

भारतीय आयुर्विज्ञान परिषद् MEDICAL COUNCIL OF INDIA

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पॉकेट - % सेक्टर - ६ द्वारका नई दिल्ली - 110 077 Pocket - 14, Sector - 8, Dwarka, New Delhi - 110 077

Platinum Jubilee (1933 - 2008)

Steno4/E:/Swati 27.04.2009/Legal/Letter (Oct 10)

No. MCI - 211(2)/2010/Ethics/Gen./33690.

Dated: 12 10 2010

To

The Registrar

All the State Medical Councils

Subject: - Order of the Hon'ble Supreme Court in WP© No. 535/1998 titled Sahara House Vs. UOI & Other connected petitions dated 01.10.2010.

Sir,

This is to inform you that the Hon'ble Supreme Court of India has directed the MCI to issue following directions to private doctors treating HIV patients: -

"Furnish the information in respect of HIV patients who are clinically evaluated to be in need of second line – Anti Retro Viral Drug in format attached to the Guidelines for Prescription of Anti Retro Viral Therapy dated 09.09.2010 issued by the Government of India on 09.09.2010 to the National Aids Control Organization (NACO)."

In pursuance to the order of the Hon'ble Supreme Court in the above referred case, you are hereby directed to circulate among all the private doctors treating HIV patients, the following information in the format enclosed with the Guidelines for Prescription of Anti Retro Viral Therapy dated 09.09.2010. Your attention is drawn to the Regulations 7.2 of the Indian Medical Council (Professional Conduct, Etiquette & Ethics) Regulations 2002 and the same is quoted hereunder for ready reference: -

7.2 If he/she does not maintain the medical records of his/her indoor patients for a period of three years as per regulation 1.3 and refuses to provide the same within 72 hours when the patient or his/her authorized representative makes a request for it as per the regulation 1.3.2."

Your attention is also invited to the Regulation 1.3.1 and 1.3.2 which requires maintenance of medical records by every physician. Regulation 1.3.1 and 1.3.2 are relevant clauses and the same are being reproduced for the sake of ready reference: -

*.3 Maintenance of medical records:

- **1.**3.1 Every physician shall maintain the medical records pertaining to his the indoor patients for a period of 3 years from the date of commencement of the treatment in a standard proforma laid down by the Medical Council of India and attached as **Appendix 3**.
- 1.3.2. If any request is made for medical records either by the patients / authorised attendant or legal authorities involved, the same may be duly acknowledged and documents shall be issued within the period of 72 hours.

दूरभाष ६ Phone: +91-11-25367033, 25367035, 25367036 ● फैक्स ६ Fax: +91-11-25367024

इमेल / E-mail : mci@bol.net.in , contact@mciindia.org ● वेबसाईट ः Website : www.mciindia.org



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In view of the directions of the Hon'ble Supreme Court, you are hereby directed to circulate among all the private doctors who are treating HIV patients, the Guidelines for Prescription of Anti Retro Viral Therapy alongwith the attached format and further direct the private doctors to furnish the information in requisite format immediately to NACO and every quarterly also.

You may also bring to the notice of the private doctors that breach of directions of the Hon'ble Supreme Court for the private doctors in furnishing the above said information would not only amount to violation of the order of the Hon'ble Supreme Court but also violation of the IMC Regulations as quoted above. You may also bring to the notice of the private doctors that they are required to follow the directions scrupulously and without breach. I may mention here that non-adherence of the above said directions by the private doctors may lead to initiation of appropriate proceedings under Indian Medical Council (Professional Conduct, Etiquette & Ethics) Regulations 2002.

A compliance report may kindly be sent to the office of the Council.

Thanking you

Yours faithfully

(Dr. Reena Yayyar)
Deputy Secretary

Enclosures:

1. Supreme Court order dated 01.10.2010

2. Guidelines for Prescription of Anti Retro Viral Therapy dated 09.09.2010 and attached format.

S U P R E M E C O U R T O F I N D I A RECORD OF PROCEEDINGS

WRIT PETITION (CIVIL) NO.535 OF 1998

SAHARA HOUSE

Petitioner(s)

VERSUS

U.O.I. & ORS

Respondent(s)

(With office report)

With W.P. (C) No.512 of 1999 (With appln(s) for amendment of the petition, directions, impleading party and ad-interim orders)

W.P. (C) No.61 of 2003 (With office report)

W.P. (C) No.311 of 2003 (With appln(s) for directions, permission to file additional documents and office report)

Date: 01/10/2010 These Matters were called on for hearing today.

CORAM :

HON'BLE THE CHIEF JUSTICE

HON'BLE MR. JUSTICE K.S. RADHAKRISHNAN HON'BLE MR. JUSTICE SWATANTER KUMAR

For Petitioner(s)

In WP 535/1998:

Mr. Naveen R. Nath, Adv. (A.C.)

In WP 512/1999:

Mr. Chander Uday Singh, Sr. Adv.

Ms. Shivangi, Adv.

Mr. Naveen R. Nath, Adv.

In WP 61/2003:

Ms. Kamini Jaiswal,Adv.
Mr. Sandeep S. Parekh,Adv.
Mr. Abhimanue Shrestha,Adv.

Mr. D.P. Singh, Adv.

In WP 311/2003:

Mr. Colin Gonsalves, Sr. Adv.

Mr. Tariq Abeed, Adv. Ms. Jyoti Mendiratta, Adv.

...2/-

For Respondent(s)

- Mr. Ashok Bhan, Adv.
- Mr. Subhash Kaushik, Adv.
- Mr. Arvind Kumar Sharma, Adv.
- Mr. Sudhir Kumar Gupta, Adv.
- Mr. Abhinav Mukerji, Adv.
- Mr. T.S. Doabia, Sr. Adv.
- Mr. Aman Ahluwalia, Adv.
- Mr. Manpreet Singh Doabia, Adv.
- Mr. Vikas Bansal, Adv.
- Ms. Sadhana Sandhu, Adv.
- Ms. Pia Singh, Adv.
- Mr. D.S. Mahra, Adv.
- Ms. Sunita Sharma, Adv.
- Mr. Aman Verma, Adv.
- Mr. Janaranjan Das, Adv.
- Mr. Ranjan Mukherjee, Adv.
- Mr. S. Bhowmick, Adv.
- Mr. S.C. Ghosh, Adv.
- Mr. T.V.George, Adv.
- Mr. G. Prakash, Adv.
- Ms. Beena Prakash, Adv.
- Mr. V. Senthil, Adv.
- Ms. Sushma Suri, Adv.
- Mr. Anuvrat Sharma, Adv.
- Ms. Alka Sinha, Adv.
- Mr. Naresh K. Sharma, Adv.
- Mr. T. Harish Kumar, Adv.
- Mr. P. Prasanth, Adv.
- Mr. V. Vasudevan, Adv.
- Mr. Pragyan P. Sharma, Adv.
- Mr. P.V. Yogeswaran, Adv.
- Mr. Gopal Subramaniam, SG.
- Mr. T.S. Doabia, Sr. Adv.
- Mr. Aman Ahluwalia, Adv.
- Ms. Sadhana Sandhu, Adv.
- Mr. Manpreet Singh Doabia, Adv.
- Ms. Pia, Adv.
- Mr. Vikas Bansal, Adv.
- Mr. D.S. Mahra, Adv.

Ms. A. Subhashini, Adv.

Mr. Ansar Ahmad Chaudhary, Adv.

Mr. Khwairakpam Nobin Singh, Adv.

Mr. Sapam Biswajit Meitei, Adv.

Mr. T.C. Sharma, Adv.

Mr. V.G. Pragasam, Adv.

Mr. S.J. Aristotle, adv.

Mr. Praby Ramasubramanian, Adv.

Mr. L.A.J. Selvam, Adv.

Mr. Edward Belho, Adv.

Ms. K. Enatoli Sema, Adv.

Mr. Rituraj Biswas, Adv.

Mr. Sanjay V. Kharde, Adv.

Ms. Asha G. Nair, Adv.

Mr. Janaranjan Das, Adv.

Mr. P.N. Ramalingam, Adv.

Mr. Ravindra Keshavrao Adsure, Adv.

Mr. Sanjay R. Hegde, Adv.

Mr. Ramesh Kumar Mishra, Adv.

Mr. Krutin Joshi, Adv.

Mr. Abhishek Malviya, Adv.

Mr. Tara Chandra Sharma, Adv.

Ms. Neelam Sharma, Adv.

Mr. Gopal Singh, Adv.

Mr. Manish Kumar, Adv.

Mr. Gopal Singh, Adv.

Mr. Rituraj Biswas, Adv.

Mr. P.P. Malhotra, ASG.

Ms. Vimla Sinha, Adv.

Mr. Shailendra Sharma, Adv.

Ms. Anil Katiyar, Adv.

Mr. Navneet Kumar, Adv.

for M/s. Corporate Law Group, Advs.

Ms. Vibha Datta Makhija, Adv.

Mr. Saurabh Mishra, Adv.

Mr. Ramesh Babu M.R., Adv.

Ms. Hemantika Wahi, Adv.

Ms. Nupur Kanungo, Adv.

Mr. A. Mariarputham, AG., Sikkim

Ms. Aruna Mathur, Adv.

Mr. Amarjeet Singh Girsa, Adv.

for M/s. Arputham, Aruna & Co., Advs.

Mr. Anil Shrivastav, Adv.

Mr. Ritu Raj, Adv.

Mr. Guntur Prabhakar, Adv.

Mr. Naresh K. Sharma, Adv.

Mr. Anjani Kumar Jha, Adv.

Mr. T.S. Doabia, Sr. Adv.

Mr. Manpreet Singh Doabia, Adv.

Ms. Sushma Suri, Adv.

Mr. Pragyan P. Sharma, Adv.

Mr. P.V. Yogeswaran, Adv.

Mr. Arun K. Sinha, Adv.

Mr. Atul Jha, Adv.

Mr. D.K. Sinha, Adv.

Mr. Anil K. Jha, Adv.

Mr. Santosh Kumar, Adv.

Mr. Manjit Singh, Adv.

Mr. Kamal Mohan Gupta, Adv.

Dr. Manish Singhvi, AAG

Mr. Devanshu Kumar Devesh, Adv.

Mr. Sahjil S. Chauhan, Adv.

Mr. Milind Kumar, Adv.

Mr. Amit Kumar, Adv.

Mr. Somesh Chandra Jha, Adv.

Ms. Rekha Bakshi, Adv.

Mr. Manoj Pant, Adv.

Mr. Ashish Kumar, Adv.

Mr. R. Nedumaran, Adv. Mr. Vimal Dubey, Adv.

Mr. D. Mahesh Babu, Adv. Mr. Ramesh Allanki, Adv.

UPON hearing counsel the Court made the following

ORDER

I.A. No.4 in W.P. (C) No.512 of 1999:

present Interlocutory Application, the petitioners herein have challenged the National AIDS Control Organisation's [for short, 'the NACO'] Directives by which the Second Line treatment is made available only to certain specified categories of persons identified and specified criteria. Interlocutory Application been moved also for a further has direction from this Court that all those who are clinically evaluated to be in need of Second Line Anti-Retroviral [for short, the ART'] drugs are provided such treatment free of cost without regard to geographical location, current registration with ART Centres, length of time on first line ART or any other condition.

Having heard arguments at length, we are of the view that, in the first instance, the Quarterly ART Reporting Format for private sector needs to be immediately supplied through NACO to all private hospitals who in turn will fill up the Reporting Format, which is annexed to the affidavit of Union of India dated 9th September, 2010. The ART Reporting Format will be posted on the Website of NACO within two days. The private hospitals would submit

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the data to NACO within two weeks after the Format is put on the Website. For further directions, let this matter stand over for four weeks.

As far private Doctors treating patients are concerned, we hereby direct Medical Council of [for short, `the MCI'], to implement above directions within two weeks from the Reporting Format being put on the Website. The MCI, in turn will issue appropriate directions to the private Doctors, to furnish the requisite information in the ART Reporting Format to NACO. The guidelines will be issued by the MCI within a period of two weeks from today. Ministry We are informed that of Health and Welfare has issued appropriate directions vide communication dated 9th September, 2010.

[Alka Dudeja] A.R.-cum-P.S.

[Madhu Saxena] Assistant Registrar No. T-11020/29/1998(Admin ART)
Government of India
Department of AIDS Control
Ministry of Health and Family Welfare
(National AIDS Control Organization)

6th Floor, Chandralok Building, 36 Janpath, New Delhi-110001 Dated: 09.09.2010

Guidelines for Prescription of Antiretroviral Therapy.

The antiretroviral therapy (ART) is now available free at 284 ART Centres across the country, wherein nearly 3.5 lakh PLHA are getting treatment. Since ART is a lifelong therapy—with significant economic burden on families, we must assess patient's financial condition on affordability of not only lifelong ART but also their capacity for good nutrition, hygiene and other related expenses. Efforts should be made to refer all PLHA to Govt. ART centres for ART and treatment of Ols. This will help them save resources for good nutrition and other family needs. This will also make them eligible for free second line ART once they develop treatment failure on first line ART over a period of time.

All those who can afford or want to take treatment in private sector must be started a rational triple Drug "first line ART (NNRTI based)" unless there is a specific contraindication for the same. The "second line ART (PI based)" should only, be resorted to in case of proven first line failure/ drug toxicity (summary of rational regimen enclosed based on National guidelines). Any unstructured irrational treatment using combination of first line and second line ARV, prescribing incomplete regimen, under dosages of ARV drugs etc by medical practitioners / clinics will have adverse impact on the structured national programme & consequent burden of drug resistance among patients as well as transmission issues. It has also been observed that many a time patients are initiated directly on second line regimen (PI based regimen). All doctors must familiarize themselves with national treatment protocols which can be accessed on NACO website www.nacoonline.org and are updated periodically.

Arr office memorandum no.- T-11020/29/1998(Admin ART) dated 26/08/2008 has already been issued in this regard by NACO and was endorsed by Hon'able Supreme Court in its judgment in Sahara house case no. 535/1998 on 1/10/2008. The court has also directed the Medical Council of India, Dental Council of India and Indian Nursing Council to

ensure compliance with these guidelines. Any irrational use of ARVs or deviation from national protocol will be viewed seriously as a professional misconduct.

It is once again emphasized that all initial ART prescriptions must be rational first line ART regimen. All private practitioners should send a quarterly report of patients with them to NACO & respective State AIDS Control Societies in the prescribed format. (copy

This issues with the approval of Secy. (Department of AIDS Control) & DG, NACO.

(Subhash Chandra) (Under Secretary to the Government of India)

- 1. Project Director, State AIDS Control Society of all States/UTs/Municipal
- 2. Principal Secretary/Secretary (Health & FW) of all States.
- 3. Director (Medical Education), Directorate of Health Services, of All States.
- 4. Director (Health Services), Directorate of Health Services, of All States with request to disseminate this to all hospitals / NGOs/ Health care providers in their state.
- 5. Nodal Officer, All ART Centres.
- 6. Regional Coordinators (CST).
- 7. All NACO officials.
- 8. The Solicitor General, India.
- 9. Medical Council of India
- 10. Dental Council of India
- 11 Indian Nursing Council
- 12. Indian Medical Association
- 13. Association of Physicians of India
- 14. Indian Academy of Paediatrics
- 15. FOGSI.

Copy for information:

- 1. PPS to HFM
- 2. PPS to MOS(H&FW)
- 3. PPS to Secy. (Health & FW)
- 4. PPS to DGHS
- 5. PS to Secy. (AC) & DG, NACO

(Subhash Chandra) Under Secretary to the Government of India

Quarterly ART Reporting Format for Private Sector

Name of District & Sta	- 4	THATE DECIDI			
of District of	ate;				
Reporting Month & Ye	ar:				
Name of Reporting ce	ntre / Doctor:				
Complete Address:	og sam mengens ga og mengelskept og skilter fill de demokalist former og skilter				
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Email :	and the second species of the second				
Contact No (land line & Mobile):					
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No. of PLHA registered with you in HIV care	Male	Female	Children	TG	Total
No. of PLHA ever started on ART by you/ your centre					-
No. of PLHA currently on ART with you/ your centre					+
No. of PLHA initiated on "First Line ART (NNRTI) based regimen		***			
No. of PLHA switched to Second line ART (PI based) due to toxicity to NNRTI					
No. of PLHA switched to second line (PI based) due to			e Carry many and and		\
No. of PLHA started on an initial second line ART (PI					
lo. of patients referred to Government ART centre					

	Guidance on Rational ART Regime	an .
First Line ART regimen	2 NRTI (or 1 NIRTI + 1 NRTI) + 1 NNRT	\$P\$\$P\$ \$P\$\$P\$\$P\$\$P\$\$P\$\$P\$\$P\$\$P\$\$P\$\$P\$\$P\$
Alternative first line ART	2 NRTI (or 1 NtRTI + 1 NRTI) + 1 PI (due	医多种 植物经济的 法经验证据证券的 经保险 化多种硫酸医多种物物 医线线线 医皮肤 化多烷酸 化二甲基二甲基甲基
Second line ART	2 NRTI (or 1 NtRTI + 1 NRTI) + 1 PI ('due	9 to treatment failura V