

Procedure For Approval of New Drugs

2774. SHRI GOVINDA CHANDRA MUNDA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the procedure/criteria for approval of new drugs in the country;

(b) whether this/procedure is uniformly followed in all systems of medicines; and

(c) if so, the details thereof and if not the reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI. D.K. THARA DEVI SIDDHARTHA): (a) to (c). The procedure/criteria for approval of 'new' drugs, belonging to modern system of medicine (Allopathic drugs), is given in Part XA of the Drugs and Cosmetics Rules, 1945. this includes examination of pre-clinical and clinical data of safety and efficacy of the 'new' drug generated abroad and within the country.

The preparation of the medicine and the mechanism of action of drugs belonging to other systems of medicine is different and therefore criteria for approval of 'new' medicine belonging to these systems would not be similar. The Drugs Controller (India), who is the approving authority for 'new' drugs, approves such medicines based on examination and recommendation of the experts.

CORRECTION STATEMENT IN RESPECT OF LOK SABHA UNSTARRED QUESTION NO. 825 ANSWERED ON 29TH JULY, 1991

In reply to part (a) of the Lok Sabha Unstarred Question No. 825 answered on the 29th July, 1991, it was inter-alia stated that "salient features of the licence agreements between N.D.M.C. and the above two parties are enclosed". However while sending reply to the above mentioned Question, salient features of the licence agreement between N.D.M.C. and the Holiday Inn was enclosed while the salient features in re-

spect of the other Hotel viz. Hotel Le Meridien was left out inadvertently.

2. The correct reply to part (a) of the Lok Sabha Unstarred Question No. 825 for 29th July, 1991 may, inter-alia, be read as under:

"salient features of the licence agreements between N.D.M.C. and the above two parties are enclosed as ANNEXURE-I AND ANNEXURE-II".

3. Inconvenience caused to the House is regretted.

(M. ARUNACHALAM)

THE MINISTER OF STATE IN THE MINISTRY OF URBAN DEVELOPMENT

New Delhi

Dated the 1st August, 1991

STATEMENT

Annexure - I

Statement referred to in reply to part (a) of Lok Sabha unstarred Question No. 825 for 29.7.91

Salient features of the licence agreements entered into by NDMC with Hotel Holiday Inn.

1. The licence has been granted for a period of 99 years at an annual licence fee of Rs. 1.45 crores.

The licence has been allowed moratorium in the payment on annual licence fees from time to time. The accumulated licence fee is payable in instalments. In the event of default in the payment of licence fee the licensee shall be liable to pay licence fee alongwith interest at 15% per annum.

2. The licensor has absolute discretion to revoke/cancel the licence in the event of licensees failing to make payment of licence fee or any other payment due against them.

3. The land would continue to be on

lease with the licensor in whom the building when constructed will also vest.

4. The FAR of the land shall not be more than 250.

5. The licensees shall complete the construction and commission of at least 100-150 rooms with complete facilities as prescribed for the 5 Star Hotel category before the commencement of Asian Games 1982.

6. The licensees shall obtain the prior approval of the Director General of Tourism to the tariff to be charged at the said 5 Star Hotel.

7. The licensor shall have the pre-emptive right to purchase the property built on the site after deducting the market value of the land.

8. The allotment will be made on the licence basis and the licenced premises including the building to be constructed will be a public premises within the meaning of the Public Premises Act.

9. The licensee shall run the 5 Star Hotel themselves. However, the licensees may allowed sub-licensees for running Car parking, Cycle-Scooter stand and shopping arcade, bank, offices (within the shopping arcade) etc.

10. The licensee after completion of the building shall not make any additions/alterations without prior permission of the licensor.

11. In the event of breach of any of the terms and conditions of the licence, the licensor shall terminate and revoke the licence.

12. The licence fee in terms of the fixed minimum annual guaranteed amount only will be enhanced after every 33 years provided that the increase in the licence fee

shall not exceed 100% of that immediately before the enhancement is due.

13. All the arrears of the licence fee and other payments due shall be recoverable in the same manner as arrears of land revenue.

14. In the event of any question, disputes or differences in regard to the terms and conditions and their interpretation, the same shall be referred to the Sole Arbitration of the Lt. Governor of Delhi and the award of the Arbitrator shall be binding on the licensee and the licensor.

Annexure - II

Salient features of the licence agreements entered into by the NDMC with Hotel Le Meridian.

1. The licence has been granted for a period of 99 years at an annual licence fee of Rs. 2.68 crores or 21% of the gross turnover of the licensees during the financial year whichever is higher. The licensee has been allowed moratorium in the payment on annual licence fees from time to time. The accommodated licence fee is payable in instalments. In the event of default in the payment of licence fee the licensee shall be liable to pay licence fee alongwith interest at 15% per annum.

2. The licensor has absolute discretion to revoke/cancel the licence in the event of licensees failing to make payment of licence fee or any other payment due against them.

3. The land would continue to be on lease with the licensor in whom the building was constructed will also vest.

4. The F.A.R. of the land shall not be more than 150.

5. The licensees shall complete the

construction and commission of at least 100-150 rooms with complete facilities as prescribed for the 5-Star Hotel category before the commencement of Asian Games 1982.

6. The licensees shall obtain the prior approval of the Director General of Tourism to the tariff to be charged at the said 5-Star Hotel.

7. The licensor shall have the pre-emptive right to purchase the property built on the site after deducting the market value of the land.

8. The allotment will be made on the licence basis and the licenced premises including the building to be constructed will be a public premises within the meaning of the Public Premises Act.

9. The licensee shall run the 5-Star Hotel themselves. However, the licensees may allowed sub licensees for running Car parking, Cycle-Scooter stand and shopping arcade, bank, offices (within the shopping arcade) etc.

10. The licensee after completion of the building shall not make any additions/alterations without prior permission of the licensor.

11. In the event of breach of any of the terms and conditions of the licence, the licensor shall terminate and revoke the licence.

12. The licence fee in terms of the fixed minimum annual guaranteed amount only will be enhanced after every 33 years provided that the increase in the licence fee shall not exceed 100% of that immediately before the enhancement is due.

13. All the arrears of the licence fee and other payments due shall be recoverable in the same manner as arrears of land revenue.

14. In the event of any question, disputes or defiances in regard to the terms and conditions and their interpretation, the same shall be referred to the Sole Arbitration of the Lt. Governor of Delhi and the award of the Arbitrator shall be binding of the licensee and the licensor.

12.00 hrs.

[English]

MR. SPEAKER: We are going to consider as to when the atrocities and attacks on harijans will be considered. I am just retiring to my chamber, and I am requesting the leaders of different all parties to assemble over there so that we can fix the time. So, I am not taking up that issue now. I am just allowing other Members to make their say.

[Translation]

SHRI DEVENDRA PRASAD YADAV (Jhanjharpur): Mr. Speaker, Sir, I have given a notice. I seek your permission to raise the question of breach of privilege under Rule 222 of the Rules of Procedure and Conduct of Business in Lok Sabha. By prominently printing my photograph on page 4, Col. 2 of the newspaper "Sunday Observer" dated 11th August, 1991 deliberately under the heading "Astitva ke ladaae la rahe D.P." (D.P. battlaing for existence) the editor, publisher, reporter Shri Alok yatri and the photographer, Shri Sandeep Mishra of the above newspaper have not only attempted to tarnish my public, social and political image among crores of people but have also tried to create hindrance in the discharge of my Parliamentary work during the session of Parliament by creating mental tension. This is clearly a case of breach of my privilege.

Mr. Speaker, Sir, you are the custodian of the rights of the hon. Member. I would request that a notice be served immediately on the said newspaper to ascertain the facts