පාර්ලිමේන්තු ප්‍රකාශන මාලා අංක - 181

ජාතික ඖෂධ නියාමන අධිකාරිය

පාර්ලිමේන්තුවේ පොදු ව්‍යාපාර පිළිබඳ කාරක සභාව විසින් සභාගත කරන ලද

වාර්තා සම්බන්ධයෙන් ස්ථාවර නියෝග 120(4) යටතේ ගරු අමාත්‍යවරයාගේ නිරීක්ෂණ

හා ගනු ලබන පියවර පාර්ලිමේන්තුව වෙත ඉදිරිපත් කිරීම

பாராளுமன்ற வெளியீட்டு தொடர் இல - 181

தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகாரபை

பாராளுமன்ற பொது முயற்சிகள் குழுவினால் முன் வைக்கப்பட்ட அறிக்கை தொடர்பாக நிலையியல் கட்டளை இலக்கம் 120(4) இன் கீழ் கௌரவ அமைச்சரின் அவதானிப்புக்களும் மற்றும் அது தொடர்பாக எடுக்கப்படும் நடவடிக்கைகளும் பாராளுமன்றத்திற்கு சமர்ப்பித்தல்

Parliamentary Series Number – 181

National Medicines Regulatory Authority

Submission of observations of the Hon. Minister in charge of the institutions and steps taken with regard to the reports tabled by the Committee on Public Enterprises in terms of Standing Order No. 120(4)

Parliamentary Series No. 181

Institution-National Medicines Regulatory Authority

Directive/Recommendation of the Committee	Actions taken/proposed to be taken in response to the observations/ any alternative actions considered/current status in accordance with the Standing Order No. 120(4)
1.2 Internal Audit Taking steps to promptly recruit an Internal Auditor for the institution and to submit a report on this to the Committee within 1 month with copies to the Auditor General.	Action was taken by the National Medicines Regulatory Authority to conduct a formal interview and to grant an appointment letter to the applicant who obtained the highest marks, on 2025.03.05 however, after accepting the appointment she resigned on 2025.03.11 due to a personal reason and thereafter, arrangements were made to grant the appointment to the applicant who obtained the second highest marks, but he also informed that he would not be able to accept the appointment. At present, Ministry of Health and Mass Media has appointed an officer to this post on a acting basis. A newspaper advertisement was published again for urgently recruiting an Internal Auditor on the permanent basis and applications have been received for the same. Accordingly, further steps are being taken in respect of making the recruitment.
1.3 Cadre as at 26 January 2025 i. Discuss the problems in carrying out internal promotions within the institution with the Department of Management Services and take steps to prepare a correct methodology.	A discussion headed by the Director General of the Department of Management Services was held on 26.05.2025 in respect of the issues related to internal promotions, and during the discussion the issues were identified. Instructions have been given to prepare a suitable methodology and proposal in this regard and submit it to the Department of Management Services.

ii. Prepare Schemes of Recruitment for the posts, for which Schemes of Recruitment (SOR) have not been prepared so far and submit them for necessary approvals and to submit a report on these matters to the Committee within 1 month with copies to the Auditor General.	i.The scheme of recruitment for the post of Technical Officer (Civil) has been submitted by the Ministry of Health to the Department of Management Services for approval on 2025.04.01 and approval was received on 2025.05.02 ii. The scheme of recruitment for the post of Cost Accountant has been prepared and submitted to the Department of Management Services for approval. iii. From among the posts approved for the National Medicines Regulatory Authority, the scheme of recruitment for the posts of Director belonging to the Senior Managerial Service category, has been submitted by the Ministry of Health to the Department of Management Services for approval on 2025.03.13 and approval was received for the same on 2025.05.02 iv. Approval has already been received for the schemes of recruitment for other posts.
iii. Since the problem related to the recruitment of employees for the posts in the primary category affects the entire public service, to consider this matter and take necessary steps to submit the necessary proposals to the government to prepare an updated methodology for the recruitment of employees for the posts in the primary category and to submit a report on these matters to the Committee within 1 month with copies to the Auditor General.	A recommendation received by the Department of Management Services.

02. Non-compliance with the provisions of the Act (a) To make proposals to collect data on the need and quantity of medicines and pharmaceutical products and to regulate the availability of medicines in the country in accordance with sub-section 14 (j) of the National Medicines Regulatory Authority Act, No. 05 of 2015.	It has already been started to collect complete data on the quantity and prices of all medicines cleared by the Sri Lanka Customs. A large percentage of the medicines available in the country are imported medicines, while the other medicines are locally manufactured. In addition to that, a small quantity of medicines is received as donations. And, there are cases where some medicines are brought to Sri Lanka from other countries through illegal means. Medicines are imported and locally supplied to the public sector based on estimates made by the Medical Supplies Division. The types and quantities of medicines available in the private sector depend on the prescription and use of medicine imported and locally supplied. Therefore, both these situations are beyond the control of the National Medicines Regulatory Authority. However, in cases where there are no registered suppliers for some medicines or when registered suppliers do not submit tenders, a shortage of such medicines will occur in the country. As suitable alternative measures to be taken in this regard, the State Pharmaceutical Corporation can directly import such selected medicines to the country and manufacture those selected medicines and motivate the local manufacturers. National Medicines Regulatory Authority has taken steps not to charge a fee for registration of medicines imported to the country in small quantities in order to encourage suppliers of such medicines.

	National Medicines Regulatory Authority has started conducting of inspections to check whether medicines illegally brought to Sri Lanka are being sold in pharmacies. For this purpose, 10 Assistant Drug Inspectors have been recruited in the last month. Data is collected through the Cusdec Number using the Asykuda System, but the quantity is not recorded.
(b) Take urgent action to create a pricing formula for regulating the prices of medicines considering regional prices, and submit a report in this regard (including relevant proposals to make the public aware the minimum prices recommended for medicines) to the Committee with a copy to the Auditor General before 12 April 2025.	The pricing formula has been created and gazetted by now. The injunction imposed has been removed.
(c)To take necessary actions to make guidelines for the evaluation of other products such as perfumes and nutritional supplements as soon as possible and to report the progress in this regard to the Committee within 3 months with copies to the Auditor General.	In the discussion held between the Ministry of Health and the National Medicines Regulatory Authority in respect of the regulation of perfumes, as per the recommendation, it was decided that a new committee should be appointed with the approval of the new cabinet and the regulation of perfumes should be taken over by the National Medicines Regulatory Authority. Accordingly, the committee was appointed under the chairmanship of the Director General of Health Services and the first meeting of the committee was held on 01.08.2025. Accordingly, plans are being prepared for the evaluation of other products such as perfumes and nutritional supplements
(d) Even though regulations were to be made to give effect to the Good Manufacturing Practices guidelines and other applicable guidelines setting out the procedures to be	Guidelines regarding the medical devices are being developed.

followed, including the specified time limits for the conduct of respective evaluations for medical devices and borderline products in terms of sub-sections 72(4) and 93(4) of the Act, the Committee observed that action had not been taken accordingly and the Committee recommended that intervention be taken in this regard.	The website has been updated to include the new regulatory procedures applicable to borderline products. Action is being taken to develop and publish the Guidelines.
(e)Even though permitted medical devices and borderline products registered in terms of sub-sections 74(1) and 95(1) of the Act were to be listed by the Minister from time to time, action had not been taken accordingly. To reconsider the issuance of the relevant gazette notification and take necessary action to publish the said lists expeditiously.	The registration process was expedited to overcome the serious situation which arose due to the delay in issuing registrations by the National Medicines Regulatory Authority. So that, even though publishing of the gazettes, was delayed, the relevant gazettes will be published within the next 3 months in accordance with sub-sections 74(1) and 95(1). The list of registered borderline products has been published on the website and necessary steps are being taken to prepare and publish the list of medical devices.
(f) Even though the Minister should have made regulations in terms of sub-sections 83(6) and 102(6) of the Act, specifying the procedures to be followed by the Medical Devices and Borderline Products Evaluation Committees and the National Medicines Quality Assurance Laboratory in conducting such testing or evaluation process, the time limits for such process, the manner in which the Evaluation Committee to conduct its meetings and the procedure to be followed at such meetings and the matters which should be included in the reports to be submitted, the Committee observed that action had not been taken accordingly and the Committee recommended that the relevant work be completed.	As per the recommendations in respect of the Cabinet Paper No. 24/0417/640/007 titled, Establishment of the National Medicines Regulatory Authority in the Building of No. 385, Suwasiripaya, approval has been granted to allocate 01 billion Rupees from the National Medicines Regulatory Authority Fund for the renovation of the Suwasiripaya building and for the improvement of the facilities of the National Medicines Regulatory Authority's laboratory. The renovation work on the roof of the laboratory is currently in the final stage.

	Necessary steps are being taken to appoint a representative with the expertise relevant to the other renovation works. Discussions were held with the Additional Secretary Procurement of the Ministry of Health and it was decided that it would be more appropriate to proceed according to the Design and Build method. Accordingly, action is being taken to call quotations and to carry out further procurement work in this regard.
(g) The instances where the refusal of registration of medical devices and borderline products had not been notified to the public by the Orders published in the Gazette in terms of sections 84(2), 85, 103(2) and 104 of the Act and although the medicines registered up to the year 2019 had been published in the Extraordinary Gazette No. 2144/20 dated 09 October 2019 action had not been taken accordingly thereafter. Examining whether instances of registration and refusal of registration have been published in the Gazette by the Orders for notifying the public of such registration and refusal of registration.	Registrations of medical devices and borderline products are published on the website and attention is paid to the necessary action to be taken in respect of rejections.
3.1 System to automate the Procurement Data System (e-NMRA automation) I. To submit a report to the Committee within 01 month with copies to the Auditor General regarding the measures to be taken in the future in respect of this database, the issues encountered in selecting the relevant institution and the measures taken to recover the amount spent, if an institutional investigation has been conducted.	Currently, investigations are being carried out by an Investigation Officer regarding the automation of the procurement data system (e-NMRA automation), and a letter seeking advice on taking the necessary legal action to recover the amount spent has been submitted to the Attorney General's Department. Accordingly, necessary action will be taken based on the advice received.

II. To submit a report to the Committee with copies to the Auditor General regarding the names of companies deleted from this data base and the types of medicines requested by those companies.	The report on the types of medicines requested by companies, which were deleted from the e-NMRA database, has been forwarded to the Secretary of the Committee on Public Enterprises and the Auditor General through Annexure 08 of my reply report No. CA/AQ/FCC02/COPE/NMRA/2025(II) dated 12.06.2025.
III. To take action on the instructions of the Ministry of Digital Economy regarding this database.	A letter has been sent to the Ministry of Digital Economy seeking instructions in this regard.
3.2 Revamping the Medicine Database I. To conduct a formal investigation into the officers who gave institutional approval to make payments of Rs.4,774,752 after the preparation of the Revamping the Medicine Database and submit an interim report within 2 months with specific recommendations (initiate the investigations within 01 month) to the Committee with copies to the Auditor General.	An investigation is being conducted to cover the recommendation of the Committee on Public Enterprises regarding the revamping of the medicines database.
II. To conduct an institutional investigation to recover the amount spent on this database and to take necessary legal action.	
III. To appoint a specific officer responsible for maintaining this database.	The Information Technology Officer (Assistant Director), who was appointed to the National Medicines Regulatory Authority on 07.05.2025, will continue to work on maintaining this database.
IV. The Committee paid attention to the importance of integrating all the institutions, namely the National Medicines Regulatory Authority, the Medical Supplies Division and the State Pharmaceuticals Corporation, into a single database, taking the instructions of the Ministry of Digital Economy and obtaining	Following the request for a discussion with the Ministry of Digital Economy regarding the data system, consent has been given. Accordingly, discussions will be held in due course, and necessary actions will be taken.

instructions from the Ministry on the future activities related to the new database by the Chief Accounting Officer in coordination with the Secretary of the Ministry of Digital Economy.	
4.1 Issuance of Letters of Waiver of Registration (WOR) I. To amend the Act/Regulations so that legal action can be taken against registered suppliers who do not supply medicines to the public sector during the procurement process, that is, those who supply medicines only to the private sector, by registering with the NMRA.	The issuance of letters for all applications submitted for Waiver of Registration (WOR) has now been concluded. Such letters are issued only with the approval of a committee comprising Medical Officers and Drug Evaluation Officers, in a formal and transparent manner. Only applications recommended by the Ministry of Health are considered by the committee, and drafts are being prepared to amend the Act.
II. To amend the Act and make the necessary interventions to control the drug mafia using the provisions for issuing WOR.	
III. Conducting investigations into substandard medicines and taking necessary action against registered suppliers who import such substandard medicines and blacklisting such suppliers.	Side effects or allergic reactions caused by drugs are reported to the SAFRAC Committee established at the National Medicines Regulatory Authority. The committee, comprising specialist Medical Officers and Drug Evaluation Officers, is currently investigating the relevant incident. In cases where serious side effects are suspected, the committee immediately informs the Medical Supply Division to temporarily suspend the use of the drug and, if necessary, refers the drug to the laboratory for further testing.
IV. To look for the possibility of constructing a laboratory to test all drugs imported into the country using the funds of the Institute.	The Quality Assurance Laboratory is currently undergoing renovation, with the roof renovation in its final stage. Rs. 1 billion funds of the National Medicines Regulatory Authority have been allocated for future procurement activities, with the approval of the

	Cabinet. In this regard, steps have been taken to obtain support from the Asian Development Bank in the following areas: • Contributing to the provision of consultancy services for the renovation of the laboratory. • Providing specialized training opportunities related to the duties of the laboratory. To enhance the laboratory's testing capacity, agreements have been reached to send drug samples to the ITI, SLSI, and SLINTEC laboratories for testing. Samples are already being sent to ITI and SLSI for testing.
V. To submit a report to the Committee within 01 month, with copies to the Auditor General including the actions taken on the above matters.	□ Requests submitted to the National Medicines Regulatory Authority, along with the recommendations of the Ministry of Health, should be documented under the supervision of the Head of the relevant Division and submitted to the WOR Committee. □ Notifying the technical reports required to be submitted with the WOR request. □ Determining the criteria to be considered by the WOR Committee. □ Issuing certificates only for WORs that receive the approval of the WOR Committee. □ Removing, by December 2023, the section stating that the National Medicines Regulatory Authority is not responsible for the production, safety, and quality of drugs imported under a WOR certificate. □ Printing WOR certificates on special paper incorporating non-observable safety features.

	□ Sending the relevant copies to the concerned institutions by post. □ Maintaining documents related to the issuance of WORs in a systematic manner.
4.2 (a) Importing medicines into the country without quality testing using the special pathway method I. To summon the former CEO and former Board members of the institution before the Committee to inquire into the facts regarding this issue. (Those officers were summoned before the Committee on 26.03.2025 and inquired into the facts)	(Those officers were summoned before the Committee on 26.03.2025 and inquired into the facts)
II. To submit a detailed report to the Committee within 01 month with copies to the Auditor General, including information on the officers responsible for the damage caused by the entry of substandard medicines into the country due to the granting of permission for the import of medicines through a special procedure excluding the normal procedure for issuing WOR.	Waiver of registration process is now carried out solely on the recommendations of a committee comprising Medical Officers and Drug Evaluation Officers. Only applications recommended by the Ministry of Health are considered by the committee. As per the recommendations of the Auditor General, this process is now conducted through an independent and impartial committee. The Chief Executive Officer will not issue WOR letters without the committee's approval. The report on the import of substandard drugs into the country using the special pathway method has been forwarded to the Secretary of the Committee on Public Enterprises and to the Auditor General through Annexure 02 of my reply report No. CA/AQ/FCC02/COPE/NMRA/2025(II), dated 22.07.2025.

(b) The Committee drew close attention to the fact that the Authority had issued 38 registration exemption certificates to a company called Savorite for the import of 38 drug items submitted through unsolicited proposals in December 2022, but the National Medicines Regulatory Authority had not conducted evaluations of the relevant drugs and therefore the Authority was not responsible for the quality, safety, and efficacy of the relevant drugs and the responsibility should be assumed by the Director of the Medical Supplies Division. I. Submitting information about the local representative of the relevant institution to the Committee with copies to the Auditor General.	No information about the local representative has been recorded.
II. To conduct an investigation into the total damage caused by the importation of 323 medicines and submit a report to the Committee within 01 month with copies to the Auditor General.	An investigation is being conducted.
III. Considering of relevant issues to overcome the weaknesses of the Act.	Considering the relevant issues to overcome the weaknesses of the Act, the section stating that there is no liability for production, safety and quality has been removed from the certificate by December 2023.
06. Import of Medicines and Devices I. That there was a severe shortage of medicines in the country by the time this Cabinet Paper was prepared, that it was included in the data base of the Medical Supplies Division and submission of documents to the Committee within 1 month to prove it.	The report prepared by the then Additional Secretary to the State Ministry of Production, Supply, and Regulation of Pharmaceuticals, Mr. R.M.S.K. Rathnayake, including information regarding the Committee's recommendation, has been forwarded to the Secretary of the Committee on Public Enterprises of the Committee on Public Accounts and to the Auditor General through Annexure 01 of my reply report No. CA/AQ/FCC02/COPE/NMRA/2025(II), dated 22.07.2025.

II. To present a report to the committee within a period of one month, containing information relevant to the confirmation of factual accuracy of the Cabinet memorandum, along with details of the officer who furnished information relevant to the preparation of the cabinet memorandum and the officer who formulated the cabinet memorandum.	The Cabinet Memorandum was prepared by the then State Ministry of Production, Supply, and Regulation of Pharmaceuticals and forwarded to the Ministry of Health for submission to the Cabinet for approval. In this process, it should be accompanied by the format titled 'Format for Submission of Cabinet Memorandum to the Cabinet.' The format, so submitted, has been forwarded to the Secretary of the Committee on Public Enterprises and to the Auditor General through Annexure 02 of my reply report No. CA/AQ/FCC02/COPE/NMRA/2025(II), submitted on 22.07.2025.
08.Import of Medicines through Special Pathway Submitting the letter sent to the Secretary to the Ministry by the Chief Executive Officer through his official E-mail account, to the Committee within a period of 02 weeks.	In the process of importing medicines through the Special Pathway system, the letter sent by the Chief Executive Officer of the National Medicines Regulatory Authority to the Secretary of the Ministry using his official email address, has been forwarded to the Secretary of the Committee on Public Enterprises and to the Auditor General through Annexure 03 of my reply No. CA/AQ/FCC02/COPE/NMRA/2025(II) dated 22.07.2025.

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