$~25

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

\+ **W.P.(C) 6523/2019 & CM Nos. 27574/2019 & 29518/2019**

M/S EUROKEM LABORATORIES (P) LTD. AND ANR. ..... Petitioners

Through: Ms Amita Gupta, Advocate.

versus

MINISTRY OF HEALTH AND FAMILY WELFARE AND ANR. ..... Respondents

Through: Mr Kirtiman Singh, Mr Shruti Dutt, Mr Prateek Dhanda, Mr Waize Ali Noor, Advocates for R1.
Mr Rishikant Singh, Advocate for R2.

6.

\+ **W.P.(C) 4672/2019**

OVERSEAS HEALTH CARE PVT. LTD ..... Petitioner

Through: Ms Amita Gupta, Advocate.

versus

MINISTRY OF HEALTH & FAMILY WELFARE & ANR ..... Respondents

Through: Mr Rishi Kant Singh, Advocate for R2.

CORAM:
HON'BLE MR. JUSTICE VIBHU BAKHRU

O R D E R

% **04.07.2019**

VIBHU BAKHRU, J

1. The petitioners are engaged in the business of manufacture and sale of drugs. They have filed the present petitions being, essentially, aggrieved by the amendment to the Indian Pharmacopoeia regarding the standards for Albendazole Tablets as introduced by respondent no.2 (Indian Pharmacopoeia Commission – hereafter 'the IP Commission') with effect from 02.01.2019 (Amendment List - 003).

2. The petitioner in W.P. (C) 4672/2019 prays that directions be issued to the respondents to grant six months' time for the implementation of the amendment (Amendment List-003 to IP-2018) introduced in respect of the drug in question. The petitioners in W.P. (C) 6523/209 pray that directions be issued to the respondents to grant twelve months' time for implementation of the amendment in question. The petitioners contend that no time has been granted by respondent no.2 to the drug manufacturers to adapt to the amended standard. The drug in question (Albendazole Tablets) manufactured by the petitioners do not meet the solubility test, as introduced by the amendments in question. The petitioners, essentially, seek that they be permitted to sell the drug in question, which does not meet the amended standards, for a period of six/twelve months to enable them to adapt the production process to produce the drug in question that conforms to the amended standards.

3. At the outset, it will be relevant to refer to the amendment in

question to the Indian Pharmacopoeia on 02.01.2019. The said amendment (Amendment List 003 to IP-2018) is set out below: -

> "Albendazole Tablets
>
> Change from: Albendazole Tablets contain Albendazole. The tablets may contain permitted flavouring agents.
>
> To: Albendazole Tablets contain Albendazole. The tablets may be chewable and may contain permitted flavouring and sweetening agents.
>
> Under Tests Insert
>
> Dissolution (2.5.2).
>
> Apparatus No. 1
>
> Medium 900 ml of 0.1M hydraulic acid.
>
> Speed and time.75 rpm and 30 minutes.
>
> Withdraw a suitable volume of the medium and filter. Dilute 1.0 ml of filtrate to 50.0 ml with 0.1 M sodium hydroxide. Measure the absorbance of tlie resulting solution at the maximum at about 308 nm (2.4.7). Calculate the content of C12H15N3O2S per tablet talcing 742 as the specific absorbance at 308 nm.
>
> D. Not less than 80 per cent of the stated amount of $C_{12}H_{15}N_3O_2S$.
>
> Labelling.
>
> Change from: The label states that the tablets should be chewed before swallowing.
>
> To: The label states, whenever applicable, tire tablets should be chewed before swallowing"

4. The aforesaid amendment is hereafter referred to as 'the

amendment in question'.

5. The petitioners were granted licences for manufacturing Albendazole 400 mg Tablets which has been extended from time to time. The standards for Albendazole Tablet was specified in IP, 1996. The standard required that the said tablets contain not less than 92.5% and not more than 107.5% of stated amount of Albendazole $C_{12}H_{15}N_3O_2S$. Thus, all manufacturers were required to conform to the said standards. It is stated that the said standard continued without any amendment up to the year 2018 till the amendment in question (Amendment List-003) was introduced by the IP Commission.

6. It is stated on behalf of the petitioners that they are holding purchase orders from various purchasers for supply of the drug in question but are unable to supply the drug in question, for the reason that they are not in a position to manufacture drug in question (Albendazole 400mg) which meets the amended standards for the said drug, as the same is not soluble. It is stated that the petitioners have secured the purchase orders pursuant to invitation to tenders that were floated prior to the amendment in question being notified.

7. It is earnestly contended on behalf of the petitioners that the petitioners would suffer significant losses and would also be exposed to claims of damages if the implementation of the amendment in question is not deferred.

8. The import of the amendment in question is that the manufacturers and dealers are now precluded from selling the drug in question (Albendazole Tables) which do not meet the solubility test.

The petitioners, in effect, seek directions to enable them to supply the drugs which do not conform to the standards as notified, in order to exhaust their stocks and to manufacture the drugs that meet the amended standards.

9. The Indian Pharmacopoeia is the official book specifying the drugs in India as specified in Second Schedule of the Drugs and Cosmetics Act, 1940. Clause 5 of the Second Schedule of the said Act is relevant and is set out below:-

"5. Other drugs:

(a)	Drugs included in the Indian Pharmacopoeia	Standards of identity, purity and strength specified in the edition of the Indian Pharmacopoeia for the time being in force and such other standards as may be prescribed. In case the standards of identity, purity and strength for drugs are not specified in the edition of the Indian Pharmacopoeia for the time being in force but are specified in the edition of the Indian pharmacopoeia immediately preceding, the standards of identity, purity and strength shall be those occurring in such immediately preceding edition of the Indian Pharmacopoeia and such other standards as may be

		prescribed.
(b)	Drugs not included in the Indian Pharmacopoeia but which are included in the official Pharmacopoeia of any other country.	Standards of identity, purity and strength specified for drugs in the edition of such official Pharmacopoeia of any other country for the time being in force and such other standards as may be prescribed. In case the standards of identity, purity and strength for drugs are not specified in the edition of such official Pharmacopoeia for the time being in force, but are specified in the edition immediately preceding, the standards of identity, purity and strength shall be those occurring in such immediately preceding of such official Pharmacopoeia and such other standards as may be prescribed.]]"

10. The IP Commission is an autonomous institute and is, *inter alia*, entrusted with the function to revise and publish the Indian Pharmacopoeia on a regular basis. The IP Commission undertakes the said function to ensure inclusion of drug monographs and their further upgradation from time to time. The IP Commission published the 8th edition of IP, 2018 which came into effect from 01.01.2019.

11. It is stated that Albendazole Tablets have been recommended by

World Health Organization (WHO) as they are effective, inexpensive and easy to administer for the treatment of helminth infections. The said drug is used widely in the National Health Programme for controlling parasitic infection in India.

12. Albendazole Tablets are sometimes swallowed whole either intentionally or unintentionally and therefore, it was felt necessary that such tablets comply with the test for dissolution. Admittedly, the International Pharmacopoeia published by WHO requires that the tablets comply with the test for disintegration or dissolution. It is affirmed on behalf of the IP Commission that the issue of the Albendazole Tablets in meeting the aforesaid standard has been the subject matter of discussions at various platforms. It is contended on behalf of IP Commission that WHO studies have shown that the dissolution properties of Albendazole Tablets in the market were poor and therefore, the monograph included in the International Pharmacopoeia for Albendazole Tablets was revised in the year 2015 to provide for the test of dissolution.

13. The learned counsel appearing for IP Commission submitted that the property of Albendazole Chewable tablets to dissolve was considered to be necessary for the said drug to be effective. He also referred to the chronology of events that had preceded the publication of the amendment in question as part of Indian Pharmacopoeia.

14. It is stated that as early as on 22.08.2016, a draft was prepared according to the International Pharmacopoeia and on 26.10.2016, the IP Commission had sent various e-mails to various drug

manufacturers for providing the method and data of dissolution testing of Albendazole Tablets. It is stated that some of the drug manufacturers had also forwarded the data for the same.

15. On 23.03.2017, the dissolution test drafted for Albendazole Tablets was sent to experts and various manufacturers for their opinion/comments. Thereafter, on 06.09.2017, a Committee was formed by the Secretary cum Scientific Director of the IP Commission for incorporation of the dissolution test in the monograph of Albendazole Tablets. It is affirmed that on 11.09.2017, IP Commission sent e-mails to various manufacturers for their opinion on inclusion of the dissolution test in Albendazole Tablets.

16. It is affirmed on behalf of IP Commission that on 27.09.2017, the meeting of an Expert Committee was held and all members had unanimously agreed that dissolution test should be included as a necessary standard for Albendazole Tablets. The dissolution test was drafted and uploaded on the website of the IP Commission for public comments on 12.10.2017.

17. The learned counsel appearing for the IP Commission has also drawn the attention to a communication received from Dr Madhur Gupta of WHO, which, *inter alia*, states that *"dissolution test being of critical importance as part of the assay in Albendozole; the revision of monograph in Indian Pharmacopoeia needs to be incorporated at the earliest ..*".

18. It is affirmed that that on 25.05.2018, the 37th Scientific Body meeting was held and at the said meeting, discussions were held on

the draft dissolution test for Albendazole Tablets. It is also affirmed that till that date, no suggestion had been received from other stakeholders. Thereafter the matter was also discussed at the Expert Working Group Meeting held from 29.08.2018 to 31.08.2018 and the experts were of the opinion that the standards be harmonized with the International Pharmacopoeia.

19. Thereafter, on 14.09.2018, the draft dissolution test as per International Pharmacopoeia was sent to certain experts and manufacturers for comments and it was also uploaded on the website of the IP Commission for public comments. The draft was again discussed by the expert working group at the meetings held on 29.10.2018 and 31.10.2018 and a dissolution test was approved in the amendment list. Thereafter, on 22.12.2018 incorporation of the dissolution test in Amendment List-003 (amendment in question) was approved at the 39th Scientific Body meeting of the IP Commission and the same was thereafter published on 02.01.2019.

20. It is clear from the above that the necessity of the drug in question being soluble cannot be disputed. There is also no material to doubt that the incorporation of the solubility test as a necessary standard was of critical importance, as also communicated by WHO

21. Undisputedly, the proposal for including the dissolution test as a part of the monograph of Albendazole Tablets was in public domain for a considerable period. The draft of the dissolution test had been uploaded on the IP Commission's website on 12.10.2017 and thereafter on 14.09.2018. Admittedly, the said standard is also a part

of the International Pharmacopoeia since 2015.

22. In view of the above, there can be no dispute that all manufacturers had sufficient notice to ensure that their products meet the international standards. The failure of certain drug manufacturers to upgrade the standards of the drugs manufactured by them cannot be accepted as a ground for deferring the implementation of such standards.

23. It is also stated on behalf of the IP Commission that there are large number of manufacturers who are producing the drug in question meeting the amended standard.

24. It was contended on behalf of the petitioners that the IP Commission had not sent any email to the petitioners but to other manufacturers. This is of little relevance and the draft test had been placed on the website of the IP Commission on two occasions. More importantly, the solubility test was already incorporated as the monograph of the drug in question in the International Pharmacopoeia way back in the year 2015.

25. It is necessary to bear in mind that the import of accepting the petitioners' contention would be that a sub-standard drug would be used by the consumers. The drug in question is also used for the health programme for deworming and is administered to a large number of persons on the Deworming Day, which is fixed twice a year. Clearly, it would not be in public interest if a drug which is relatively ineffective is permitted to be used.

26. Ms Amita Gupta, learned counsel appearing for the petitioners

had contended that in several other cases, the IP Commission had granted relaxation for implementing the changes introduced in the Indian Pharmacopoeia. In particular, she referred to a letter dated 10.12.2014, which was issued by the IP Commission relaxing the implementation of the changes prescribed in IP Addendum, 2015 for a period of three months. She had also relied on a similar letter dated 27.03.2018 in respect of the standards prescribed in IP-2018. She submitted that a similar relaxation ought to be granted in respect of the amendment in question (Amendment List-003 to IP-2018).

27. The said contention is unpersuasive. It has been affirmed on behalf of the IP Commission that after publication of IP-2014 and IP Addendum, 2015, the IP Commission had received various representations by stakeholders to relax the time for implementing the same to comply with the new drug monograph that had been added by the IP Commission. Similarly, after publication of IP-2018, similar requests were made for extending the time to implement to the new standards. He submitted that such relaxations were not granted in respect of upgradation that were already included in the IP standards.

28. In view of the above, the case of the petitioners cannot be considered similar to the instances where the IP Commission had granted such relaxation. In view of the above, the contention that the period for implementing the amendment in question was also required to be deferred, cannot be accepted. Since it is also relevant to note that it is not disputed that the dissolution test has been a part of the International Pharmacopoeia since 2015 and there is no justifiable

reason for the petitioners not to have taken preparatory steps for manufacturing drugs of the requisite standards.

29. In view of the above, this Court does not find any infirmity in the action of the IP Commission in issuing the Amendment in question (Amendment List-003 to IP-2018) with effect from 02.01.2019.

30. The petitions are unmerited and are, accordingly, dismissed. The pending applications are disposed of.

VIBHU BAKHRU, J

JULY 04, 2019
pkv