SLACPT NEWS

The Official Newsletter of the Sri Lanka Association of Clinical Pharmacology and Therapeutics
December 2023 Volume 8 Issue 2

Equitably available, affordable, safe and quality use of medicines for challenging times

In this issue...

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SLACPT Theme 2023-2024

Equitably available, affordable, safe and quality use of medicines for challenging times

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Follow us on

President's Message

Dear members of SLACPT,

I trust this message finds you all in good health and spirits as we usher in the new year. Over the past six months, our association has been actively engaged in various significant events and activities aimed at enhancing the pharmaceutical sector and ensuring the well-being of our community.

In August, we celebrated the induction of the new SLACPT President, a momentous occasion that marked the beginning of a renewed commitment to the advancement of pharmaceutical practices in our country.

One of our major accomplishments during this period was the completion of the report on Challenges and Barriers to the effective supply of pharmaceuticals. This comprehensive report, handed over to the Secretary of Health during the induction, outlines critical recommendations to address issues impacting the seamless delivery of pharmaceuticals. The report has been widely disseminated, reaching the Treasury, Members of Parliament, and has been forwarded to both the President and Prime Minister for their consideration through the Treasury.

Addressing concerns in the pharmaceutical supply chain, we wrote to the NMRA regarding the supply of a falsified immunoglobulin product. Furthermore, we conducted a webinar to educate the medical community on the normal registration process and the problems associated with the indiscriminate granting of Waivers of Registration (WOR) without proper evaluation. The webinar fostered a constructive dialogue, and I am pleased to report that the discussion that followed was rich and insightful. This effort was pivotal in raising awareness and fostering a deeper understanding of the challenges faced by the pharmaceutical sector. Such initiatives are instrumental in enhancing awareness and fostering a collective understanding of the processes affecting pharmaceutical regulation and supply within our community.

Taking proactive steps, SLACPT also corresponded with the Ministry committee soliciting submissions on revisions required to the NMRA Act. We highlighted the importance of implementing the provisions outlined in our report, stressing the need for proper oversight and regulation rather than revising the Act, as the need at the current time.

I am pleased to inform you that, considering the pressing issues within the pharmaceutical sector, I agreed to serve on the NMRA Board and accepted the appointment. Despite the delay in appointing a pharmacologist to the Board for over a year, I am optimistic that our involvement, coupled with the recent appointment of Dr. Ananda Wijewickrama as the Chairman of NMRA, will contribute to the reestablishment of effective regulatory mechanisms. The recommendations outlined in our report also have the potential to implement robust systems for pharmaceutical supplies, mitigating the risk of shortages and ensuring efficient management within budgetary allocations. We look forward to positive developments in the coming months on implementing the recommendations.

In a noteworthy development, the Magistrates Court requested the SLACPT to provide expert advice on some questions related to the supply of falsified human immunoglobulin product to the Ministry of Health. I am sincerely thankful for the swift response and invaluable support from the committee members, who played a crucial role in providing timely and insightful answers to the questions posed. This showcases the recognition that SLACPT has gained as experts in the field of pharmacology and our commitment to serving the community and contributing our expertise to matters of public importance.

As we embark on a new year, I extend my heartfelt wishes to each one of you for a productive, successful, and fulfilling year ahead. Let us continue to work together to uplift the pharmaceutical sector and contribute to the well-being of our community.

Best Regards,
Professor Priyadarshani Galappatthy
President, Sri Lanka Association of Clinical Pharmacology and Therapeutics

Message from the Secretary

Dear Members and Friends,

It is my pleasure to send this message as the Secretary of the Sri Lanka Association of Clinical Pharmacology and Therapeutics (SLACPT). As highlighted by our President, Professor Priyadarshani Galappatthy the association has embarked on numerous activities and initiatives during 2023 in line with our theme "Equitably available affordable quality use of medicines for challenging times". The SLACPT has been in the forefront during these challenging times to ensure the access to quality assured and affordable medicines to all Sri Lankans, engaging with numerous stakeholders, including the Ministry of Health, Sri Lanka. One of the first projects by the Association in 2023 was the undertaking of a situational analysis on the invitation of the Ministry of Health, to identify challenges and barriers in the Supply of Medicines to state sector institutions in Sri Lanka. I am happy to say that we have been able to complete this task within a short period of time with voluntary contributions from our members, and the final report was officially handed over to the Secretary Health during the Ceremonial Induction of Prof. Priyadarshani Galappatthy as the President of SLACPT in August 2023. This multi-stakeholder situational analysis sheds light and provides recommendation on how to overcome barriers and ensure efficient supply of medicines to state sector institutions.

Furthermore, we have identified the need for capacity building of Health Care Professionals in the country in relations to the Regulation of Medicines. In line with this several activities have been planned by the Association. In October, a Webinar was conducted by expert speakers from the SLACPT in collaboration with the Sri Lanka Medical Association (SLMA), on the Drug Registration Process and Waiver of Registration. In addition the association continued its engagement in regular CME activities with other professional colleges in Sri Lanka, and three such activities have already been completed with the Sri Lanka College of Dermatologist (SLCD), the College of Specialists in Rheumatology & Rehabilitation Sri Lanka (CSRRSL) and the Sri Lanka Medical Association (SLMA). Numerous other activities are lined up for 2023/24 and I invite all of you to join hands with us in these endeavors.

Thank you,
Best Regards,
Professor Priyanga Ranasinghe,
Secretary, Sri Lanka Association of Clinical Pharmacology and Therapeutics

Ceremonial Induction of the President of SLACPT for the year 2023/2024

The ceremonial induction of the President of SLACPT for the year 2023/2024 was held on Saturday, 12th August 2023 from 6.00 p.m. onwards at the Auditorium of UCFM Tower.

The event unfolded with a ceremonial procession, followed by the symbolic lighting of the oil lamp. Professor Asita de Silva, the outgoing President of SLACPT for the term 2021/2022, delivered the welcome address.

After the welcome address, Professor Priyadarshani Galappatthy was inducted as the president of SLACPT for the year 2023/2024. Professor Priyadarshani Galappatthy presented the 'Past President's Medal' to her predecessor, Professor Asita de Silva.

The event was graced by esteemed Guests of Honor, including Professor Vidya Jyothi Vajira H.W. Dissanayake, Dean of the Faculty of Medicine at the University of Colombo and President of Sri Lanka Medical Council, and Dr. Asela Gunawardana, the Director General of Health Services at the Ministry of Health. Mr. S. Janaka Sri Chandraguptha, Secretary, Ministry of Health addressed the gathering as the Chief Guest.

Professor Priyadarshani Galappatthy delivered the presidential address on the theme of "Equitably available, affordable, safe and quality use of medicines for challenging times" emphasizing the pivotal role that clinical pharmacology plays in addressing contemporary healthcare challenges.

The SLACPT report to the Ministry of Health on Challenges and barriers for effective supply of medicines to the state sector and recommendations to the Ministry of Health was presented by Professor Priyadarshani Galappatthy to Mr.. S, Janaka Sri Chandraguptha, Secretary, Ministry of Health

The event concluded on a note of appreciation, with Professor Priyanga Ranasinghe, the Secretary of SLACPT, extending a heartfelt Vote of Thanks. The ceremonial proceedings concluded with a musical performance by three talented students of the Colombo Medical Faculty and followed by a reception. The induction ceremony not only marked the formal commencement of a new leadership era but also underscored the commitment of SLACPT to advancing the field of clinical pharmacology and therapeutics for the betterment of healthcare in Sri Lanka.


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Sri Lanka Association of Clinical Pharmacology and Therapeutics
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Induction of the President SLACPT 2023
Asita de Silva
Immediate past president
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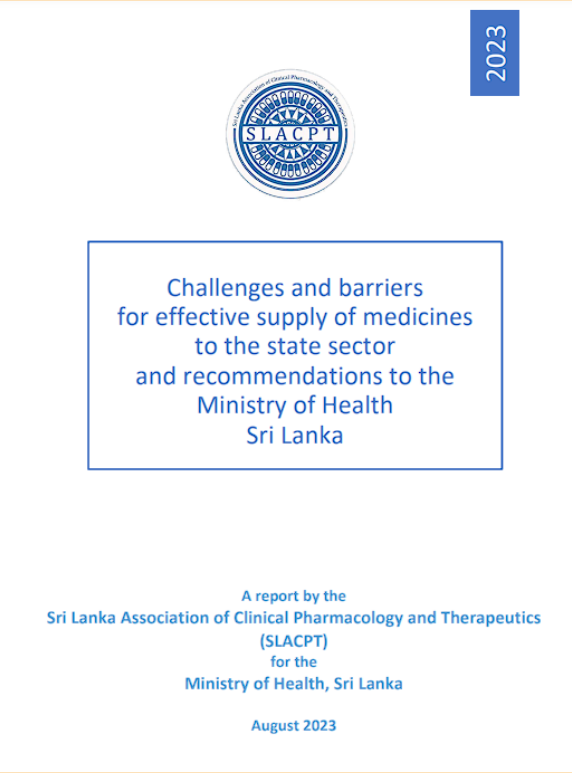
Report on supply of medicines to Ministry of Health

In the background of economic crisis and shortage of medicines in the state sector, the Secretary to the Ministry of Health requested the Sri Lanka Association of Clinical Pharmacology and Therapeutics to assist the Ministry of Health in finding solutions to this crisis.

SLACPT undertook the assignment and prepared the report titled "Challenges and barriers for effective supply of medicines to the state sector and recommendations to the Ministry of Health Sri Lanka". The report was prepared by Prof Priyadarshani Galappatthy, Prof R.L. Jayakody, Prof Rohini Fernandopulle, Prof Priyanga Ranasinghe and Dr. Chiranthi Liyanage.

The report was prepared using literature review of relevant publications, desk review of relevant reports, data analysis of pharmaceutical supplies, cost analysis of Medical Supplies Division data, analysis of data provided by the National Medicines Regulatory Authority and qualitative analysis of concerns and opinions expressed by stakeholders. More than ten stakeholder meetings were held with members of MSD, NMRA, SPC, pharmaceutical industry, Treasury officials, Regional Directors of Health Services, hospital directors and representatives of Coleges and Associations.

The report identifies 22 challenges and barriers in the supply of pharmaceuticals and also makes 30 recommendations to resolve the crisis. Furthermore challenges and barriers faced by MSD, NMRA, SPC, specialist colleges, hospital pharmacists forecasting medicines requirements and recommendations to overcome them are also included in the report. The key findings of government audit reports and their recommendations and suggestions given by the government Treasury are also included. The report was presented on the Secretary of Health, Mr. S Janaka Sri Chandraguptha by Prof Priyadarshani Galappatthy, President SLACPT at the induction ceremony on 12th August 2023. The report can be accessed from the SLACPT website https://slacpt.lk/2023/10/01/report-to-ministry-of-health/



Webinar on Drug Registration Process and Waiver of Registration (WOR)

SLACPT in collaboration with Sri Lanka Medical Association organized a webinar on "Drug Registration Process and Waiver of Registration (WOR)" on 30th October 2023 fom 12.30 p.m. to 1.30 p.m. through Zoom platform. The resource persons were Professor Rohini Fernandopulle and Professor Asita de Silva and the webinar was moderated by Professor Priyadarshani Galappatthy. Dr Vinya Ariyaratne, president SLMA gave introductory remarks on the importance of the topic for the information of the medical community. The webinar was organized in a timely manner to increase the awareness among the medical fraternity regarding the topic given the irregularities identified with the supply of falsified and poor quality medicines to the hospitals in recent times.

Waiver of Registration (WOR)
From Exception to Rule

Granting permission to import and supply a particular pharmaceutical product in specified quantities in special circumstances without the registration is referred to as Waiver of Registration (WOR). National Medicines Regulatory Authority (NMRA) Act specifies that permission is granted in special circumstances such as to save a life, to control an outbreak of an infection, or an epidemic or any other national emergency or for national security. The permission is granted on the request made by the Ministry of Health or on a request made by an individual or an organization recommended by the Ministry of Health. The Act also specifies that the importer should be responsible for the accountability and management of the medicine and should sumit routine reports.

NMRA issued guidelines for the WOR in 2019 and the WOR requests are reviewed by the WOR Subcommittee appointed by the NMRA. The final decision regarding the request is made by the WOR Subcommittee. Validity period of WOR is one year.

Despite attempting to reduce the number of products for which WOR is granted, still the number of granted WOR remained high as depicted in the following table. Although the number granted reduced over the years from 2018 -2022 with increased number of not granted WOR. In 2023 the numbers granted WORs increased significantly as these were granted only with approval by the CEO of NMRA without the approval by the WOR subcommittee or the MEC under a special pathway approved by the Board for emergency purchases. The number of WORs granted in 2023 were not provided by the NMRA for analysis and is not available on the website either. Recently many complaints were made on the unusually large number of WOR issued by the NMRA administration, without the approval of relevant NMRA committees under the special pathway created. This breakdown of laid down procedures led to the huge problem of falsified and substandard products entering the market such as the falsified immunoglobulin prodouct and many fraudulent activities pertaining to the purchase of medicines which were highlighted in media and led to legal proceedings.

Examining the grounds for granting Waiver of Registration (WOR), the most common requirement is when there are no registered suppliers for items needed in government tenders. Occasionally, even with valid registrations, companies may refrain from participating in SPC tenders for various reasons, such as non-payment of dues from prior supplies that happened following the economic crisis. Additionally, pharmaceutical importers may show disinterest in securing registration for medicines that are needed in small quantities or lack profitability in sales.

Table 1: Waiver of Registrations during the last 5 years

	2018	2019	2020	2021	2022
Granted	136	270	185	93	98
Not granted	0	98	183	208	130
Decision unclear or not mentioned	64	44	10	19	12
Decision pending	2	7	33	18	28
Order cancelled (WOR not needed any more)	2	0	3	0	0
Total submitted for WOR	204	419	414	338	268

From the Report by SLACPT on Challenges and barriers for effective supply of medicines to the state sector and recommendations to the Ministry of Health Sri Lanka

The NMRA website contains the list of products submitted for Waiver of Registration (WOR) at each Medicines Evaluation Committee (MEC) meeting, offering details on whether the request was approved and the reasons for denial. However, the information is not regularly updated, and the most recent lists of granted WORs are unavailable. Reasons for not granting WOR, include the availability of registered suppliers, excessively high quoted prices, lack of justification from the requesting party, and sufficient stocks with the Medical Supplies Division (MSD). In recent years, the procurement of medicines through WOR has become a common occurrence rather than an exception, posing a potential risk to the quality of pharmaceuticals entering the country.

There were indications of political involvement in the registration process, wherein WOR was granted to numerous pharmaceuticals without following established guidelines. This prompted various professional organizations to express grievances to the relevant authorities, inform the public, and proceed to legal actions. Urgent measures are required to enforce existing WOR guidelines rigorously, ensuring applicants submit all necessary documents. Further revisions to the guidelines and steps to restrict the number of WOR applications are necessary to minimize the use of inadequately evaluated products in Sri Lanka.

WOR has become an example where the exceptions became the rule. Exceptions are consistently granted without proper scrutiny, they may become the standard practice, potentially undermining the integrity of the regulatory framework unless corrective actions are taken.

A Child with Steven Johnson Syndrome

The following is compiled from the CME activity done in collaboration with Sri Lanka College of Dermatologists on 4th May 2023. The CME acitivity was presented by Dr Sobana V Mahendrarajan, Senior Registrar in Clinical Pharmacology and Therapeutics, Dr Kasun Nayanakantha, Registrar in Dermatology, Dr Sriyani Samaraweera, Consultant Dermatologist and Prof Shalini Sri Ranganthan, Professor in Pharmacology. The session was moderated by Prof Priyadarshani Galappatthy, President, SLACPT and Dr Chandani Udagedara, President, Sri Lanka College of Dermatologists.

Case Summary

An 8-year and 6-month-old boy presented with high-grade fever and an erythematous rash. Initially treated by a general practitioner with medications including paracetamol, famotidine, cetirizine, omeprazole, and prednisolone, the child developed alarming symptoms six hours later. These included an ulcer on the tongue, cracked lips, eye redness, and an erythematous rash progressing to blistering, covering 25-30% of the body, mucous membranes, eyes, and oral mucosa. Additional symptoms comprised cough, breathing difficulties, dysuria, abdominal pain, watery stools, and vomiting.

Clinical observations showed bilateral conjunctivitis, cracked lips, and a positive Nikolsky sign. Vital signs indicated a heart rate of 140/min, blood pressure of 100/72 mmHg, and respiratory rate of 36/min. Arterial blood gas analysis revealed low oxygen levels. Laboratory findings included leukopenia, elevated C-reactive protein, and decreased albumin. Diagnosis of Steven Johnson Syndrome (SJS)/Toxic Epidermal Necrolysis (TEN) overlap syndrome was made. Management involved stopping the culprit drug, intravenous dexamethasone, human immunoglobulin, and supportive care. The child recovered with pigmentary changes and healing mucosal lesions upon discharge.

Steven Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)

SJS and TEN are severe skin reactions differing in the percentage of epidermal detachment. SJS involves <10% body surface area (BSA), SJS/TEN overlap 10-30%, and TEN >30%. Incidences are 6.3, 0.7, and 0.5 cases per 100,000, respectively, with the highest occurrence in the 11-15 age group. Risk factors include slow acetylators, immunosuppression, and drug usage. Mortality rates range from 5-50%. Causes in children include infections (50%), drugs (carbamazepine, cotrimoxazole, etc.), vaccinations, and unknown factors. Pathogenesis involves a unique immune response to drugs, resulting in keratinocyte apoptosis and epidermal necrosis.

Diagnosis is mainly based on clinical signs and symptoms and often skin biopsy is not

required. Acute complications include secondary infections, massive transepidermal fluid loss, pneumonia, gastrointestinal haemorrhage, tracheal or bronchial erosions, glomerulonephritis, and multiorgan failure. Chronic complications include cutaneous scarring, phimosis, vaginal synechia, nail dystrophy, diffuse hair loss, sicca syndrome and eye malformations.

Management of SJS/TEN include stabilization and supportive care, stopping the suspected drugs and immunomodulatory therapy.

Key Messages

- The dangers of irrational use of many medicines including famotidine, omeprazole, prednisolone for a febrile illness in a child as highlighted in this case report.
- Using medicines without proper indications lead to increased risk of harm compared to benefits of the medicines.
- The causality assessment pointing to one medicine can be difficult in this type of situations in the absence of history of previous allergic reactions to any of the medicines and as rechallenge is not justified.

Role of Causality Assessment

Adverse Drug Reactions (ADR) are unintended, noxious responses to medications. ADRs are classified by type, frequency, seriousness, severity, outcome, systems involved, and mechanism. Causality assessment gauges the association between the drug and the adverse event. World Health Organization ADR Causality Assessment criteria involve timing, effects after drug withdrawal, literature evidence, absence of alternative explanations, and rechallenge effects. Categories include certain, probable, possible, unlikely, conditional, and unassessable.

In this case, the causality assessment was crucial for understanding the association between the prescribed drugs and the onset of SJS/TEN. This systematic approach aids in classifying adverse events, guiding further inquiries, fulfilling regulatory requirements, determining causative relationships, recognizing signals, justifying label changes, and facilitating data exchange and scientific publications.

WHO launched the publication,s Medication safety for look-alike, sound-alike (LASA) medicines

The World Health Organization has published a technical document titled 'Medication safety for look-alike, sound-alike (LASA) medicines'. Medication errors are a leading cause of patient harm globally and LASA medicines are a well-recognized cause of medication errors that are due to orthographic (look-alike) and phonetic (sound-alike) similarities between medicines, which can be confusing. Look-alike medicines appear visually the same with respect to packaging, shape, colour and/or size, while sound-alike medicines are similar in the phonetics of their names, doses and/or strengths. Confusions can occur between brand-brand, brand-generic or generic-generic names.

Health care facilities need to prospectively design and implement strategies to identify LASA medication errors and build a robust system that intercepts them before they result in patient harm. Many preventive strategies that can be implemented by healthcare professionals and institutions are presented on preventing LASA errors to reduce the risk of medication-related harm. Professor Priyadarshani Galappatthy is a main contributing author of this WHO publication. The WHO held a webinar on 20th October 2023 to launch this document and the webinar recording, the presentations and the publication can be accessed via WHO website at https://www.who.int/news-room/events/detail/2023/10/20/default-calendar/medication-safety-webinar--medication-safety-for-look-alike--sound-alike-medicines

SLACPT in Action

1. SLACPT has written to the Secretary, Ministry of Health on the supply of falsified immunoglobulin urging to adhere to WOR guidelines
2. SLACPT submitted its observations to the notice by Ministry of Health requesting submissions on NMRA Act on the need to implement provisions in the Act
3. SLACPT was requested by the courts to submit expert advice on queries pertaining to the human immunoglobulin and a committee was appointed and answers were submitted.

Wall of Fame

The Sri Lanka Association of Clinical Pharmacology and Therapeutics is very pleased to announce the following appointments and accomplishments of its members:

Professor Priyadarshani Galappatthy was appointed to the Board of Directors of the National Medicines Regularity Authority as the Pharmacologist.

Professor Asita de Silva was named in the prestigious world's top 2% scientists list published by Elsevier for the year 2022.

Professor Priyanga Ranasinghe received the board certification as the first Specialist in Clinical Pharmacology and Therapeutics in Sri Lanka.

He was also named in the prestigious world's top 2% scientists list published by Elsevier for the year 2022.

Upcoming Events

MCQ Course on Pharmacology for MD Selection Examinations February 2024

MCQ Course Targeting MD Selection Exams Organized by the

SRI LANKA ASSOCIATION OF CLINICAL PHARMACOLOGY & THERAPEUTICS (SLACPT)

10th and 17th February 2024

10th February		
09.00 – 10.30 am	Respiratory and Autonomic nervous system pharmacology	Professor Channa Ranasinha Professor in Pharmacology and Specialist in Pulmonology
10.45 am – 12.15 pm	Prescribing in rheumatology	Dr. Sujeevani Kurukulasuriya Senior lecturer in Pharmacology and Specialist in Rheumatology and Rehabilitation
01.00 pm – 02.30 pm	Cardiovascular pharmacology	Professor Priyanga Ranasinghe Professor in Pharmacology
02.45 – 04.15 pm	Basic pharmacology	Professor Pradeepa Jayawardhana Professor in Pharmacology
17th February		
09.00am – 10.30 am	Pharmacology of gastrointestinal and liver diseases	Professor Anuradha Dassanayake Professor in Pharmacology and Specialist in General Medicine
10.45 am – 12.15 pm	Pharmacology in special populations	Dr. Thilanka Seneviratne Senior lecturer in Pharmacology and Specialist in Paediatrics
01.00 pm – 02.30 pm	Antidiabetic agents	Dr. Vipula Bataduwaarachchi Senior lecturer in Pharmacology
02.45 pm – 04.15 pm	Pharmacology of anti-infectives	Dr. Chiranthi Liyanage Senior lecturer in Pharmacology

Course fee: Rs.2,500/= (to be paid on or before 8th February 2024)

(Reserve your place by paying the fee since only a limited number will be registered)

HOW TO REGISTER?

By filling the google form. https://forms.gle/kePDwuJFgMDxNkUz8

Please upload payment slip to the google form.

Payments to be made to the following account.

- ✓ Conducted on a zoom platform

A/C Name -
SRI LANKA ASSOCIATION OF CLINICAL PHARMACOLOGY AND THERAPEUTICS
A/C Number – 167200180013901
Bank - Peoples' Bank
Branch - 00167 Colombo Town Hall

FOR MORE INFORMATION: 0112961139
Ms. Ishini(ishinitharuka3@gmail.com)
Ms. Eshani (achilaranasinghe1@gmail.com)

SRI LANKA ASSOCIATION OF CLINICAL PHARMACOLOGY & THERAPEUTICS (SLACPT)

In collaboration with

IUPHAR INTERNATIONAL UNION OF BASIC AND CLINICAL PHARMACOLOGY

ClinPharm 2024

11th -13th July 2024

CALLING FOR ABSTRACTS

- Word count should not exceed **300** words of text
- Abstracts should be sent via e-mail to **abstracts@slacpt.lk**

For abstract submission guidelines

SCAN ME

Submission Deadline

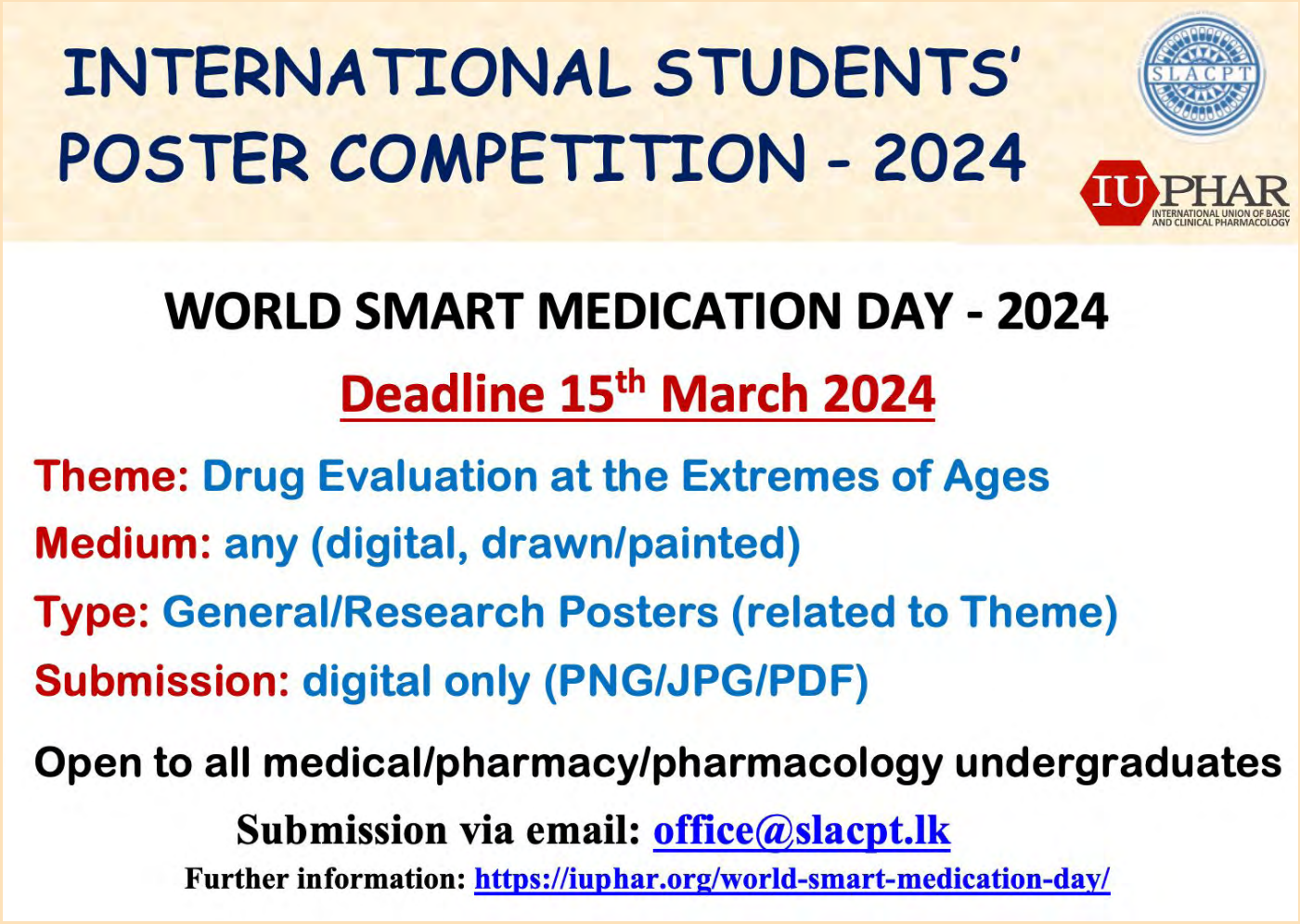
20th APRIL 2024

For further information

Email - office@slacpt.lk , Ms. Chinthani Liyanage – jchinthani.liayanage@gmail.com

Telephone: Ms. Inoka Gammune – 011269748 3/0713020255

International Students' Poster Competition 2024
World Smart Medication Day 2024



Write to Us!

SLACPT welcomes suggestions from readers towards improving the image of the Association and the newsletter. Please send your suggestions to:

Email: office@slacpt.lk