IN THE COURT OF APPEAL OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

In an application under an in terms of Article 140 of the Constitution for mandates in the nature of writs of certiorari and prohibition.

Case No. Writ Application
No: C.A. (Writ) 793/2023

1. **Sri Lanka Chamber of the Pharmaceutical Industry**
   C/o The Ceylon Chamber of Commerce,
   No.50, Nawam Mawatha,
   Colombo 02.

2. **PrathabanMylvaganam,**
   President,
   Sri Lanka Chamber of the Pharmaceutical Industry,
   C/o The Ceylon Chamber of Commerce,
   No.50, Nawam Mawatha,
   Colombo 02.

3. **Azam Mohamed Jaward,**
   Senior Vice President,
   Sri Lanka Chamber of the Pharmaceutical Industry,
   C/o The Ceylon Chamber of Commerce,
   No.50, Nawam Mawatha,
   Colombo 02.

4. **Bogahawattegedara Nandana Shantha Bandara,**
   Vice President,

Sri Lanka Chamber of the
Pharmaceutical Industry,
C/o The Ceylon Chamber of
Commerce,
No.50, Nawam Mawatha,
Colombo 02.

PETITIONERS

Vs.

1. **Hon. Dr. Ramesh Pathirana**
   Minister of Health,
   Ministry of Health,
   Suwasiripaya,
   No.385, Ven.
   BaddegamaWimalawansa Thero
   Mawatha,
   Colombo 10.

2. **The Secretary**
   Ministry of Health,
   Suwasiripaya,
   No.385, Ven.
   BaddegamaWimalawansa Thero
   Mawatha,
   Colombo 10.

3. **SirimalAbayaratne**
   Chairman

4. **Dr. Ananda Wijewickrema**
   Member

5. **Indrajith Aponsu**
   Member

6. **Prof. Chandrasiri Abyessinghe**
   Member

7. **Prof. Ruwan Jayathilake**
   Member

8. **Dr. Mahanama Gunasekara**
   Member

9. **AchinthaHewanayake**
   Member

10. **W.M. Niluka Weerasekara**
    Member

    The 3rd to 10th Respondents all at,
    The Pricing Committee,
    The National Medicines Regulatory Authority,
    No.120, Norris Canal Road,
    Colombo 10.

11. **The National Medicines Regulatory Authority,**
    No.120, Norris Canal Road,
    Colombo 10.

RESPONDENTS

Before: Hon. D.N. Samarakoon, J.

Hon. Neil IddawalaJ.

Counsel: Dr. Romesh De Silva, P.C., for the Petitioner.

Mr. Sumathi Dharmawardena, A.S.G., P.C., for the Respondents.

Supported on :14.12.2023

Written submission tendered on: Not tendered by any party

Decided on:22.12.2023

D.N. Samarakoon, J

This matter was supported in Open Court from 10.55 a.m. by the learned President's Counsel appearing for the petitioners. The Court also heard submissions made by the learned Additional Solicitor General, President's Counsel for all the respondents, who appeared in Court on direct notice given by the petitioners too from 11.40 a.m. The learned President's Counsel for the petitioners were heard in reply from 12.05 p.m. and both counsel briefly clarified certain positions thereafter.

The petitioners are "**Sri Lanka Chamber of the Pharmaceutical Industry**" and three others. The respondents are "Minister of Health" and ten others, the 03rd to 10th being "The Pricing Committee" of "The National Medicines Regulatory Authority" and the 11th respondent "The National Medicines Regulatory Authority".

The 01st petitioner, according to the petition, is constituted by importers, manufacturers, distributors, wholesalers and retailers of pharmaceuticals and medicinal devices and the majority of the business enterprises, which are engaged in the pharmaceutical business.

The learned President's Counsel for the petitioners drew the attention of the Court to section 118 of National Medicines Regulatory Authority Act, which is

the first section in Part III "Pricing of Medicines, Medical Devices and Borderline Products". It says,

"118. Pricing of medicines.

(1) –

(a) The Authority shall appoint a Committee to be known as the Pricing Committee.

(b) The composition, powers and functions of the Pricing Committee shall be as prescribed.

(2) –

(a) The Authority shall in consultation with the Pricing Committee, determine the introductory price of medicines, medical devices and borderline products at the time of registration, based on the criteria as may be prescribed.

(b) For the purpose of paragraph (a) the Authority shall consider the prevailing market prices of similar products within the same therapeutic class, International Reference Prices and other factors as may be prescribed.

(3) For the purpose of determining the prices of New Chemical Entities, the Authority shall consider the prices in the region, the benefit of the new product and the cost effectiveness.

(4) The Minister shall in consultation with the Pricing Committee, the Consumer Affairs Authority and all stakeholders and taking into consideration all other relevant factors including the provisions of the Consumer Affairs Authority Act No. 09 of 2003, **prescribe a pricing mechanism for medicines, medical devices and borderline products**".

The petitioners emphasise on the words "**prescribe a pricing mechanism**" and submit that what is in operation under the existing statutory regime is not "price control" but the prescribing of a "pricing mechanism."

Whereas it is submitted, that from time to time, the pricing of pharmaceuticals has assumed political significance and been discussed in the public and political sphere, the petitioners state that price control results in the choice of the consumer being restricted and more importantly a diminution in the quality of drugs being imported such that reasonable quality drugs cannot be imported in a meaningful or profitable manner given the price controls. (paragraphs 08 and 12 of the petition)

It is further submitted, that, in other countries where price controls have been introduced, in a transparent, consultative and rational manner that ensures that patients are not deprived of quality products and the freedom of choice, whereas in this country it has been implemented in an opaque, non consultative, haphazard and irrational manner devoid of logical thinking. (paragraphs 15 and 16 of the petition)

For example, the petitioners draw the attention of the Court to P.03, which the petitioner's claim is a list of medicines that is not available because of the price control.

The first item in P.03 is Cipla, which the petitioner's say is a medicine given to avert nausea resulting from chemotherapy. The second one, Ceftriaxone Disodium is an antibiotic given prior to surgery.

Attention is then drawn to P.12 which contains a gazette dated 15th June 2023 in which Cefuroxime is priced at Rs. 144.19. It is shown, referring to a table also in P.12 where the price of the same medicine in India is Indian Rs. 51.43. When converted to local currency, it is Indian Rs. 51.43 x 3.92 = Rs. 201.61. However the Maximum Retail Price prescribed is Rs. 144.19. Hence what is actually worth Rs. 201.61 has to be sold at Rs. 144.19.

The petitioners submit, that, this is illogical on the face of it. According to the petitioners this makes the particular medicine not available in the

market, because importing it from India and selling in the local market has to be done at a loss.

It was also submitted, that, hence the maximum price in India is Rs. 201.61 (in local currency) If 75% of that is taken as the cost and converted to US $ it is 0.460. It is because 25% has been discounted in India and taken as the cost price and when 0.12% of insurance which is 0.001 and freight 5.0% which is 0.023 are added it is 0.484. That is the CIF price. When it is calculated at the exchange rate at the time of import 330.00 it is 159.72, which is the CIF in LKR. After the Bank and Clearing charges, which is arbitrarily fixed at 5.0% and added 7.98 the landed cost is 167.54.

Referring to paragraph (b) of the prayer, which is for a writ of prohibition, Dr. de Silva further said, that, there was another case in 2019 by the petitioners which said that the Minister cannot impose Price Control under section 118, which was not the main relief in that case, which was for a writ of certiorari, but in this case the petitioners go into the core issue which is that the Minister cannot impose Price Control but a pricing mechanism.

The learned Additional Solicitor General, President's Counsel referred the Court to document marked "X" attached to the petition, which is the earlier writ application filed by the Sri Lanka Chamber of the Pharmaceutical Industry. At page 000033 he referred to paragraph 124(c) (d) (e) and (f).

Paragraph (c) says,

> "However section 118 of the NMRA Act which is the primary legislation which must prevail, does not provide any power for the pricing committee to recommend to the NMRA methods of determining MRP price revisions of medicinal products…"

It was submitted that in the present application they say no there is a pricing committee, there is a pricing mechanism. There is a clear approbate and reprobate.

Then he directly went into paragraph (f) which says,

> "Thus the petitioners are advised to state that in the detailed examination of the provisions of the NMRA Act it is clear that price revision is a matter which solely and exclusively falls under the purview of the 01st respondent Minister and there is no way that this position can be circumvented or subverted in any manner whatsoever".

Therefore, he submitted, that the petitioners are trying to mislead the Court, confuse the Court, confuse the people of the country and suck the cash out of poor people of this country. If there is no regulator where we do stand? If the Minister cannot regulate the prices, where do we stand. Are we to be at the mercy to sell the properties and by the medicine? We know the exorbitant prices of medicine. They have admitted, that, pricing committee cannot act only Minister can act.

The Court then observed, that, in (c) the word used is "price revision" not "price control." He also submitted, that, there is no author of P.12. He asked what is the price Mark Up in India vis-à-vis the Factory Price and Market Price. Dr. de Silva pointed out it is 20% but the learned ASG said there is no document.

The learned ASG referred to page 2A of Gazette dated 15.06.2023 which gives the price of "Clarithromycin". That is Rs. 72.50 for a 250mg tablet. In Gazette dated 15.03.2022 the same medicine was Rs. 61.65. He said the same tablet was Rs.31.50 in 2016 and it was increased to Rs. 61.65. Then he pointed out, that, in Gazette dated 29.04.2022 it was Rs. 86.31 and the time period was 60 days or 45 days. Did they come to quash the Gazette? He said that these price increases were done due to several requests made by several letters which have not been marked by the petitioners.

Hence the submission of the learned ASG was that price increases, at the request of the petitioners, have been effected.

When the dollar rate came down on 15.06.2023, the price has come down. Hence there was a mechanism. The petitioners got alarmed when the Minister said that he is going to go out of this basket of medicines and regulate the price of other medicines too. Therefore he submitted, that, the petition should be dismissed in limine.

It is true, that, at page 000033 in paragraph (c) the petitioners have stated in the earlier case, that, section 118 does not provide any power for the pricing committee, but that was for "price revision" but not for "price control". There appears to be a fine distinction between the two. What section 118(4) says is that "The Minister shall in consultation with the Pricing Committee,…prescribe a pricing mechanism for medicines, medical devices and borderline products".

Hence, there is a matter to be looked into by this Court. Hence formal notice should be issued.

There are seven interim orders prayed for.

For instance, the first interim order in paragraph (i) is to prevent the respondents from imposing price control on any medicine in respect of which price control has not already been issued. This is a wider interim order.

But what is referred to in paragraph (j) has a condition, that, the above should not be done without the Minister first prescribing a pricing mechanism under NMRA Act No. 05 of 2015.

Further, what is under paragraph (l) is to prevent doing the above without consultation with the Pricing Committee, the Consumer Affairs Authority and all stakeholders inclusive of the 01st respondent and its members and taking into consideration all other relevant factors including the provisions of the Consumer Affairs Authority Act No. 09 of 2003.

Therefore even if the interim orders in paragraphs (j) and (l) are issued the respondents can effect a pricing mechanism subject to following the procedure referred to in those paragraphs.

Although the respondents did not bring it to the notice of this Court, in **Union Of India &Ors vs M/S. Cipla Ltd. &Anr on 21 October, 2016,** it has been held, that,

> "171. **Under these circumstances, we are clearly of the view that in matters where public interest is involved, the Court ought to be circumspect in granting any interim relief.** The consequence of an interim order might be quite serious to society and consumers and might cause damage to public interest and have a long term impact. **We make it clear that it is not our intention to suggest to any Court how and in what circumstances interim orders should or should not be passed but it is certainly our intention to make it known to the Courts that the time has come when it is necessary to be somewhat more circumspect while granting an interim order in matters having financial or economic implications."**

Having considered the above judgment too and the fact that haphazard price control can make the medicine not available at all in the market, to buy that even at a higher price, this Court issues the above interim orders under paragraphs (j) and (l) only to be effective until the final determination of this case.

However since the INR price and price Mark Up in India as well as CIF and exchange rate and also the dollar rate are subject to fluctuations, if any compelling matters are urged by any party before the Court, the Court will consider the issuing of any other interim orders as well as vacating any interim order already issued or modify them as the circumstances require.

The parties are urged to take steps to conclude this matter expeditiously.

Judge of the Court of Appeal.

Hon. Neil Iddawala J.,

I agree.

Judge of the Court of Appeal.