



31st January 2023

Media release

Re. Inappropriate request to the National Medicines Regulation Authority (NMRA) on 'Waiver of Registration' (WoR) for supply of over 300 varieties of medicines by non-evaluated, unregistered suppliers using the Indian Credit line (ICL) under a cover of a cabinet decision

We, Ceylon College of Physicians, College of Surgeons of Sri Lanka, Sri Lanka College of Obstetricians and Gynecologists and the Sri Lanka College of Paediatricians, the four professional Colleges of Medicine represented in the National Medicines Regulatory Authority (NMRA), are deeply concerned about the irregular nature of approving medicines to be imported for the use of Sri Lankan public. Usually, before importing a drug the NMRA has to evaluate and register it. However, for the last meeting of the Medicines Evaluation Committee (MEC) of the NMRA a list of about 330 drugs, each in large quantities, which are to be purchased through the Indian Credit Line, was submitted for approval and none of these were evaluated or registered by the NMRA. We were informed that the Chief Executive Officer of NMRA has approved about 275 of these by giving a waiver of registration without any check on quality, efficacy or safety of those drugs, to be used in government hospitals and sales through State Pharmaceutical Corporation outlets. We note that several of these drugs are not essential drugs and therefore, not necessary to import during this economic crisis. Some of these drugs are not even in the list of drugs purchased by the Ministry of Health. In addition to importation of these drugs for the Government hospitals, approval had been sought for some drugs for the importation by the State Pharmaceutical Corporation for the private market.

The practice adopted recently approving drugs of which the quality, safety and the efficacy is not assessed can put the lives of our patients in danger. Furthermore, this will lead to a waste of the money as these will be purchased from a loan through the Indian Credit Line which the people will have to repay. We have raised this issue with the

Chairman of the NMRA but with the lukewarm response we had, we have decided to write to His Excellency the President seeking his intervention. Therefore, we have sent the following letter, which is self-explanatory. We sincerely believe that prompt action will be taken to stop these irregularities and to ensure the safety of patients.



27th January 2023

His Excellency Ranil Wickremasinghe
The President, Democratic Socialist Republic of Sri Lanka
Presidential Secretariat, Colombo 01.

Dear Sir,

Re. Inappropriate request to the National Medicines Regulation Authority (NMRA) on 'Waiver of Registration' (WoR) for supply of around 300 varieties of medicines by Savorite Pharmaceuticals and others from the Indian Credit line (ICL) under a cover of a cabinet decision

We wish to convey to you the concerns and reservations held by the Councils of the Ceylon College of Physicians, College of Surgeons of Sri Lanka, Sri Lanka College of Obstetricians and Gynaecologists and the Sri Lanka College of Paediatricians, on the request placed before the board members of the NMRA and the Medicinal Evaluation Committee (MEC) of the NMRA to provide a waiver of registration for around 300 varieties of medicines to be purchased by the Ministry of Health from Savorite Pharmaceuticals (Pvt) Ltd and others from the ICL under a cover of a cabinet decision.

We are very much concerned of possibility of sub-standard, non-evaluated medications made available in the public sector hospitals due to attempts by the officials of the ministry of health to obtain non-evaluated WoR, contravening the recommendations of your excellency as the finance minister made when granting the cabinet approval for this process.

The salient factors are listed below for perusal by you and the cabinet of Ministers of Sri Lanka.

1. We are extremely pleased to note Your Excellency's and the Cabinet of Ministers' recent pledge to utilise all avenues including the unutilised credit from the ICL for importing essential medicines presently in short supply.
2. We are heartened by observations of the Finance Ministry under the signature of Your Excellency in your capacity as the Minister of Finance made to the cabinet paper, stating that this is an unsolicited proposal and provided conditional approval. The conditions stipulated by Your Excellency are,
 - a) The prices and quality of medicines need to be reviewed
 - b) Procedures applicable to private sector pharmaceuticals suppliers be followed.
3. Two requests, one from the Secretary to the Ministry of Health and the other from the Director of Medical Supplies Division (MSD) to offer a WoR to Savorite Pharmaceuticals for 36 medicines has been submitted to the NMRA Board. A further list of 277 medicines were submitted by the CEO-NMRA for recommendation for WoR to the MEC. We wish to bring to Your Excellency's notice that these requests

are in contravention of the condition (b) laid down by Your Excellency as the Minister of Finance.

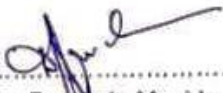
4. The Secretary of Ministry of Health states in his letter that lifesaving medicines are in short supply. We wish to place on record that several of the medicines listed cannot in any reasonable sense be classified as lifesaving medicines and many having NMRA registered multiple Indian suppliers. Hence the Secretary's statement is factually flawed.
5. The attempts of the Ministry of Health to subvert the Finance Ministry directives as well as the move to import non-life saving medicines falsely declaring them to be so and attempt to as well as asking for a WoR for an antibiotics supplier from a company had multiple quality failures in injectable antibiotics, makes us question the bona fides of the Ministry of Health officials.
6. We believe that the usual registration/purchase process can be carried out within a quick time frame to ensure quality, safety and cost effectiveness of the medicines sought to be obtained from the said company.

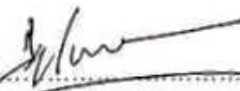
We seek your Excellency's intervention to compel the Ministry of Health to act within the NMRA Act and the Finance Ministry procurement directives to ensure accountability and transparency of processes as well as to ensure an uninterrupted supply of timely, good quality, safe and cost-effective medicines to the hospitals in Sri Lanka. We believe that these are not mutually exclusive processes.

We shall also be most obliged if your excellency could table this communication at the next meeting of the Cabinet of Ministers for their information too.

Thank you,

Yours sincerely,


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CC: 1. Secretary, Ministry of Finance
2. Secretary, Ministry of Health
3. Chairman, NMRA