of India has been instituted by the petitioners seeking enforcement of the fundamental right to health, which forms an integral part of the right to life guaranteed under Article 21 of the Constitution of India. Petitioner No.1, Federation of Medical & Sales Representatives Association of India, is a Trade Union registered under the Trade Unions Act, 1926 and is stated to be the only national organisation representing field workers, having local units in about 300 cities and towns across the country. Petitioner No.2 is the Secretary of petitioner No.1, whereas petitioner No.3 is the National Coordinator of *Jan Swasthya Abhiyan*, an organisation engaged in health-related issues and stated to have been working as a watchdog in relation to the pharmaceutical industry for several decades. The petitioners have been raising, since 2005, concerns regarding unethical marketing practices in the pharmaceutical industry and have been engaging with the Government seeking an effective regulatory framework. The issues raised in the present petition, concerning the regulation of pharmaceutical marketing practices, the integrity of medical prescriptions, affordability of medicines and, ultimately, the protection of the health and lives of citizens, undoubtedly assume immense public importance.

2. The principal grievance of the petitioners is with regard to the alleged prevalence of unethical marketing and promotional practices adopted by pharmaceutical companies in their dealings with healthcare professionals. The petitioners have set up a case that such practices include, *inter alia*, direct or indirect monetary

benefits, gifts, hospitality, sponsored travel, entertainment and other inducements extended to medical practitioners with a view to influencing their drug prescribing practices. According to the petitioners, such practices have the potential to result in over-prescription or irrational prescription of medicines, prescription of drugs in excess of therapeutic requirements, prescription of irrational combinations of medicines and a preference for high-valued or over-priced branded medicines.

3. The petitioners contend that the consequences are not confined to an increase in the cost burden upon patients but extend to serious implications for public health, including adverse drug reactions, irrational consumption of medicines and the emergence of antimicrobial/antibiotic resistance. They further contend that while the medical profession is subject to statutory ethical restrictions governing its relationship with pharmaceutical companies, including restrictions against acceptance of gifts, hospitality, travel facilities and monetary benefits, there is no corresponding enforceable regulatory regime under which pharmaceutical companies can be proceeded against for inducing or facilitating such conduct.

4. The petitioners contend that the aforesaid regulatory gap has persisted notwithstanding repeated governmental recognition of the need to curb unethical pharmaceutical marketing practices. It is their case that the Department of Pharmaceuticals formulated the Uniform Code for Pharmaceutical Marketing Practices, 2015[1], initially to be voluntarily adopted by pharmaceutical companies, but that the voluntary nature of the UCPMP, 2015 has rendered it ineffective, there being no adequate statutory mechanism for monitoring, transparency, accountability or enforceable consequences for its violation. The petitioners rely upon the subsequent deliberations and communications of the Government wherein the need for statutory backing and mandatory implementation of the UCPMP, 2015 was acknowledged, as also upon India's obligations under the International Covenant on Economic, Social and Cultural Rights and the United Nations Convention against Corruption. On this basis, the petitioners assert that the absence of an enforceable legal framework regulating unethical marketing practices by pharmaceutical companies has a direct bearing upon the right to health under Article 21 of the

1 For short, "UCPMP, 2015".

Constitution of India and warrants appropriate legislative measures and, in the interregnum, judicial intervention. They accordingly seek either the conferment of statutory force to the UCPMP, 2015 or the laying down of appropriate guidelines by this Court, in exercise of its jurisdiction under Articles 32, 141, 142 and 144 of the Constitution of India, until suitable legislation is enacted.

5. Based on the aforesaid averments, the following reliefs have been sought by the petitioners: -

> "**1.** To direct the Respondents to give the Uniform Code of Pharmaceutical Marketing Practices statutory basis and make it effective by providing a monitoring mechanism, transparency, accountability as well as consequences of violations;
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> **2.** To direct that till an effective law is enacted as prayed above, this Hon'ble Court may lay down the guidelines to control and regulate unethical marketing practices by pharmaceutical companies or in the alternative make the existing Code binding with such modifications/additions as this Hon'ble Court may find proper and reasonable, which should be followed by all the authorities/courts under Articles 32, 141, 142 and 144 of the Constitution.
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> **3.** For such other order(s) as this Hon'ble Court may deem fit and proper in the facts and circumstances of the present case."

6. This Court issued notice in the present petition on 11th March, 2022. Thereafter, the matter was adjourned from time to time awaiting the responses of the parties. *Vide* order dated 18th November, 2025, this Court granted Mr. Sanjay Parikh, learned senior counsel, three days' time to furnish a brief note setting out his suggestions and directed that a copy thereof be shared with Mr. K.M. Nataraj, learned Additional Solicitor General as well as with Mr. Kapil Sibal, Mr. Kavin Gulati, and Mr. Gaurav Sharma, learned senior counsel appearing for the parties/intervenors. The Court further granted Mr. Nataraj three weeks to obtain instructions on behalf of the Union of India and permitted the other respondents to file their responses. Mr. Kaleeswaram Raj, learned counsel, was also permitted to forward his suggestions to the learned Additional Solicitor General and other counsel appearing for the respondents.

7. When the matter was taken up on 16th December, 2025, this Court noted that, pursuant to the order dated 18th November, 2025, Mr. Sanjay Parikh, learned senior counsel, and Mr. Kaleeswaram Raj, learned counsel, had furnished their respective suggestions to Mr. K.M. Nataraj, learned Additional Solicitor General, and the other learned counsel appearing in the matter. Mr. Tushar Mehta, learned Solicitor General appearing for the Union of India sought time to deliberate upon the issues with the concerned officers and place the outcome before the Court. Thereafter, the matter was taken up on several occasions, during which the Court was apprised that deliberations between the concerned authorities were ongoing and that efforts were being made to arrive at a concrete solution. The suggestions furnished by the learned counsel for the petitioners and the intervenors were also directed to be placed before the competent authority for consideration. On 28th July, 2026, noting that sufficient time had already been granted and that no concrete outcome of the deliberations had been placed before the Court, this Court, by way of a last opportunity, deferred the matter and directed that the decision, if any, taken pursuant to the ongoing deliberations be placed before the Court.

8. When the matter was taken up on 8th September, 2026, Mr. Tushar Mehta, learned Solicitor General, apprised the Court that an affidavit had been filed on behalf of Respondent No. 1 (Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals) and Respondent No. 3 (Ministry of Health and Family Welfare). The affidavit sets out the deliberations undertaken amongst the concerned Departments pursuant to the directions of this Court, with a view to strengthening the regulatory framework governing pharmaceutical marketing practices. A meeting was held on 7th August, 2026 between the Secretaries of the Department of Pharmaceuticals and the Department of Health and Family Welfare, wherein the existing framework was discussed with particular focus on the need for greater transparency, independent scrutiny and improved compliance monitoring. Thereafter, a further meeting was held on 10th August, 2026 with representatives of the Indian Drug Manufacturers' Association (IDMA), Indian Pharmaceutical Alliance (IPA) and Organisation of Pharmaceutical Producers of India (OPPI) wherein the industry associations apprised the Departments of the existing compliance, self-declaration, disclosure and complaint-handling mechanisms and suggested measures for graded enforcement and greater clarity.

9. So far as medical professionals are concerned, the affidavit places reliance upon the existing statutory and regulatory framework governing professional misconduct, particularly the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. Regulation 6.8.1 places restrictions on the acceptance of gifts, travel facilities, hospitality and cash or monetary grants by medical practitioners from the pharmaceutical and allied healthcare industry, while permitting *bona fide* medical research subject to the prescribed safeguards. The said framework further regulates the professional affiliations of medical practitioners with the pharmaceutical industry and prohibits them from endorsing drugs or products of the industry, subject to the requirements prescribed therein. Violation of these provisions attracts disciplinary action, including censure and, in appropriate cases, removal of the name of the medical practitioner from the Indian Medical Register or State Medical Register for the period prescribed under the Regulations.

10. As regards the pharmaceutical industry, the affidavit records that the Government proposes to constitute a three-member Committee to examine the issues arising in the present proceedings and to make recommendations as to the appropriate statutory and regulatory framework for regulating the conduct of pharmaceutical companies, particularly to ensure that such companies do not indulge in unethical practices in their dealings with medical practitioners. The Committee is intended to consider the existing regulatory mechanisms, the need for greater transparency and accountability, and the measures required to strengthen enforcement, and to place its recommendations before the Government for appropriate action. In the meantime, and until the recommendations of the Committee are considered and acted upon by the Government, the existing Uniform Code for Pharmaceutical Marketing Practices, 2024 (UCPMP, 2024) shall continue to govern pharmaceutical marketing practices.

11. Mr. Sanjay Parikh, learned senior counsel, submitted that the present proposal is not the first occasion on which the Union of India has constituted a Committee to examine the issue. He referred to the counter affidavit dated 28th September, 2022 filed on behalf of the Union of India, which records that, on 12th September, 2022, a High-Level Committee under the Chairmanship of the Member (Health), NITI Aayog, with representation from the Department of Health and Family Welfare, Department of Pharmaceuticals and

the Central Board of Direct Taxes, was constituted to examine the provisions governing pharmaceutical marketing practices, align the interventions of the concerned Departments for their effective implementation, and consider the requirement of a legally enforceable mechanism for regulating such practices, including by studying practices followed across the globe. The Committee was expected to submit its recommendations within 90 days. Learned senior counsel submitted that, despite the constitution of the said Committee, no concrete outcome has emerged therefrom, and the issue continues to remain unresolved.

12. However, learned senior counsel in all fairness submitted that he has no objection to the constitution of the newly proposed Committee and the petitioners do not seek to come in the way of the process proposed by the Union of India. He fairly acknowledged that the issues arising for consideration involve matters of policy, and that the formulation of an appropriate regulatory framework must ultimately emerge from a considered decision of the Union of India. He, however, submitted that such decision-making ought to be preceded by a meaningful and effective consultative process, particularly having regard to the nature and wider ramifications of the issues involved. It was accordingly urged that the proposed Committee may take into consideration the suggestions already furnished by the petitioners and afford the concerned stakeholders the opportunity to place their views before it before finalising its recommendations, so that the ultimate policy decision is informed by a comprehensive consideration of the competing concerns and perspectives.

13. The learned counsel appearing for the intervenors, in substance, adopted the submissions advanced by learned senior counsel appearing for the petitioners. They also expressed their desire to place their respective views and suggestions before the Committee to be constituted by the Union of India and requested that an opportunity for making such representation be afforded to them.

14. Responding to the aforesaid submission, Mr. Tushar Mehta, learned Solicitor General, controverted the submission advanced by learned senior counsel for the petitioners with regard to the earlier High-Level Committee, submitting that the same was not borne out by the record. He submitted that the issue of strengthening the regulatory framework governing pharmaceutical marketing practices had been under consideration of the Union of India for several years.

Various options for according legal enforceability to the UCPMP, 2015, including mechanisms under the Essential Commodities Act, 1955 and the Drugs and Cosmetics Act, 1940, had been examined. He further submitted that the High-Level Committee constituted in September, 2022 under the chairmanship of Dr. V.K. Paul had specifically examined the requirement of a legally enforceable mechanism and international practices and, upon such consideration, had recommended strengthening the existing framework rather than making the UCPMP, 2015 statutory at that stage. According to the learned Solicitor General, the recommendations of the said Committee acted as a catalyst in formation of the UCPMP, 2024, which has introduced enhanced disclosure and oversight mechanisms, CEO self-declarations, stricter provisions relating to gifts, brand reminders, physician samples and CME activities, defined timelines for complaints, audit and referral mechanisms, and the Apex Committee for Pharma Marketing Practices (ACPMP) under the Chairmanship of the Secretary, Department of Pharmaceuticals. He thus submitted that the assertion that the earlier exercise had yielded no concrete outcome was contrary to the record.

15. We have heard the learned counsel appearing for the parties at considerable length and have given our anxious and thoughtful consideration to the submissions advanced. We have also carefully examined the pleadings, documents and other material placed on record.

16. At the outset, this Court considers it appropriate to observe that the issues arising in the present proceedings are of considerable public importance. The matter concerns the adequacy of the existing statutory and regulatory framework governing pharmaceutical marketing practices and the mechanisms for their implementation, monitoring and enforcement. This Court is, therefore, called upon to examine whether the existing framework adequately addresses the concerns relating to ethical practices, transparency and accountability in the pharmaceutical sector, while keeping in view the larger public interest in accessible and affordable healthcare.

17. The material placed before us, including the submissions and material furnished by the petitioners and the intervenors, indicates that the existing framework has not proved entirely effective in preventing and curbing unethical practices in the pharmaceutical sector. The concerns brought to our notice are of considerable significance. In a

sector which has a direct bearing upon the health and well-being of citizens, the efficacy of the regulatory framework cannot be assessed merely by the existence of prescribed norms; it must also be judged by their efficacy, implementation and enforcement. The material on record, therefore, warrants a careful examination of the measures required to strengthen the existing regulatory mechanism, so as to ensure that such practices are effectively checked and do not gain further ground, while safeguarding the larger public interest in ensuring the availability of ethical, accessible and affordable healthcare services.

18. This aspect also finds reflection in the stand taken by the Union of India itself. The material placed on record demonstrates that the concerns arising in these proceedings have been engaging the attention of the involved Departments and have been the subject of deliberations at the highest level. Significantly, the Union of India has now proposed to constitute a Committee to comprehensively examine the issues arising in the present proceedings and to make recommendations regarding the appropriate statutory and regulatory framework for regulating the conduct of pharmaceutical companies, particularly with a view to ensuring that pharmaceutical companies do not indulge in unethical practices in their dealings with medical practitioners. The constitution of such a Committee itself reflects the need for a closer examination of the existing framework and the measures required to strengthen it.

19. The proposed exercise assumes significance as the efficacy of any regulatory framework depends not merely upon the standards and obligations prescribed therein, but equally upon the existence of effective mechanisms for implementation, monitoring, transparency and accountability. It is necessary to ensure that the safeguards incorporated in the regulatory framework are capable of being meaningfully enforced in practice, and that appropriate measures are available to identify, address and prevent violations. Such a framework must, ultimately, ensure that the legitimate interests of the pharmaceutical industry are balanced with the paramount consideration of protecting patients and safeguarding the larger public interest in ethical, accessible and affordable healthcare.

20. At this juncture, it is necessary to bear in mind the constitutional and institutional contours within which the present issue falls for consideration. The regulation of pharmaceutical marketing practices

entails questions of legislative and executive policy, including the choice of the appropriate statutory framework, the nature and extent of regulatory oversight, the permissible contours of industry practices, and the mechanisms for monitoring and enforcement. These matters fall primarily within the domain of the Union of India and its authorities, who are better equipped, by virtue of their institutional expertise and access to relevant material, to assess the competing considerations and formulate an appropriate regulatory policy. This Court, while exercising its constitutional jurisdiction, must therefore remain mindful of the doctrine of separation of powers and cannot substitute its own policy determination for that of the executive. At the same time, the Court is required to ensure that the regulatory framework ultimately adopted is consistent with the constitutional guarantees and the larger public interest.

21. At the same time, judicial restraint cannot be understood as requiring this Court to remain indifferent where the material before it discloses concerns having a direct bearing upon public health and the right to health. The present proceedings have already resulted in a consultative exercise being undertaken by the Union of India, culminating in the proposal to constitute a Committee to examine the issues arising herein and to recommend an appropriate statutory and regulatory framework. At this stage, therefore, the role of this Court is not to enter into the domain of policy formulation, but to facilitate a meaningful and effective consultative process, ensuring that the concerns raised and the suggestions placed before the Court receive due and objective consideration. Such an approach would preserve the institutional boundaries between the judicial and executive domains while ensuring that the exercise undertaken by the competent authorities is comprehensive, informed and capable of translating into an effective regulatory framework in the larger public interest.

22. In view of the aforesaid discussion, and having regard to the constitutional obligation to protect the right to health as well as the continuing need for an effective and enforceable framework to regulate pharmaceutical marketing practices, we consider it appropriate to exercise our jurisdiction under Articles 32 and 142 of the Constitution of India. The directions which follow are intended to secure effective implementation of the existing framework and to facilitate the ongoing exercise of the Union of India towards evolving an appropriate regulatory mechanism.

23. In exercise of the powers under Articles 32 and 142 of the Constitution of India, and in furtherance of the constitutional mandate under Article 21, this Court hereby issues the following directions: -

A. The Union of India shall, if not already constituted, constitute the Committee proposed by it within a period of two weeks from the date of this order.

B. The Committee so constituted shall undertake a holistic and comprehensive examination of all issues relating to unethical pharmaceutical marketing practices, including the adequacy of the existing statutory and regulatory framework, the efficacy of the mechanisms presently in place for monitoring, oversight and enforcement, and the measures required to ensure greater transparency, accountability and effective compliance, with a view to strengthening the regulatory framework and safeguarding the larger public interest.

C. The Committee shall take into consideration the material already placed on record before this Court by the petitioners and the intervenors, and shall also afford them a reasonable opportunity to place before it their respective views, suggestions and concerns. The Committee shall also provide an appropriate opportunity to other stakeholders concerned with the subject matter to place their representations, so as to enable a comprehensive and informed consideration of all aspects of the issues under examination.

D. The Committee shall duly consider the suggestions, representations and concerns placed before it by the petitioners, the intervenors and other stakeholders, and shall, upon an objective and comprehensive consideration thereof, make its recommendations to the Union of India regarding the appropriate regulatory and/or statutory framework for effectively regulating pharmaceutical marketing practices, keeping in view the need for transparency, accountability and effective enforcement.

E. For the purposes of undertaking an informed, comprehensive and objective examination of the issues, the Committee shall be at liberty to seek the assistance of such technical, professional and domain experts, institutions or bodies as it may consider necessary, and may obtain such expert inputs

as may be required for a proper appreciation of the regulatory, medical, pharmaceutical and other relevant aspects arising for its consideration.

F. The Committee shall endeavour to complete the entire exercise in a time-bound manner and submit its recommendations to the Union of India within a period of two months from the date of its first meeting, after duly undertaking the consultative process and considering the material and suggestions placed before it.

G. The Union of India shall, upon receipt of the recommendations of the Committee, duly consider the same and take an appropriate and reasoned decision at the earliest, having regard to the constitutional mandate under Article 21 of the Constitution of India and the larger public interest involved in ensuring ethical, transparent and accountable pharmaceutical marketing practices.

24. The Union of India shall file a compliance affidavit before this Court, setting out the steps taken pursuant to the aforesaid directions, including the constitution of the Committee, the date of its first meeting, the manner in which the consultative process has been undertaken, and the progress made towards completion of the exercise. The affidavit shall also place on record the recommendations of the Committee and the decision taken thereon by the Union of India, together with the further measures proposed to be undertaken for strengthening the regulatory framework governing pharmaceutical marketing practices. The compliance affidavit shall be filed within two weeks of the expiry of the period prescribed for completion of the exercise by the Committee.

25. List on 29th January, 2027, as Part-Heard, for consideration of the compliance affidavit to be filed by the Union of India.

Result of the case: Directions issued.

†*Headnotes prepared by:* Ankit Gyan