

To,

June 25, 2025

Dr. Rajeev Singh Raghuvanshi,
Drugs Controller General of India (DCGI),
Central Drugs Standard Control Organization,
Ministry of Health and Family Welfare,
Directorate General of Health Services,
Government of India FDA Bhavan, ITO, Kotla Road,
New Delhi -110002.

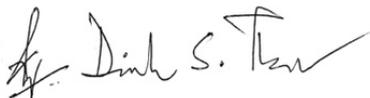
Dear Dr. Raghuvanshi,

Sub: Regarding the CDSCO's legal strategy in the case pertaining to the constitutionality of Rule 106B of the Drugs & Cosmetics Rules, 1945

1. I am writing this letter to bring to your attention the questionable legal strategy adopted by your predecessors at the CDSCO with regard to a petition filed before the Supreme Court challenging the constitutionality of Rule 106B of the Drugs & Cosmetics Rules, 1945.
2. As you may know, Rule 106B limits the alcoholic content in homeopathic preparations at 12% v/v for 30 ml sold in the open market. This rule was originally introduced in 1994 after a similar Rule 161 was brought in to limit the amount of alcohol in certain Ayurvedic preparations. The notification published Rule 106B in the Gazette of India, in 1994, is attached as **Annexure A**. The aim of the rule was to limit the amount of alcohol in homeopathic preparations since it came into evidence that many persons were consuming these preparations as a substitute for higher priced alcoholic beverages.
3. The homeopathic industry was deeply unhappy with Rule 106B and they filed multiple petitions before four different High Courts. The High Courts dismissed all the challenges against Rule 106B and in 2014 the Supreme Court too dismissed three appeals against the decisions of the High Courts on 5th December 2014.
4. A year later, in 2015, a manufacturer of homeopathic preparations filed a constitutional challenge against Rule 106B before the Calcutta High Court alleging that the Government never laid the rule before both houses of Parliament for 30 days as required by Section 38 of the Drugs & Cosmetics Rules, 1945. The Calcutta High Court found merit in that argument and restrained the Government from enforcing the provision until such time that it complied with the requirements of Section 38. Similar challenges were filed by the industry before the High Court of Punjab & Haryana, High Court of Himachal Pradesh, High Court of Rajasthan, High Court of Uttarakhand, High Court of Delhi and High Court of Patna and similar orders were procured against the continued operation of Rule 106B.

5. At this juncture, if the CDSCO had procured competent legal advice, it would have simply complied with the provisions of Section 38 by placing Rule 106B before both Houses of Parliament for a period of 30 days. Instead, in February, 2017 the CDSCO authorised R. Chandrashekhar, Deputy Drugs Controller to file a transfer petition requesting the Supreme Court to transfer to itself, all the pending cases before all High Courts. The transfer petition was allowed by the Supreme Court and all the petitions were transferred to itself on 10th November, 2017. A copy of the Supreme Court's order is attached as **Annexure B**. The matter has remained pending before the Supreme Court without any resolution since that date. As a result, Rule 106B has not been enforced for the last ten years since the first stay granted by the Calcutta High Court.
6. Given the manner in which the CDSCO has conducted this litigation, it is evident that it is receiving poor legal advice. While I am writing to other competent authorities seeking that they place Rule 106B before both Houses of Parliament, I request you to conduct a comprehensive review of the manner in which the CDSCO conducts litigation. Very often, the department does not file appeals challenging questionable orders, as was the case with regard to the Section 26A order against a fixed dose combination (FDC) of Flupenthixol and Melitracen. It lost twice before the High Court of Karnataka and never filed an appeal. As a result, a FDC deemed to be lacking in a therapeutic justification continues to be sold in the Indian market. Similarly in this case, it needlessly filed a transfer petition instead of placing Rule 106B before both Houses of Parliament, which would have resolved the issue promptly.
7. As I am sure you will agree with me, regulatory law is part science and part law. The CDSCO cannot afford to ignore sound legal strategy while dealing with the pharmaceutical industry. Creating a litigation policy for the department and ensuring transparency in the conduct of litigation will go a long way in ensuring better outcomes. Even simple measures such as publishing the details on the CDSCO's website of all litigation pending in different parts of the country and the officers responsible for the same will help improve accountability within the CDSCO and of the CDSCO toward the citizens of India.
8. I sincerely hope you take appropriate measures to revamp the manner in which the CDSCO handles its litigation so as to prevent other such cases like the litigation against Rule 106B do not languish in the courts for want of sound legal strategy which has not been enforced for 10 years now.

Sincerely,



Dinesh Thakur
SW4, World Spa West
Sector 31,
Gurugram, Haryana, 122001
dinesh.thakur@gmail.com

Annexure A



भारत का राजपत्र The Gazette of India

असाधारण
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 81]

नई दिल्ली, मंगलवार, फरवरी 22, 1994/फाल्गुन 3, 1915

No. 81]

NEW DELHI, TUESDAY, FEBRUARY 22, 1994/PHALGUNA 3, 1915

स्वास्थ्य और परिवार कल्याण मंत्रालय
(स्वास्थ्य विभाग)

ग्रधिमूचना

नई दिल्ली, 22 फरवरी, 1994

मा. का. नि. 108(प्र).—ओपधि और प्रमाधन मामगी नियम 1945 का और संशोधन करने के लिए कनिषय नियमों का एक प्रारूप, ओपधि और प्रमाधन मामगी ग्रधिनियम, 1940 (1940 का 23) की धारा 12 और धारा 33 की अपेक्षानुसार भारत के राजपत्र, असाधारण, भाग 2, खंड 3, उपखंड (1), तारीख 3 जुलाई, 1992 में भारत सरकार के स्वास्थ्य और परिवार कल्याण मंत्रालय (स्वास्थ्य विभाग) की ग्रधिमूचना संख्यांक मा. का. नि. 662(प्र), तारीख 3 जुलाई, 1992 द्वारा प्रकाशित किया गया था जिसमें उक्त सभी व्यक्तियों से, जिनके उससे प्रभावित होने की संभावना थी, उक्त तारीख से, जिसको राजपत्र की प्रतियां जनता को उपलब्ध करा दी गई थी, साठ दिन की अवधि की समाप्ति के पूर्व आक्षेप और सुझाव मांगे गए थे।

और राजपत्र की प्रतियां जनता को 4 दिसम्बर, 1992 को उपलब्ध करा दी गई थीं।

और केन्द्रीय सरकार ने, उक्त प्रारूप नियम के संबंध में जनता से प्राप्त आक्षेपों और सुझावों पर विचार कर लिया है।

प्रतः, प्रव. केन्द्रीय सरकार, उक्त ग्रधिनियम की धारा 12 और धारा 33 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, ओपधि सहाहकार

बॉर्ड से परामर्श करने के पश्चात् ओपधि और प्रमाधन मामगी नियम 1945 का और संशोधन करने के लिए निम्नलिखित नियम बनाती है, अर्थात्—

(1) इन नियमों का मंथित नाम ओपधि और प्रमाधन मामगी (प्रथम संशोधन) नियम, 1994 है।

(2) ये राजपत्र में प्रकाशन की तारीख से चार मास के पश्चात् प्रवृत्त होंगे।

2. ओपधि और प्रमाधन मामगी नियम, 1945 के विान 103 क में :

(i) उपनियम (प्र) में, खंड (5) के पश्चात् परन्तुक के स्थान पर निम्नलिखित परन्तुक रखा जाएगा, अर्थात्—

“परन्तु यदि आधान में संयुक्त होमियोपैथिक ओपधि का कुल परिमाण 30 मिलीलीटर या उससे कम है तो लेबल पर एल्कोहल संरक्षक कथित करना आवश्यक नहीं होगा।”

(ii) उपनियम (द) के पश्चात् निम्नलिखित नियम अंतःस्थापित किया जाएगा, अर्थात् :-

“106 ख. परिमाण और प्रविशानता पर प्रतिबंध—ऐसी कोई होमियोपैथिक ओपधि जिसमें वो/बी एल्कोहल (एथिल एल्कोहल) 12 प्रतिशत से अधिक है 30 मिलीलीटर से अधिक की पैकिंग या बोतलों में

पेक और विक्रम नहीं की जाएगी, सिवाय इसके कि उसका 100 मिली-लीटर में अधिक की पैकिंग या बोतलों में अथवा नालों/ओषधानियों को विक्रम किया जा सकेगा।”

[सं. 18-6/92—डी. सी. (डी एम एस एवं पी एफ 5)]

शैलजा चन्द्र, संयुक्त सचिव

औषधि और प्रसाधन सामग्री नियम, 1945, 1-5-79 तक यथा संशोधित रूप में स्वास्थ्य और परिवार कल्याण (स्वास्थ्य विभाग) उपखंड में जिनमें औषधि और प्रसाधन सामग्री, अधिनियम और नियम (पी. डी. बी. एम.) भी सम्मिलित हैं, अन्तर्निष्ठ हैं। तत्पश्चात् उक्त नियमों में भारत के राजपत्र भाग-2, खंड-3 (3) (i) में प्रकाशित निम्न-लिखित अधिसूचनाओं द्वारा संशोधित किए गए हैं:—

1. सा. का. नि. 1241 तारीख 6-10-1979
2. सा. का. नि. 1242 तारीख 6-10-1979
3. सा. का. नि. 1243 तारीख 6-10-79
4. सा. का. नि. 1281 तारीख 12-10-79
5. सा. का. नि. 430 तारीख 19-4-80
6. सा. का. नि. 779 तारीख 26-7-80
7. सा. का. नि. 540(अ) तारीख 22-9-80
8. सा. का. नि. 680(अ) तारीख 5-12-80
9. सा. का. नि. 681(अ) तारीख 5-12-80
10. सा. का. नि. 682(अ) तारीख 5-12-80
11. सा. का. नि. 27(अ) तारीख 17-1-81
12. सा. का. नि. 478(अ) तारीख 6-8-81
13. सा. का. नि. 62(अ) तारीख 15-2-82
14. सा. का. नि. 462(अ) तारीख 22-6-82
15. सा. का. नि. 510(अ) तारीख 26-7-82
16. सा. का. नि. 13(अ) तारीख 26-7-82
17. सा. का. नि. 318(अ) तारीख 1-5-84
18. सा. का. नि. 331(अ) तारीख 8-5-84
19. सा. का. नि. 460(अ) तारीख 20-6-84
20. सा. का. नि. 487(अ) तारीख 2-07-84
21. सा. का. नि. 89(अ) तारीख 16-2-85
22. सा. का. नि. 758(अ) तारीख 10-10-85
23. सा. का. नि. 17(अ) तारीख 7-1-84
24. सा. का. नि. 1049(अ) तारीख 29-5-86
25. सा. का. नि. 1060 (अ) तारीख 5-9-86
26. सा. का. नि. 1115(अ) तारीख 30-9-86
27. सा. का. नि. 71(अ) तारीख 30-1-87
28. सा. का. नि. 570(अ) तारीख 12-6-87
29. सा. का. नि. 626(अ) तारीख 2-7-87
30. सा. का. नि. 792(अ) तारीख 17-9-87
31. सा. का. नि. 371(अ) तारीख 14-3-88
32. सा. का. नि. 75(अ) तारीख 2-6-88
33. सा. का. नि. 675(अ) तारीख 2-6-88
34. सा. का. नि. 676(अ) तारीख 2-6-88
35. सा. का. नि. 677(अ) तारीख 2-6-89
36. सा. का. नि. 681(अ) तारीख 6-6-88
37. सा. का. नि. 735(अ) तारीख 24-6-88
38. सा. का. नि. 813(अ) तारीख 27-7-88
39. सा. का. नि. 944(अ) तारीख 21-9-88
40. सा. का. नि. 43(अ) तारीख 20-1-89
41. सा. का. नि. 44(अ) तारीख 20-1-89
42. सा. का. नि. 100(अ) तारीख 14-2-89
43. सा. का. नि. 443(अ) तारीख 12-4-89

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44. सा. का. नि. 588(अ) तारीख 2-6-89.
45. सा. का. नि. 691(अ) तारीख 11-7-89
46. सा. का. नि. 784(अ) तारीख 28-8-89
47. सा. का. नि. 16(अ) तारीख 1-10-89
48. सा. का. नि. 731(अ) तारीख 23-8-90
49. सा. का. नि. 865(अ) तारीख 25-10-90
50. सा. का. नि. 11(अ) तारीख 7-1-91
51. सा. का. नि. 223(अ) तारीख 19-4-91
52. सा. का. नि. 246(अ) तारीख 1-5-91
53. सा. का. नि. 301(अ) तारीख 7-6-91
54. सा. का. नि. 302(अ) तारीख 7-6-91
55. सा. का. नि. 491(अ) तारीख 25-7-91
56. सा. का. नि. 495(अ) तारीख 25-7-91
57. सा. का. नि. 532(अ) तारीख 14-8-91
58. सा. का. नि. 626(अ) तारीख 14-10-91
59. सा. का. नि. 668(अ) तारीख 7-11-91
60. सा. का. नि. 730(अ) तारीख 10-12-91
61. सा. का. नि. 59(अ) तारीख 22-1-92
62. सा. का. नि. 305(अ) तारीख 4-3-92
63. सा. का. नि. 445(अ) तारीख 30-1-92
64. सा. का. नि. 597(अ) तारीख 17-6-92
65. सा. का. नि. 663(अ) तारीख 3-7-92
66. सा. का. नि. 723(अ) तारीख 11-8-92
67. सा. का. नि. 798(अ) तारीख 1-10-92
68. सा. का. नि. 877(अ) तारीख 17-11-92
69. सा. का. नि. 909(अ) तारीख 7-12-92
70. सा. का. नि. 923(अ) तारीख 14-12-92
71. सा. का. नि. 27(अ) तारीख 22-1-93 (शुद्धिपत्र)
72. सा. का. नि. 28(अ) तारीख 22-1-93
73. सा. का. नि. 86(अ) तारीख 26-2-93
74. सा. का. नि. 296(अ) तारीख 24-3-93
75. सा. का. नि. 373(अ) तारीख 13-4-93 (शुद्धिपत्र)
76. सा. का. नि. 374(अ) तारीख 13-4-93 (शुद्धिपत्र)
77. सा. का. नि. 447(अ) तारीख 10-6-93 (शुद्धि पत्र)
78. सा. का. नि. 658(अ) तारीख 19-10-93

शुद्धिपत्र

शुद्धिपत्र

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 22nd February, 1994

G.S.R. 108(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required by Sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), with the Notification of the Government of India, in the Ministry of Health and Family Welfare (Department of Health) Number GSR 662(E), dated

the 3rd July, 1992 in the Gazette of India Extraordinary Part II, Section 3, Sub-section (i), dated the 3rd July, 1992 inviting objections and suggestions from all persons likely to be affected thereby before the expiry of period of sixty days from the date on which the copies of the Gazette were made available to the public.

And whereas the copies of the Gazette were made available to the public on the 4-12-92.

And whereas the objections and suggestions received from the public on the said draft rules have been taken into consideration by the Central Government.

Now, therefore, in exercise of the powers conferred by Sections 12 and 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely :—

1. (1) These rules may be called the Drugs and Cosmetics (1st Amendment) Rules, 1994.

(2) They shall come into force after four months from the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in rule 106 A :—

(i) In sub-rule (a), after clause (v), the proviso shall be substituted namely :—

“Provided that in case that the total quantity of the pharmacopoeial Homoeopathic medicine in the container is 30 millilitre or less, it will not be necessary to state the content of alcohol in the label.”

(ii) after sub-rule (c) the following rule shall be inserted, namely :—

“106-B. Prohibition of quantity and percentage—No homoeopathic medicine containing more than 12% alcohol v/v (Ethyl Alcohol) shall be packed and sold in packing or bottles of more than 30 millilitres, except that it may be sold to hospitals/dispensaries in packings or bottles of not more than 100 millilitres.”

[No. 18-6/92(DC)DMS & PFA]

SHAILAJA CHANDRA, Jt. Secy.

Note : The Drugs & Cosmetics Rules, 1945 as amended upto 1-5-1979 is contained in the publication of the Ministry of Health & Family Welfare (Department of Health) containing the Drugs & Cosmetics Act and the Rules (PDGHS-61). Subsequently the said rules have been amended by the

following notifications published in Part II, Section 3, Sub-section (i) of the Gazette of India, namely :—

1. GSR 1241 dated 6-10-1979
2. GSR 1242 dated 6-10-1979
3. GSR 1243 dated 6-10-1979
4. GSR 1281 dated 12-10-1979
5. GSR 430 dated 19-04-1980
6. GSR 779 dated 26-7-1980.
7. GSR 540(E), dated 22-9-1980
8. GSR 680(E), dated 5-12-1980
9. GSR 681(E), dated 5-12-1980
10. GSR 682(E), dated 5-12-1980.
11. GSR 27(E), dated 17-1-1981
12. GSR 478(E), dated 6-8-1981
13. GSR 62(E), dated 5-2-1982
14. GSR 462(E), dated 22-6-1982
15. GSR 510(E), dated 26-7-1982
16. GSR 13(E), dated 7-1-1983
17. GSR 318(E), dated 1-5-1984
18. GSR 331(E), dated 8-5-1984
19. GSR 460(E), dated 20-6-1984
20. GSR 487(E), dated 2-7-1984
21. GSR 89(E), dated 16-2-1985
22. GSR 758(E), dated 10-10-1985
23. GSR 17(E), dated 7-1-1986
24. GSR 1049(E), dated 29-8-1986
25. GSR 1060(E), dated 5-9-1986
26. GSR 1115(E), dated 30-9-1986
27. GSR 71(E), dated 30-1-1987
28. GSR 570(E), dated 12-6-1987
29. GSR 626(E), dated 2-7-1987
30. GSR 792(E), dated 17-9-1987
31. GSR 371(E), dated 24-3-1988
32. GSR 75(E), dated 2-6-1988
33. GSR 675(E), dated 2-6-1988
34. GSR 676(E), dated 2-6-1988
35. GSR 677(E), dated 2-6-1988
36. GSR 680(E), dated 6-6-1988
37. GSR 735(E), dated 24-6-1988
38. GSR 813(E), dated 27-7-1988
39. GSR 944(E), dated 21-9-1988 Corrigendum
40. GSR 43(E), dated 20-1-1989 Corrigendum
41. GSR 44(E), dated 20-1-1989 Corrigendum
42. GSR 100(E), dated 14-2-1989 Corrigendum
43. GSR 443(E), dated 12-4-1989
44. GSR 588(E), dated 2-6-1989 Corrigendum
45. GSR 691(E), dated 11-7-1989
46. GSR 784(E), dated 28-8-1989
47. GSR 16(E), dated 10-1-1990

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| 48. GSR 731(E), dated 23-8-1990 | 65. GSR 663(E), dated 3-7-1992 |
| 49. GSR 865(E), dated 25-10-1990 | 66. GSR 723(E), dated 11-8-1992 |
| 50. GSR 11(E), dated 7-1-1990 | 67. GSR 796(E), dated 1-10-1992 |
| 51. GSR 223(E), dated 19-4-1991 | 68. GSR 904(E), dated 2-11-1992 |
| 52. GSR 246(E), dated 1-5-1991 | 69. GSR 877(E), dated 17-11-1992 |
| 53. GSR 301(E), dated 7-6-1991 | 70. GSR 923(E), dated 14-12-1992 |
| 54. GSR 302(E), dated 7-6-1991 | 71. GSR 27(E), dated 22-1-1993 (Corrigendum) |
| 55. GSR 491(E), dated 25-7-1991 | 72. GSR 28(E), dated 22-1-1993 |
| 56. GSR 495(E), dated 25-7-1991 | 73. GSR 86(E), dated 26-2-1993 |
| 57. GSR 532(E), dated 14-8-91 | 74. GSR 296(E), dated 24-3-1993 |
| 58. GSR 626(E), dated 1-10-1991 | 75. GSR 373(E), dated 13-4-1993 |
| 59. GSR 668(E), dated 1-11-1991 | 76. GSR 374(E), dated 13-4-1993 |
| 60. GSR 730(E), dated 10-12-1991. | 77. GSR 447(E), dated 10-6-93 (Corrigendum) |
| 61. GSR 59(E), dated 22-1-1992 | 78. GSR 658(E), dated 19-10-93 |
| 62. GSR 305(E), dated 4-3-1992 Corrigendum | |
| 63. GSR 445(E), dated 30-4-1992 | |
| 64. GSR 597(E), dated 17-6-1992 | |

Annexure B

ITEM NO.201

COURT NO.9

SECTION XIIA

S U P R E M E C O U R T O F I N D I A
R E C O R D O F P R O C E E D I N G S

Petition(s) for Special Leave to Appeal (C) No(s). 17839/2007

(Arising out of impugned final judgment and order dated 20/07/2007 in WP No. 21636/1994 passed by the High Court of A.P. at Hyderabad)

RAMAKRISHNA PHARMASEUTICALS

Petitioner(s)

VERSUS

UNION OF INDIA & ORS.

Respondent(s)

(with appln. (s) for impleadment and intervention and office report)

[FOR FINAL DISPOSAL]

WITH

SLP(C) No. 6431/2008

(With Interim Relief and Office Report)

SLP(C) No. 9486/2008

(With Interim Relief and Office Report)

W.P.(C) No. 148/2010

(With appln.(s) for stay and appln.(s) for intervention and stay and office report)

Date : 05/12/2014 These petitions were called on for hearing today.

CORAM :

HON'BLE MR. JUSTICE MADAN B. LOKUR

HON'BLE MRS. JUSTICE R. BANUMATHI

For Petitioner(s)

SLP 17839

Mr. Vidya K. Sagar, Adv.

Mr. S. K. Sabharwal, Adv.

SLP 6431

Mr. Praveen Kumar Singh, Adv.

Mr. Balkrishan Sharma, Adv.

Mr. M.D. Ziauddin Ahmad, Adv.

Mr. Rajiv Shankar Dvivedi, Adv.

SLP 9486

Mr. Akhilesh Kr. Pandey, Adv.

Mr. Shrish Kumar Misra, Adv.

WP 148

Mr. Partha Sil, Adv.

Signature Not Verified

Digitally signed by
Pardeep Kumar
Date: 2014.12.05
17:05:58 SAST
Reason: 

For Respondent(s) Mr. K. Datta, Adv.
Mr. Manish Srivastava, Adv.
Mr. Ashish Verma, Adv.
Mr. Abhay Kumar, Adv.

Mr. Atishi Dipankar, Adv.

Mr. P.S. Patwalia, ASG
Ms. Sunita Sharma, Adv.
Ms. Charul Sareen, Adv. for
Mr. D. S. Mahra, Adv.

UPON hearing the counsel the Court made the following
O R D E R

SLP (C) Nos. 17839/2007, 6431/2008, 9486/2008:

Special leave petitions are dismissed. Pending application(s), if any, stands disposed of.

W.P. (C) No. 148 of 2010:

Learned counsel for the petitioners seeks withdrawal of writ petition.

Writ Petition is, accordingly, dismissed as withdrawn with liberty to the petitioners to approach the High Court.

(PARDEEP KUMAR)
AR-cum-PS

(JASWINDER KAUR)
COURT MASTER