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

1. People's Movement for the Rights of Patients (PMRP),
   214/3, Hospital Road,
   Kalubowila,
   Dehiwala.
2. Christine Perera,
   Honorary Joint Secretary,
   People's Movement for the Rights of Patients,
   27/1, Andarawatta Road,
   Polhengoda,
   Colombo 5.
3. M.K.P. Chandralal,
   Attorney-at-Law,
   People's Movement for the Rights of Patients,
   282A1/1,
   Kadawatha Road,
   Nadimala,
   Dehiwala.

   Petitioners

CASE NO: CA/WRIT/208/2016

Vs.

1. Hon. Rajitha Senaratne,
   Minister of Health, Nutrition and
   Indigenous Medicine,
   Ministry of Health, Nutrition and
   Indigenous Medicine,
   Suwasiripaya,
   385, Rev. Baddegama
   Wimalawansa Thero Mawatha,
   Colombo 10.
2. Anura Jayawickrema,
   Secretary,
   Ministry of Health, Nutrition and
   Indigenous Medicine,
   Suwasiripaya,
   385, Rev. Baddegama
   Wimalawansa Thero Mawatha,
   Colombo 10.

2A. Udaya R. Seneviratne,
   Secretary,
   Ministry of Health, Nutrition and
   Indigenous Medicine,
   Suwasiripaya,
   385, Rev. Baddegama
   Wimalawansa Thero Mawatha,
   Colombo 10.

2B. Mrs. B.G.S. Gunathillake,
   Secretary,
   Ministry of Health, Nutrition and
   Indigenous Medicine,

Suwasiripaya,
385, Rev. Baddegama
Wimalawansa Thero Mawatha,
Colombo 10.

3. Prof. Asitha de Silva,
National Medicinal Regulatory
Authority,
120, Norris Canal Road,
Colombo 10.

4. Dr. Kamal Jayasinghe,
Director Laboratory Services,
Ministry of Health, Nutrition and
Indigenous Medicine,
Suwasiripaya,
385, Rev. Baddegama
Wimalawansa Thero Mawatha,
Colombo 10.

5. Dr. P.G. Mahipala,
Director General,
Ministry of Health, Nutrition and
Indigenous Medicine,
Suwasiripaya,
385, Rev. Baddegama
Wimalawansa Thero Mawatha,
Colombo 10.

5A. Dr. J.M.W. Jayasundera Bandara,
Acting Director General Health,
Ministry of Health, Nutrition and
Indigenous Medicine,

Suwasiripaya,
385, Rev. Baddegama
Wimalawansa Thero Mawatha,
Colombo 10.

5B. Dr. Anil Jasinghe,
Director General of Health
Services,
Ministry of Health, Nutrition and
Indigenous Medicine,
Suwasiripaya,
385, Rev. Baddegama
Wimalawansa Thero Mawatha,
Colombo 10.

6. Mr. Priyantha Ratnayake,
7. Dr. Ananda Wijewickrama,
8. Dr. B.G. Rathnasena,
8A. Dr. Nissanka Jayawardena,
9. Dr. Lilanthi de Silva,
9A. Dr. Lakkumar Fernando,
10. Dr. Gamini Perera,
10A. Dr. Sanath Lanerolle,
11. Prof. R.L. Jayakody,
12. Dr. Dilanthi Herath,
12A. Dr. Nithushi Samaranayake,
13. Dr. Kapila Ranasinghe,
14. Mrs. Riyasa Ahmed,
14A. Mrs. H.M.C. Herath
15. Prof. Narada Warnasuriya,
15A. Dr. B.G.N. Ratnasena,

Members,
National Medicinal Regulatory Authority,
120, Norris Canal Road,
Colombo 10.

16. Hon. Attorney General,
Attorney General's Department,
Colombo 12.

17. Dr. Palitha Abeykoon,
Member,
National Medicinal Regulatory Authority,
120, Norris Canal Road,
Colombo 10.

Respondents

Before: Mahinda Samayawardhena, J.

Counsel: Palitha Kumarasinghe, P.C., with Harith de Mel for the Petitioners.
Sanjeewa Jayawardena, P.C., with Charitha Rupasinghe for the 7th-12th and 15th Respondents.
Manohara Jayasinghe, S.S.C., for the 1st-5th, 14th and 16th Respondents.

Decided on: 02.05.2019

Samayawardhena, J.

Introduction

The petitioners filed this application basically against the 1st respondent seeking to quash by way of writs of certiorari the following decisions:

a) Appointment of the 3rd respondent as a member of the National Medicines Regulatory Authority (NMRA) by letter marked D;
b) Appointment of the 3rd respondent as the Chairman of the Authority; and
c) Appointment of the 4th respondent as the Acting Chief Executive Officer of the Authority by letter marked M.

What is the National Medicines Regulatory Authority?

In Sri Lanka, the National Medicines Regulatory Authority was created by National Medicines Regulatory Authority Act, No.5 of 2015.

As the long title of the Act states the NMRA is responsible for the regulation and control of registration, licensing, manufacture, importation and all other aspects pertaining to medicines, medical devices, borderline products and for the conducting of clinical trials in a manner compatible with the national medicines policy.

According to section 3 of the Act, the objects of the Authority shall be to:

a) ensure the availability of efficacious, safe and good quality medicines, medical devices and borderline products to the general public at affordable prices;

b) function as the central regulator for all matters connected with the registration, licensing, cancellation of registration or licensing, pricing, manufacture, importation, storage, transport, distribution, sale, advertising and disposal of medicines, medical devices and borderline products;

c) ensure that all activities related to registration, licensing and importation of medicines, medical devices, borderline products and investigational medicinal products are carried out in a transparent, sustainable and equitable manner;

d) encourage the manufacturing of good quality medicines in Sri Lanka with a view to assuring the availability of essential medicines at affordable prices;

e) promote the safe and rational use of medicines, medical devices and borderline products by health care professionals and consumers;

f) recommend appropriate amendments to relevant laws pertaining to medicines, medical devices and borderline products;

g) educate the general public, health care professionals and all stakeholders on medicines, medical devices and borderline products;

h) regulate the promotion and marketing of medicines, medical devices and borderline products;

i) regulate the availability of the medicines, medical devices and borderline products;

j) conduct post marketing surveillance on quality, safety and adverse reaction of the medicines, medical devices and borderline products; and

k) regulate all matters pertaining to the conduct of clinical trials in Sri Lanka.

Section 146 of the Act defines "*borderline products*" as "*the products having combined characteristics of medicines and foods, medicines and medical devices or medicines and cosmetics*".

Section 14 of the Act, which describes the powers and functions of the National Medicines Regulatory Authority, reads as follows:

The powers and functions of the Authority shall be to:

a) decide on classifying a product as a medicine, medical device, borderline product or any other product;

b) authorize registration and licensing of medicines, medical devices, borderline products and investigational medicinal products or cancel or suspend any such registration or licence in terms of this Act;

c) regulate the registration, licensing, manufacture, importation, storage, re-packing, transportation, distribution, sale, advertising, promotion, recall and disposal of medicines, medical devices, borderline products or investigational medicinal products;

d) authorize registration and regulation of Pharmacies and medicines stores;

e) issue licences for manufacture, import, storage, distribution, transport and sale of medicines, medical devices, borderline

products or investigational medicinal products and to cancel such licences in terms of this Act;

f) appoint sub-committees as may be necessary for the effective discharge of the functions of the Authority;

g) grant approval for the custom clearance of consignments of medicines, medical devices, borderline products, raw materials, packing materials, machinery or laboratory material needed for local manufacture of medicines, medical devices, borderline products or investigational medicinal products subject to the provisions of this Act and any other written law;

h) conduct awareness programmes in relation to medicines, medical devices and borderline products and post market surveillance on the quality and safety of medicines, medical devices, borderline products and investigational medicinal products which are registered and licensed under this Act;

i) monitor the registration and licensing process and the usage of medicines, medical devices, borderline products or investigational medicinal products which are registered and licensed under this Act for adverse reactions through use thereof, and to take immediate and necessary action in such an instance;

j) collect data on quantities of medicines, medical devices, borderline products or investigational medicinal products imported under licences;

k) collect data on utilization of medicines, medical devices, borderline products and investigational medicinal products in Sri Lanka, including data on expenditure of industry and trade, relating to promotional activities;

l) advise the Minister on matters which are required to be prescribed;

m) acquire, hold, take or give on lease or hire, mortgage, pledge, sell or otherwise dispose of, any movable or immovable property;

n) charge fees where necessary and appropriate in the discharge of its functions;

o) recognize and appoint other local or overseas laboratories for testing of any medicine, medical device or borderline product as may be deemed necessary;

p) follow Good Regulatory Practices (GRP) as prescribed in regulations;

q) determine the initial price of medicines, medical devices and borderline products and advise the Minister on subsequent price revisions;

r) provide information pertaining to the functions of the Authority to the stakeholders and general public; and

s) issue, review and update guidelines, recommendations, directives and rules as applicable to medicines, medical devices and borderline products.

The industry involved in medicine, medical devices, borderline products and investigational medicinal products is undoubtedly a multi-billion dollar industry globally, and prone to corruption. Hence there is a dire need to keep it under strict regulation and supervision particularly in the best interests of one of the most vulnerable segments in the society-the sick.

From the above provisions of the Act alone, it is abundantly clear that the National Medicines Regulatory Authority, being

the central regulator for all matters connected with medicine, is a very important body with enormous powers, which can make a huge impact on the society.

Appointment of the 3rd respondent as a Member of the NMRA

Section 4 of the Act provides for the constitution of the National Medicines Regulatory Authority. It reads as follows:

> *The Authority shall consist of the following:*
> *(a) ex-officio members-*
> *(i) the Director-General of Health Services;*
> *(ii) the Secretary to the Treasury or his nominee; and*
> *(iii) the Chief Executive Officer of the Authority appointed under section 15 who shall function as the Secretary to the Authority;*
> *(b) Following persons who shall be appointed by the Minister (hereinafter referred to as "appointed members")-*
> *(i) four specialist clinicians attached to the Ministry of Health, representing the following clinical disciplines, nominated by their respective professional bodies-*
> *(A) General Medicine;*
> *(B) General Surgery;*
> *(C) Peadiatrics; and*
> *(D) Gynecology and Obstetrics;*
> *(ii) a Professor in Pharmacology of any University in Sri Lanka established under the Universities Act, No.16 of 1978, appointed in rotation for every three years,*

in consultation with the respective Deans of Faculties of Medicine;

(iii) a Professor or Senior Lecturer in Pharmacy of any University in Sri Lanka established under the Universities Act, No.16 of 1978, appointed in rotation for every three years, in consultation with the respective Deans of relevant Faculties;

(iv) four professionals, who have gained eminence in the fields of management, law, accountancy or health respectively.

According to the letter marked D, the appointment of the 3rd respondent to the National Medicines Regulatory Authority has been made by the 1st respondent in terms of section 4(b)(iv) of the Act.

This vacancy was created by the 1st respondent by removing the Accountant from the Authority. Letter marked C dated 20.05.2016 sent by the 1st respondent to the said Accountant reads: "*Please be informed that you are removed from the said office forthwith since I want to strengthen the authority with more health professionals.*" Letter D referred to earlier is of the same date.

This appointment, in my view, violates section 4(b)(iv) of the Act. If the accountancy professional is removed from the Authority, he shall be replaced with another accountancy professional. As the subsection stands today, the purposive interpretation which could be given to it is that four professionals each of the

respective professions of management, law, accountancy and health shall constitute the Authority.

The learned Senior State Counsel appearing for the 1st respondent argues that what is stated in section 4(b)(iv) is that the 1st respondent can appoint "four professionals, who have gained eminence in the fields of management, law, accountancy or health respectively" and not "management, law, accountancy and health", and therefore the appointment of another health professional in place of accountancy professional is not bad in law. The learned Senior State Counsel goes further to argue that the word "respectively" used in the subsection is superfluous and therefore shall be disregarded.

I am unable to accept that argument.

If that argument is accepted, the 1st respondent can, under that subsection, appoint four management professionals or four law professionals or four accountancy professionals or four health professionals. That interpretation leads nothing but to absurdity.

If the National Medicines Regulatory Authority needs to be strengthened with more health professionals, subsection 4(b)(iv) shall be amended to simply read as "*four health professionals*" instead of stating "*four professionals, who have gained eminence in the fields of management, law, accountancy or health respectively*."

The word "respectively", which finds a prominent place at the beginning of the subsection in the Sinhala version of the Act,

cannot be disregarded. ("පිළිවෙලින් කළමණාකරණය, නීතිය, ගණකාධිකරණය හෝ සෞඛ්‍ය යන ශ්‍රේෂ්ත්‍රවල විශිෂ්ඨත්වයක් දක්වා ඇති වෘත්තිකයන් හතර දෙනෙකු.")

Instead, the word "or" found in that subsection shall be taken to mean "and" as that was the word the 1st respondent meant to be used as seen from the speech made by the 1st respondent in Parliament at the second reading of the Bill and reported in Hansard. This interpretation is in keeping with the spirit and intention of this special piece of legislation.

> මේ අධිකාරියට සෞඛ්‍ය සේවා අධ්‍යක්ෂ ජනරාල්වරයා නිල බලයෙන් පත් වෙනවා. ඒ වාගේම ප්‍රධාන විධායක නිලධාරියෙක් පත් වෙනවා. ඒ තුන් දෙනා වාගේම වෛද්‍ය ක්‍රමයේ ප්‍රධාන ක්ෂේත්‍ර හතරක් නියෝජනය කරමින් physician කෙනෙක් surgeon කෙනෙක්, paediatrician කෙනෙක් හා VOG කෙනෙක් පත් වෙනවා. ඒ ප්‍රධාන කාණ්ඩ හතරෙන් හතර දෙනෙක් පත් වෙනවා. වෛද්‍ය ඖෂධවේදය-Pharmacology - පිළිබඳ මහාචාර්යවරයෙක් පත් වෙනවා. ඒ වාගේම pharmacy පිළිබඳ මහාචාර්යවරයෙක් හෝ ජ්‍යෙෂ්ඨ කථිකාචාර්යවරයෙක් පත් වෙනවා. ඒ වාගේම කළමනාකරණය, නීතිය, ගිණුම්කරණය හා සෞඛ්‍ය ක්ෂේත්‍රයන්හි ප්‍රවීණතාව ලද වෘත්තිකයන් හතර දෙනෙකුත් පත් වෙනවා. මොකද අපිට කිව්වා සාමාන්‍ය වෛද්‍යවරුන්ගෙනුත් එක් කෙනෙක් පත් කරන්න කියා.
>
> විශේෂඥවරුන් ගැන ඒ ගොල්ලන්ගෙන් නොයෙකුත් complaints තිබුණ, "අපිත් මේකට බොහොම ආසයි. නියම විධියට මේ කටයුතු කරගෙන යන්න අපි තමයි කැමති. ඒ නිසා අපෙනුත් එක් කෙනෙක් පත් කරන්න" කියා. ඒ නිසා ඒ අයගෙනුත් හතර දෙනෙක් පත් කළා. ඇත්තටම ඒ අධිකාරියේ සභාපතිවරයා පත් කරන්නට මට තමයි බලතල තිබුණේ. මම අවසානයේදී කිව්වා, "මට එහෙම තනි අයිතියක් අවශ්‍ය නැහැ" කියා. මම ඒ amendment එක අද පසුව ඉදිරිපත් කරනවා. "The Minister shall,

> with the consultation of the members of the Authority, appoint one of them" මෙම සංශෝධනයෙන් මගේ- අමාත්‍යාවරයාගේ - තනි බලයට නොවෙයි, ඒ ගොල්ලන්ව consult කරලා, ඒ ගොල්ලන්ගේ අනුමැතිය ඇතුව එක් කෙනෙක්ව පත් කිරීම දක්වා මම බලතල අඩු කර ගත්තා. මම කිව්වා, ''මේ අධිකාරිය සම්බන්ධයෙන් ඇමතිවරයාට තිබෙන බලතල පුළුවන් තරම් අඩු කරන්න'' කියා.

Parliamentary debates reported in Hansard can be made use of to interpret a Statute.

In *Shiyam v. OIC Narcotics Bureau [2006] 2 Sri LR 156 at 164-165* a Full Bench of the Supreme Court stated as follows:

> *Thus, Justice Mark Fernando had recognized section 3(1) of the Bail Act as a provision which excludes 'any other written law which makes express provision for the release on bail of persons accused or suspected of offences under that written law.' This position could be further clarified by an examination of the parliamentary proceedings pertaining to the Bail Bill.*
>
> *Learned Deputy Solicitor General for the respondents contended that the parliamentary proceedings could be used by the Court to ascertain the intention of the legislature.*
>
> *Until the land mark decision in Pepper v. Hart [1993] 1 All ER 42 the rule followed by the English judges had been that parliamentary debates reported in Hansard could not be referred to in order to facilitate the interpretation of a statute. However, by the decision in Pepper v. Hart (supra), a new practice came into being relaxing the exclusionary*

rule and permitting reference to parliamentary material. Referring to this new approach, Lord Griffiths in Pepper v. Hart (supra) stated that,

"The Courts now adopt a purposive approach which seeks to give effect to the true purpose of legislation and are prepared to look at much extraneous material that bears upon the background against which the legislation was enacted."

In Sri Lanka, the Courts were reluctant to consider the proceedings in the Parliament for the purpose of interpretation. However, the attitude of our Courts took a new turn tilting towards a purposive approach in J.B. Textiles Industries Ltd. v. Minister of Finance and Planning [1981] 1 Sri LR 156 where Samarakoon, C.J., expressed the view that,

"Hansards are admissible to prove that course of proceedings in the legislature."

Since the decision in J.B. Textile Industries Ltd., (supra), our Courts had acted with approval the acceptability in perusing the Hansard for the purpose of ascertaining the intention of the Parliament. Manawadu v. Attorney General [1987] 2 Sri LR 30. In fact in De Silva and Others v. Jeyaraj Fernandopulle and Others [1996] 1 Sri LR 22 Mark Fernando, J. adopted the observations of Samarakoon, C.J. in J.B. Textiles Industries Ltd., case (supra) which stated as follows:

"The Hansard is the official publication of Parliament. It is published to keep the public informed of what takes place in Parliament. It is neither sacrosanct nor untouchable."

It is therefore apparent that the Court which now adopts a purposive approach, could refer to the Hansard for the purpose of ascertaining the intention and the true purpose of the legislature in order to interpret the legislation which is ambiguous, obscure or leading to an absurdity.

The speech made by the then Hon. Minister of Justice, Prof. G. L. Peiris at the introduction of the Bail Act, would thus be important in the interpretation of section 3(1) of the Bail Act.

Hence the appointment of the 3rd respondent as a member by letter marked D is bad in law and therefore null and void *ab initio*.

Appointment shall be for the Balance Period only

Letter D further states that "*Your term of office shall be for a period of three years*". This is also bad in law.

According to section 9(1) of the Act the appointed member shall hold office for a period of three years. Section 9(4)(c) says that when a member is removed and another appointed in his place, the latter "*shall hold office for the unexpired period of the term of office of the member whom he succeeds*."

After the institution of this action by the document marked R10 dated 05.08.2016 this has later been corrected by the 1st

respondent to say that the appointments of the 3rd respondent as a Member and Chairman shall expire on 13.05.2018.

Conflict of Interest

Letter D further states:

> *Apart from the above, you may need to declare before accepting the appointment that you have no financial or other conflict of interest of the affairs of the Authority, which is likely to affect adversely in discharging your functions as a member of the Authority within the last 3 years and at present.*

This has been included in the Letter of Appointment marked D in view of section 6 of the Act, which reads as follows:

> *6(1) The Minister shall, prior to appointing a person as a member of the Authority, satisfy himself that such person has no financial or other conflict of interest in the affairs of the Authority, as is likely to affect adversely, the discharging of his functions as a member of the Authority.*
>
> *(2) The Minister shall also satisfy himself, from time to time, that no member of the Authority has since being appointed acquired any such interest.*
>
> *(3) The person to be appointed as a member of the Authority shall be a person who has not been engaged in any employment or assignment in the pharmaceutical industry within the period of three years immediately prior to such appointment.*

(4) No person shall engage in any employment or assignment in the pharmaceutical industry within the period of three years immediately after such person ceased to be a member of the Authority.

(5)(a) A member of the Authority who is in any way, directly or indirectly interested in any contract made or proposed to be made by the Authority shall disclose the nature of his interest at a meeting of the Authority; and

(b) Such disclosure shall be recorded in the minutes of the Authority and the member shall not participate in any deliberation or decision of the Authority with regard to that contract.

(6) Minister may make regulations to further specify and give effect to the provisions of this section.

(7) For the purposes of this section-

"a member of the authority" includes the Chairman, an appointed member and an ex-officio member; and

"conflict of interest" includes any dealing with any company or undertaking which engages in manufacturing, importation, distribution or sale of medicines, medical devices, borderline products or investigational medicinal products.

In terms of section 146 "*investigational medicinal product*" means a product which is under investigation by a clinical trial or equivalent studies which may include a medicine, medical device or a borderline product.

Section 7(d) of the Act is also relevant in this regard. It reads:

> *A person shall be disqualified from being appointed or continuing as a member of the Authority, if he has any financial or other interest as is likely to affect prejudicially the discharge by him of his functions as a member of the Authority.*

Letter marked D is the Letter of Appointment appointing the 3rd respondent as a member of the Authority. According to this letter, the 1st respondent has asked the 3rd respondent to declare, before accepting the appointment, that the latter has no financial or other conflict of interest of the affairs of the Authority, which is likely to affect adversely in discharging his functions as a member of the Authority within the last 3 years and at present.

This is also violative of section 6(1) of the Act which requires "*The Minister shall, prior to appointing a person as a member of the Authority, satisfy himself that such person has no financial or other conflict of interest in the affairs of the Authority, as is likely to affect adversely, the discharging of his functions as a member of the Authority*."

I am unable to accept the argument of the learned Senior State Counsel that: "*Theoretically, the Minister can rely on the general reputation of the intended appointee and his own intuition and form an opinion that such a conflict of interest does not exist. Importantly, section 6(1) does not set out any particular procedure the Minister should follow to satisfy himself that no conflict of*

interest exists." The 1st respondent is there performing a public duty and not a private duty.

The learned President's Counsel for the petitioner and the learned President's Counsel for the 7th-12th and 15th respondents strenuously contend that as there is a conflict of interest, the 1st respondent could not have appointed the 3rd respondent as a member of the Authority. It is noteworthy that the 7th-12th and 15th respondents are also Members of the Authority.

It is important to realize that the word used in section 6(1) and 7(d) is "*likely*". Section 6(1) speaks of "*financial or other conflict of interest*" as is likely to affect "*adversely*" in the discharge of duties as a member. Section 7(d) is, in my view, couched in even broader terms. It speaks of "*financial or other interest*" (not necessarily conflict of interest) as is likely to affect "*prejudicially*" in the discharge of duties as a member. The test under section 7(d) is objective. By looking at those sections it is clear that, a member of the Authority, like Caesar's wife, must be above suspicion. The member shall, as seen from subsections 6(2)-(4), maintain that position not only during the course of his holding the office, but before and after, for a period of three years.

Let me now advert to the reply of the 3rd respondent to the letter marked D. The letter D was replied by the 3rd respondent by the letter marked E dated 31.05.2016. By that letter, the 3rd respondent has first accepted the appointment.

Thereafter the 3rd respondent has stated as follows:

In accepting the aforesaid appointment I need to keep you fully informed of my existing obligations that I need to continue with.

I have held various positions in academia over 23 years and have been a university professor in pharmacology since 2005. I am presently (as well as within the last three years) engaged in the following areas of work in my professional capacity:

1. Teaching and examining undergraduate and postgraduate medical students.

2. Performing, administering and managing medical research, including clinical trials, in collaboration with local and international investigators and institutions. This is done through the Clinical Trials Unit (CTU), Faculty of Medicine, University of Kelaniya and RemediumOne (Pvt) Ltd, a company established as a public-private partnership, which is affiliated to the Faculty of Medicine, University of Kelaniya. I am a Director of both, the CTU and RemediumOne.

3. Private consultation practice outside university working hours.

To the best of my knowledge, I have no reason to believe that any of the above functions conflict with my responsibilities as a member of the National Medicines Regulatory Authority nor will they adversely affect the authority's functions. However, I will resign from the Board of Directors of RemediumOne to avoid any appearance of a conflict of interest, real or perceived, and however remote.

If we take letter E at its best, by that letter the 3rd respondent admits that he is presently (as well as within the last three years) engaged in at least "*clinical trials*". This is one area, according to the Act, the Authority is seriously concerned with. In terms of section 3, one of the objects of the Authority is to regulate all matters pertaining to the conduct of clinical trials in Sri Lanka, and the long title of the Act states that there will be a "*Clinical Trials Regulatory Division*" in the Authority.

According to section 6(7), "*conflict of interest*" includes any dealing with any company or undertaking which engages in *inter alia* "*investigational medicinal products*", and according to section 146 "*investigational medicinal product*" means a product (such as medicine, medical device or a borderline product) which is under investigation by a *clinical trial*.

According to letter E, the 3rd respondent has been conducting clinical trials in collaboration with local and international investigators and institutions through the Clinical Trials Unit of the Faculty of Medicine, University of Kelaniya and RemediumOne (Pvt) Ltd, a company established as a public-private partnership, which is affiliated to the Faculty of Medicine, University of Kelaniya.

The learned President's Counsel strenuously submits that there is no proof except the *ipse dixit* of the 3rd respondent in document marked E that RemediumOne is a company established as a public-private partnership with the University or any other. According to clause 3 of the Articles of Association of RemediumOne marked H dated 25.09.2009, the company is a

fully private owned company and "*Any invitation to the public to subscribe for shares or other securities of the Company is prohibited*". There is no mention about any partnership with the Kelaniya University in the Articles of Association. Further, according to the Articles of Association, the initial shareholders are the 3rd respondent, a businessman and an engineer. By looking at the objects of the company-all medically related-the learned President's Counsel submits that the 3rd respondent who plays the central role in the company is in fact the *alter ego* of the company. As seen from the Annual Return of the company on 11.08.2015 marked H1, the former two shareholders-the businessman and the engineer-have ceased to be shareholders and new shareholders have come in. According to H1, the 3rd respondent holds 1 share and his wife 31,000 shares.

The 3rd respondent, as seen from H2, has, after his appointment as a member of the Authority, resigned from the Board of Directors of the company. But the owners of a company are not the Directors but the Shareholders.

Document marked I is the webpage of RemediumOne.

Under tab "*About Us*" it says:

> *As Sri Lanka's pioneering clinical research company, our research management services span multiple disciplines from paediatrics to geriatrics, diabetes to oncology, and subspecialty medicine to ophthalmology. We have access to a wide network of tertiary-care hospitals and <u>offer our valued partners complete clinical trial management services</u>*

> *from submission to close out at selected healthcare institutions. This is achieved by identifying highly qualified medical specialists, providing suitably trained manpower, dedicated coordination and an uncompromising attention to quality. Our trained Clinical Research Coordinators are permanently based in clinical trial sites at number of government hospitals throughout the country. We have an excellent track record of providing such services to both academic institutions and multinational pharmaceutical companies involving drug development.*

Under the Tab "*Our Partners*" it says:

> *Over the last four years we have developed strong collaborative links with a number of multi-national companies and Clinical Research Organizations including Covance, Ecron-Accunova, Ergomed, INC Research, Pharm-Olam, Quintiles, and SIRO-Clinpharm. In addition, we work closely with centres of academic excellence including the Universities of Oxford and Nottingham, National University of Singapore, Duke-NUS, Duke Clinical Research Institute and George Institute for many investigator-sponsored studies.*

The document marked J is the webpage of the Clinical Trials Unit of the Faculty of Medicine, University of Kelaniya.

Under the Tab "*About Us*" it *inter alia* says:

> *The CTU, through its exclusive partnership with RemediumOne, Sri Lanka's pioneering clinical research*

> *company, facilitates the conduct of clinical trials in these disease areas by providing suitably trained manpower, scientific and logistical support, coordinating facilities, and other support for academic institutions as well as multinational pharmaceutical companies involved in the development of novel therapeutic interventions.*

Under the Tab "*Activities*" it says:

> *As an academic research unit, the CTU has the advantage of having access to a large number of patients from multi-specialty tertiary care hospitals as well as the community, and to research knowledge and expertise available in other university departments. Coupled with the excellent project management skills that RemediumOne bring into the equation, we are in a unique position to design and conduct our own research as well as participate in large multi-centre clinical research programmes.*

Under the Tab "*Contacts*", the only contactable person is the 3rd respondent.

An Agreement entered into between the University of Kelaniya and RemediumOne regarding conducting of Clinical Trials was tendered by the petitioners with the counter affidavit marked R. Clause 2 of that Agreement reads as follows:

> *2. PAYMENT TERMS*
> *The University shall receive remuneration under this Agreement, amounting to Five percent (5%) of REMEDIUMONE's individual Client contract value up to US$*

> *200,000 and thereon at Two percent (2%) where the value of each such contract is in excess of US$ 200,000 up to a maximum remuneration of US$ 50,000 per Client contract. Payment shall be made as an annual payment during the period of the contract between REMEDIUMONE and Client and strictly on money received basis. This clause shall become operative upon the execution of this Agreement.*

In such contracts between the University and RemediumOne, it is seen, RemediumOne retains 95% of the contract value whereas only 5% goes to the University. This clause alone explains the nature of the business of RemediumOne and the relationship between the University and RemediumOne in conducting Clinical Trials.

The petitioners have also tendered documents with counter affidavit marked N, O and P obtained from Sri Lanka Clinical Trials Registry to show the engagement of RemediumOne and the 3rd respondent with the pharmaceutical industry.

The learned Senior State Counsel also argues that:

> *Section 6(3) prohibits the appointment of a person who has been engaged in any "employment" or "assignment" in the "pharmaceutical industry" within the three year period preceding the appointment. "Pharmaceutical industry" is not an ambiguous expression and can be defined with relative certainty. The pharmaceutical industry consists of public and private organizations that discover, develop, manufacture and market medicines for human and animal health.*

The argument of the learned Senior State Counsel is that the 3rd respondent is not a person who has been engaging in any employment or assignment in the pharmaceutical industry. I am unable to agree. According to the learned Senior State Counsel himself "*The pharmaceutical industry consists of public and private organizations that discover, develop, manufacture and market medicines for human and animal health*", and according to the RemediumOne webpage marked I, "*We have an excellent track record of providing such services to both academic institutions and multinational pharmaceutical companies involved in drug development*."

It is clear that the activities/business of RemediumOne fall within the regulatory framework of the Authority, and the interests of RemediumOne are obviously commercial in nature and profit driven.

The learned Senior State Counsel in his written submissions by way of epilogue *inter alia* says that:

> *The 3rd respondent has achieved the highest level of academic attainment in one of the most complex and sophisticated disciplines at one of the most prestigious universities in the world-Doctor of Philosophy from the University of Oxford in Clinical Pharmacology. He is an accomplished and respected medical professional and academic. He has received a multiplicity of awards and accolades throughout his career. There has never been any credible complaint against him. His competence has never*

been questioned; character never assailed; and commitment never doubted.

Neither the petitioners nor the 7th-12th and 15th respondent members of the Authority who support the case of the petitioners dispute these facts.

It is abundantly clear that the legislature in its wisdom has, through the Act, taken every possible and conceivable steps to see that a person who has any semblance of financial or other conflict of interest as is likely to affect adversely or prejudicially in the discharge of his duties is not appointed as a member of the Authority.

The learned President's Counsel for the petitioners has lucidly explained it in the following manner:

a) *The 3rd respondent was the Founding Director and Shareholder of RemediumOne (Pvt) Ltd;*
b) *His wife still remains a Shareholder of RemediumOne;*
c) *The 3rd respondent is the Director of the Clinical Trials Unit of the University of Kelaniya Medical Faculty;*
d) *The CTU University of Kelaniya and RemediumOne are in partnership to provide 'Contract Research Organizations' the facilities to conduct Clinical Trials in Sri Lanka;*
e) *These Clinical Trials are in relation to Medicines and Pharmaceutical products;*
f) *Most of the Clinical Trials are funded/sponsored by Pharmaceutical Companies;*

g) *The result of any Clinical Trial would be important for the said products path to be administered to patients in Sri Lanka;*

h) *It may be that CTU Kelaniya University and RemediumOne do not carry out work to bring out a particular desired result and may even act with all high standard of ethics and morality;*

i) *The question is not about RemediumOne and CTU Kelaniya University trying to bring a desired result. The issue is that they are in a position to give a result to the said Clients.*

j) *There is no doubt that there is conflict of interest and there is likely to be a conflict of interest in the situation.*

The learned President's Counsel for the 7th-12th and 15th respondent members of the Authority adds that:

> *It is obvious that any prudent business person/entity will be drawn to approach RemediumOne/the Kelaniya University for their Clinical Trial needs and other related requirements/needs including the carrying out the facilitation of clinical trials etc. [including the most crucial obtaining of regulatory clearances], and would be attracted and driven to securing the services of none other than the person who is operating as the head of the NMRA.*

The crucial question is not whether the 3rd respondent did or whether he will, but whether he can.

I accept the arguments mounted by the learned President's Counsel regarding conflict of interest.

For the aforesaid reasons, it is my considered view that the 3rd respondent could not have been appointed as a member of the Authority, particularly in terms of section 4(b)(iv), 6(1), 6(3), 7(d) of the Act, and therefore the appointment made by the document marked D is *ultra vires*.

Appointment of the 3rd Respondent as the Chairman

Section 5(1) of the Act reads as follows:

> *The Minister shall, in consultation with the Authority, appoint one of the appointed members to be the Chairman of the Authority.*

According to section 5(4), the term of office of the Chairman shall be the period of his membership of the Authority.

In terms of section 5(1), the Minister shall appoint one of the appointed members to be the Chairman of the Authority "*in consultation with the Authority*".

It is the contention of the learned President's Counsel for the petitioners that the 1st respondent did not consult the Authority prior to the said appointment. This is confirmed by the learned President's Counsel for the 7th-12th and 15th respondent members of the Authority, who state that "*It is emphatically submitted that these respondents were never consulted prior to the appointment*"—vide paragraphs 5(iii), 64-66 of the written submissions. The learned President's Counsel for the petitioners submits that, the position of the 1st respondent that he consulted some members on the 13th May 2016 is not

supported by any Minutes of such meeting and in any event "*no consultation could have taken place on the 13th May 2016 in respect of a person who is not a Member of the NMRA at the time*."

If the 3rd respondent could not have been appointed as a member of the Authority in the first place, it is obvious that he could not have been appointed as the Chairman of the Authority.

The appointment of the 3rd respondent as the Chairman of the Authority for the period covered in the document marked D and later amended by document marked R10 is therefore *ultra vires*.

Appointment of the 4th Respondent as the Acting CEO

On the direction of the 1st respondent, the 4th respondent has been appointed as the Acting Chief Executive Officer by letter marked M dated 03.06.2016.

Section 15(1) of the Act reads as follows:

> *The Authority shall in consultation with the Minister, appoint to the Staff of the Authority a Chief Executive Officer from among persons who hold a postgraduate degree from a recognized University in Medicine, Pharmacology, Pharmacy or any other related discipline with at least five years management experience at senior executive level.*

It is clear that it is the Authority which has the power to appoint a Chief Executive Officer, whether permanent or acting, in consultation with the Minister.

This has later been corrected as seen from documents marked R16, R16A-R16C.

The appointment made by document marked M is *ultra vires*.

Futility

The learned Senior State Counsel appearing for the 1st-5th, 14th and 16th respondents states thus:

> *The petitioner filed this application seeking to quash the appointment of the 3rd respondent as both a member and Chairman of the Authority. He was appointed as a member on 20th May 2016 and as Chairman on 13th June 2016. However, the respondent's term of office as a member (and consequently his Chairmanship) came to an end on 13th May 2018. This is not disputed by the petitioner. He has subsequently been appointed as both a member and a Chairman-on 15th May 2018 and 18th May 2018 respectively. To be clear, these appointments are independent and distinct from his previous appointment. The petitioner continues to challenge only the now expired appointments. It is for this reason that [it is] submitted that this application is futile. No meaningful purpose will be served by granting certiorari. Even if this Court holds that the respondent's appointment was illegal that ruling will apply only to the appointment actually challenged.*

I do concede that the ruling in this case will apply only to the appointments actually challenged, i.e. previous appointments,

but I do not concede that no purpose would be served by allowing the application.

It is well settled law that rights of the parties shall be determined at the time of the institution of the action. *(Talagune v. De Livera [1997] 1 Sri LR 253 at 255, Kalamazoo Industries Ltd v. Minister of Labour and Vocational Training [1998] 1 Sri LR 235 at 248, Lalwani v. Indian Overseas Bank [1998] 3 Sri LR 197 at 198)*

In the application for writ of mandamus, in *Abayadeera v. Dr. Stanley Wijesundara, Vice Chancellor, University of Colombo [1983] 2 Sri LR 267 at 280,* it was held that:

> *The petition in this case was filed on 30.6.83. The Emergency (Universities) Regulations No. 1 of 1983, cited by learned counsel for the petitioners, and on which he founded an argument, were made on 21.7.83. In our view these regulations have no application, for, rights of parties are their rights at the date the petitioners' application was made (Jamal Mohideen & Co. v. Meera Saibo 22 NLR 268, 272, Silva v. Fernando 15 NLR 499, 500) and must be decided according to the law as it existed when the application was made (10 NLR 44 at 51); Ponnamma v. Arumugam 8 NLR 223, 226.*

In *Kalamazoo Industries Ltd v. Minister of Labour & Vocational Training [1998] 1 Sri LR 235 at 248*, the petitioners sought to quash the arbitral award by certiorari and prohibition. Dismissing that application, Jayasuriya J. *inter alia* stated:

> *It is trite law that a court or tribunal must determine and ascertain the rights of parties as at the date of the institution of the action or as at the date of the making of the reference for arbitration. Commencement of the action is the time at which the rights of the parties are to be ascertained. Vide Silva v. Fernando 15 NLR 499 (PC), Mohamed v. Meera Saibo 22 NLR 268, Bartleet v. Marikkar 40 NLR 350. The claim and demand on behalf of the workers who were members of the fourth respondent trade union had been made on 12th of March, 1988. The reference by the Minister of Labour for settlement by arbitration had been made on the 24th of November, 1989 and the statement of the matter in dispute has been framed by the Commissioner of Labour and specified on the 24th of November, 1989. In the circumstances, the arbitrator had jurisdiction, authority and right to decree the grant of a salary increase of Rs. 250 with effect from 24.11.89.*

Therefore this Court is duty bound to make a determination concerning the rights of the parties at the time of the institution of the action.

The learned President's Counsel for the petitioner, as seen from the early journal entries, has desperately sought to support the application for an interim order and notice, but the same had been kept on postponing on various reasons due to no fault of the petitioner.

The Court will not be acting in vein by allowing the application notwithstanding the appointments challenged in this application are no more live issues.

In *Sundarkaran v. Bharathi [1989] 1 Sri LR 46* the petitioner-appellant applied for certiorari and mandamus against the refusal to issue a liquor license for 1987. When it came before the Supreme Court the matter was only academic as the year 1987 had lapsed. Nonetheless, whilst allowing the appeal, Amarasinghe J. took the view that "*The court will not be acting in vain in quashing the determination not to issue the licence for 1987 because the right of the petitioner to be fully and fairly heard in future applications is being recognised*."

In *Nimalasiri v. Divisional Secretary, Galewela [2003] 3 Sri LR 85*, Sripavan J. (later C.J.) stated:

> *Learned State Counsel urged that it is a futile exercise to issue a writ of certiorari because the decision complained of related to the year 2002 which had already expired. However, following the decision in Sudakaran v. Barathi and others [1989] 1 Sri LR 46 this Court issues a writ of certiorari quashing the decision of the second respondent contained in the letter dated 27.08.2002 marked (P4). Thus this Court is not acting in vain because the right of the petitioner to be fully and fairly heard in future application is recognized.*

Conclusion

The appointment of the 3rd respondent as a member of the National Medicines Regulatory Authority by document marked D amended by R10, and the appointment of the 3rd respondent as the Chairman during that period covered in the said documents, and the appointment of the 4th respondent as the Acting Chief Executive Officer by document marked M are bad in law and therefore null and void *ab initio*. I quash those appointments by way of writ of certiorari.

Application of the petitioner is allowed with costs.

Judge of the Court of Appeal