Malithi Alahapperuma v National Medicines Regulatory Authority (NMRA)

RTIC Appeal (In-Person Hearing)/ [547/2018] heard together with RTIC Appeal (In-Person Hearing)/ [465/2018]- Order adopted subsequent to the hearing/ consideration at a part of the formal meeting of the Commission on 04.12.2018]

Order under Section 32 (1) of the Right to Information Act, No. 12 of 2016 and Record of Proceedings under Rule 28 of the Right to Information Rules of 2017 (Fees and Appeal Procedure)

Chairperson: Mr. Mahinda Gammampila
Commission Member: Ms. Kishali Pinto-Jayawardena
Commission Member: Mr. S.G. Punchihewa
Commission Member: Dr. Selvy Thiruchandran
Commission Member: Justice Rohini Walgama

Director-General: Mr. Piyathissa Ranasinghe

Appellant: Malithi Alahapperuma

Notice issued to: Designated Officer, National Medicines Regulatory Authority (NMRA)

Appearance/ Represented by:

Appellant - Not present
PA - Not present

RTI Request filed on	08.02.2018
IO responded on	26.03.2018
First Appeal to DO filed on	02.04.2018, 04.05.2018
DO responded on	No response
Appeal to RTIC filed on	13.07.2018

Brief Factual Background:

The Appellant by the letter dated 08.02.2018 requested the following information,

RTI No:	**Information in the RTI Request**
RTI 01	Regulations or guidelines issued on method of preparation, the manufacture, preservation, packaging, storing and testing of any medicine in the interest of or for the prevention of injury to, the health of the user or purchaser as per Section 142 (2) (h) of the NMRA Act No.05 of 2015.
RTI 02	Details (including dates) / copies of the guidelines issued by the Authority to the NMQAL on testing or analysis of articles submitted to the NMQAL.

RTI 03	1. Regulations issued on the procedure to be followed by the Medicines Evaluation Committees in the conduct of its functions and the transaction of its business as per Section 142 (2) (x) of NMRA Act No.05 of 2015 and 2. Regulations issued on the procedure to be followed by the Medicines Evaluation Committee for the respective evaluations and matters which should be included in reports as per Section 142 (2) (z) of NMRA Act No.05 of 2015
RTI 04	As per Section 47 (4) of the NMRA Act No.05 of 2015, Regulations or Guidelines issued on procedures to be followed, including specified time limits for conduct of respective evaluations, to give effect to GMP guidelines, GRP guidelines, may be recommended by the Authority. 1. Details (including dates)/ Copies of Regulations issued: i. For procedures to be followed, including specified time limits, for conduct of respective evaluations, ii. Giving effect to GMP guidelines, and if no such regulations have been issued, then information on any direction given by the Authority on providing such regulations and iii. Giving effect to GRP and if no such regulations have been issued, information regarding any direction provided by the Authority on passing such regulations.
RTI 05	As per Section 3 (j) of the NMRA Act No.05 of 2015, the objective of the Authority is to conduct post-market surveillance on quality, safety and adverse reaction of the medicines, medical devices and borderline products. 1. Has the Authority or any Division functioning under the NMRA issued any guidelines on any aspect relating to post-market surveillance? 2. What is the nature of post-market surveillance activities conducted under the NMRA for pharmaceutical drugs? 3. Officers authorized to engage in post-market surveillance? 4. Dates and all information pertaining to audits conducted by authorized officers from 20th March 2015 to date?
RTI 06	Formula used to determine prices of drugs not listed as 48 scheduled drugs under Gazette No. 1989/61 dates 21st October 2016.
RTI 07	As per Section 47 (1) of the NMRA Act No.05 of 2015, the guidelines are to be issued to the Medicines Evaluation Committee (MEC) by the Authority for evaluation of medicines and other related items. Details (including dates) / copies of the guidelines issued by the Authority to the MEC in this regard.
RTI 08	1. Members of the Authority appointed as per Section 4 of the NMRA Act No.05 of 2015,

	2. Minutes of the meetings of the Authority held according to Section 10 of the NMRA Act No.05 of 2015 from 20th March 2015 to date and 3. Attendance list of the meetings of the Authority from 20th March 2015 to date.
RTI 09	1. Members of National Advisory Committee appointed as per Section 31 of the NMRA Act No.05 of 2015, 2. Minutes of the meetings of the National Advisory Committee held according to Section 10 and Section 37 of the NMRA Act No.05 of 2015 from 20th March 2015 to date and 3. Attendance list of the meetings of the National Advisory Committee from 20th March 2015 to date.

The Information Officer (IO) on 26.03.2018 responded stating that the NMR (Public Authority) is unable to share the requested information regarding the price regulation of essential medicines. Furthermore the IO had stated that Verite Research, the institution on behalf of which the Appellant was making the request is proposing to develop pricing strategies for medicines at the request of the Sri Lankan Chamber of Pharmaceutical Industry (SLCPI) and is receiving a contract fee for same from this Chamber. Dissatisfied with the response of the IO the Appellant lodged an appeal with the DO on 02.04.2018 and 04.05.2018. As the DO failed to respond with the time period stipulated under the Act the Appellant preferred an appeal to the Commission on 13.07.2018.

Minutes of the hearing

The Appellant and the Public Authority were not present.

The Appellant by letter dated 05.12.2018 informed the Commission the following reasons of non-attendance to the hearing on 04.12.2018,

"……- Upon following due procedures and yet not having any success in obtaining information, I appealed to the RTI Commission with regard to the 16 requests. For the ease of processing, I submitted two appeals to the Commission: (i) for the 9 requests acknowledged by the NMRA; and (ii) for the 7 requests for which the NMRA did not respond. I was called in for a hearing at the RTI Commission on 27th November 2018 (Appeal number: RTIC Appeal/465/2018) with regard to one of my appeals. However, at the hearing, all 16 requests were taken for discussion and the RTI Commission issued instructions to the NMRA to file a submission relating to the information denied and information for which no response was given. The follow-up hearing has been fixed for 29th January 2019. I have now received a letter for a second hearing (Appeal number: RTIC Appeal/547/2018) which was to be held at 11.30am on 4th December 2018. However, since all 16 requests were already discussed at the hearing held on 27th November 2018 and I am yet to receive the responses as directed by the RTI Commission from the NMRA, I believe a second hearing would be redundant."

Notices directed to be sent to the Appellant and the Information Officer (IO)/ Designated Officer (DO) required to be present under and in terms of Section 15 (a) of the RTI Act.

The matter is re-fixed for hearing on 29.01.2019
The Appeal is adjourned.

RTIC Appeal (In-Person Hearing)/ [547/2018] heard together with RTIC Appeal (In-Person Hearing)/ [465/2018] - Order adopted subsequent to the hearing/ consideration at a part of the formal meeting of the Commission on 29.01.2019]

Order under Section 32 (1) of the Right to Information Act, No. 12 of 2016 and Record of Proceedings under Rule 28 of the Right to Information Rules of 2017 (Fees and Appeal Procedure)

Chairperson: Mr. Mahinda Gammampila
Commission Member: Ms. Kishali Pinto-Jayawardena
Commission Member: Mr. S.G. Punchihewa
Commission Member: Dr. Selvy Thiruchandran
Commission Member: Justice Rohini Walgama

Director-General: Mr. Piyathissa Ranasinghe

Appellant: Malithi Alahapperuma

Notice issued to: Designated Officer, National Medicines Regulatory Authority (NMRA)

Appearance/ Represented by:

Appellant – Malithi Alahapperuma
Sachintha Fernando
M de Silva – AAL

PA - A Ajith Priyadarshana
H A Pushpakumara – IO
Gopi Krishantha de Silva
Arjuna Pathmaperuma
Hemasiri Gunathilake

Matters arising in the course of the Hearing

Counsel for the Appellant submitted that the information requests were consolidated as requested by the Commission in order simplify the information requests and receiving of the

information. Counsel further submitted that the NMRA had honoured the requests and the Appellant was provided with a substantial part of the information requested.
However, the Appellant contended that she was not satisfied with information provided under the following, namely;

1. Timelines of the NMRA as requested under RTI 04
2. Minutes of meetings negotiating pricing as requested under RTI 08
3. Minutes of stakeholder meetings as requested under RTI 09

In responding to the queries, the NMRA responded as follows;

1. Timelines of the NMRA as requested under RTI 04

The PA is still in the process of setting up and streamlining its functioning as a unit, and the relevant drafting pertaining to regulations, as requested, is being communicated with the Legal Draftsman's Department and the first draft is still in the process of being finalised. Accordingly the PA is unable to give a specific time limit. However it intends to circulate the drafts among the Public as soon as the process is complete.

2. Minutes of meetings negotiating pricing as requested under RTI 08

The pricing and strategies as discussed are still being negotiated and release of this information in a premature state could be problematic and hinder the smooth functioning of the NMRA and affect future strategies. However, the criterion that is been used for the pricing had been provided to the Appellant.

3. Minutes of stakeholder meetings as requested under RTI 09

As discussed in the above query, release of stakeholder meeting minutes in a premature state could be problematic and hinder the smooth functioning of the NMRA and affect future strategies.

In response, the Appellant submitted that the criterion provided was a rigid list which does not incorporate many of the crucial elements that the Appellant expects it would entail.

The Commission, agreeing with the PA with regard to its inability to provide accurate timelines, queried the PA if it could expand the ambit of the information provided under the other two headings without causing any prejudice to the functioning of the PA and to revert on the matter at the next hearing.

The Appeal is hereby adjourned.
Next date of hearing: 09.04.2019
******