Assessment of Pharmaceutical Price Regulation in Sri Lanka – Summary of Key Findings

Verité Research was commissioned by the Sri Lanka Chamber of Pharmaceutical Industries (SLCPI) to conduct an independent assessment of the regulatory structure governing the pharmaceutical sector in Sri Lanka with a special focus on price regulations.

Access to quality assured pharmaceutical products is a key factor that determines the health and wellbeing of people. As a result, government regulation in this sector is considered necessary to ensure availability of quality assured medicines at affordable prices.

In Sri Lanka, the National Medicines Regulatory Authority (NMRA) Act No. 05 of 2015 established the NMRA (hereafter referred to as the Authority). The Authority functions as the central regulator with the task of governing the pharmaceutical sector, and is required to ensure the '*availability of efficacious, safe and good quality medicines…to the general public at affordable prices*.'[1] The NMRA Act repealed the Cosmetics, Devices and Drugs (CDDA) Act No. 27 of 1980 which previously regulated certain aspects pertaining to medical drugs and devices in Sri Lanka.

Regulation of pharmaceutical prices is a direct regulatory practice deployed by many health regulatory authorities and a key policy measure adopted by governments to enhance affordability of medicines. The most recent initiative adopted in Sri Lanka to achieve affordability is through Gazette No. 1989/61 of 21st October 2016 which applies a Maximum Retail Price (MRP) to 48 scheduled drug formulations (identified as 'essential medicines'). Gazette No. 1989/61 was subsequently amended by Gazette No. 2049/31 of 14th December 2017 applying a 5% increase to MRPs of the 48 scheduled drug formulations.

The fact that the drugs are affordable is not, by itself, sufficient to protect consumers. If the drugs required are not available, or the available drugs are not of good quality, it also harms consumer interests. Therefore, it is necessary to ensure that the regulatory system in place is able to bring about affordable drug prices, without compromising availability of good quality drugs in the health system.

The study assesses regulatory policies governing the pharmaceutical sector on the basis of three factors considered to encapsulate the whole process, namely, (i) Design; (ii) Implementation; and (iii) Monitoring and Review, defined below. These factors are drawn from the WHO Guidelines on Pharmaceutical Pricing Policies. Each of these factors are analysed on the basis of three criteria also discerned from the abovementioned WHO Guidelines, namely:

Criteria	Issues Addressed
Tangibility	Is there a clearly defined framework setting out the processes/mechanisms to govern aspects of pharmaceutical regulation?
Fairness and Objectivity	Are policies designed, implemented and executed in a manner that is not discriminatory and does not leave room for undue discretionary actions?
Visibility/Openness	Are measures and details of actions taken in terms of design, implementation and review publicly accessible and open to stakeholder engagement?

[1] Section 3(a) of the National Medicines Regulatory Authority Act No. 05 of 2015

This document presents a summary of the main issues identified under each factor mentioned above.

Design: *WHO Guidelines provide that policies should be based on an appropriate legislative framework and governance and administrative structures, supported by technical capacity.* *The 'design' section is an assessment of the legislative and administrative framework governing pharmaceuticals in Sri Lanka in the context of achieving the objectives mentioned above.*	
Tangibility	**Gaps in provisions dealing with pricing:** Section 118 of the NMRA Act sets out a framework for pricing of pharmaceuticals, and identifies the Authority, Pricing Committee, the Consumer Affairs Authority, Minister of Health and stakeholders, as parties involved in the process. There are, however, gaps in the provisions dealing with these parties. The Act has detailed provisions on the composition, powers, functions, and financing of the Authority, but the same is not done for the Pricing Committee and 'stakeholders', who are also to be consulted by the Minister of Health to prescribe a pricing mechanism for pharmaceuticals. Gaps in legislation on such aspects can leave space for prescription of pricing mechanisms without consultation of identified parties; and/or result in discretionary actions in defining and appointing persons to these institutions, which may not be in the best interests of consumers. Provisions need to be effected on (i) designations to be included in the Pricing Committee; (ii) nature of consultations; (iii) details of meetings; and (iv)identifying the specific process to be effected by these institutions in the pricing process.
	Availability of guidelines relating to pre-market quality assurance: Pre-market quality assurance, effected at the point of registration, is handled by the Medical Evaluations Committee (MEC) and the National Medicines Quality Assurance Laboratory (NMQAL). While there are provisions for the Authority to pass guidelines to assess quality of medicines at registration, there are no provisions to make these guidelines available to the public. Further, the Minister is authorised to pass regulations upon review and revision of these guidelines, which would enable publication of guidelines, although as at 31st March 2018, none of these regulations have been passed. The existing guidelines on the NMRA website are insufficient as it does not cover all relevant aspects, and available information is insufficient to ascertain whether the existing information is up to date. Quality assurance mechanisms is an area already subject to significant criticism by various stakeholders, including the Minister of Health. Consumers tend to purchase expensive branded products, partly due to low confidence in the quality of generic medicines in the market. Guidelines are necessary to ensure that quality assurance mechanisms are comprehensive and effective to protect consumer interests.
Fairness and Objectivity	**Clarification on nature of involvement of all relevant parties in determining pricing mechanism:** The Pricing Committee and stakeholders are identified as parties to be consulted by the Minister of Health in prescribing a pricing mechanism. The Act, however, lacks details on the nature of involvement or consultations with these abovementioned parties. The existing framework leaves space for the Minister to formulate a pricing mechanism without formal involvement of stakeholders identified in the NMRA Act. This issue, coupled with the lack of information publicly available on composition of

	the Pricing Committee and details of pricing formulas/mechanisms, could result in actions which do not necessarily take the best interests of consumers into account. The Act needs to outline the nature of consultations with these parties, and specify the means by which these parties are to be factored into the pricing mechanism process, such as by way of a written submission or active consultations; or requiring approval of these parties for pricing mechanism to be passed.
	Application of conflict of interest clauses: Members of the Authority are subject to a strict conflict of interest clause, outlined in Section 6 of the Act. Given the role of the Authority on aspects relating to pricing, quality assurance and registration of pharmaceuticals, this clause is necessary to ensure that Authority acts fairly and is not subject to bias. The clause does not, however, extend to the Minister of Health or other divisions set up in the Act, such as Pricing Committee, who are all involved in actions to ensure the overall objectives of the Act are met. Given that details of pricing committees are also not publicly disclosed, it prevents any means of checking potential conflicts. Steps need to be taken to mitigate potentially perverse outcomes arising from this process and a means of doing so is to adopt stronger safeguards on the appointment process.
	Extent of Minister's influence on aspects pertaining to pricing, registration and quality assurance: Even though the NMRA is set up to operate independently from the Ministry of Health, the Act still provides substantial power to the Minister in terms of pricing decisions, approval of guidelines/rules, appointments to authority, among others. An associated weakness in the NMRA Act is that the Minister's decisions are not subject to adequate checks, as the conflict of interest clause is not applicable on the Minister, and are not necessarily subject to the purview of the Appeals Committee established under the NMRA. The lack of publicly available information on matters pertaining to the Pricing Committee and mechanism further impedes oversight.
Openness/ Visibility	**Publication of basis for determination of pricing mechanism:** The pricing formula used to determine MRPs for 48 essential medicines has not been published through an official document, nor does the Act specify that the pricing mechanism/formula developed by the Minister under Section 118 of the NMRA Act is to be made available to the public. Further, despite references to the pricing mechanism being based on evidence based research conducted with the assistance of the WHO, evidence of the process was actually not available nor accessible from relevant institutions. Stakeholders need to understand the process and be able to present inputs and concerns as appropriate, as pharmaceutical pricing has an impact on consumers and suppliers. Publication of the formula is a means through which stakeholders can engage in the process.
	Wide ambit of secrecy clause: Despite secrecy clauses being a usual provision in pharmaceutical regulations in jurisdictions such as UK and Australia, the ambit of the clause in the NMRA Act is wider in Sri Lanka. The NMRA has already been rather closed in providing information on aspects such as pricing to the public. The culture of secrecy instituted in the NMRA further works against openness required to uphold stakeholder interests and reduces availability of information needed to further public interest.

Implementation: *WHO Guidelines provide that if regulation of pharmaceutical prices is introduced, effective implementation is necessary to ensure compliance. The 'implementation' sector is an assessment of the administrative structures, along with the technical capacity, to ensure compliance with legislative provisions and achieve objectives.*	
Tangibility	**Clarification of institutional framework for pricing of pharmaceuticals***:* Prior to establishment of the NMRA, pricing of pharmaceutical drugs was under the purview of the CAA. In 2012, the CAA imposed price freezes on drug formulations and from 2014 onwards, price revisions had to be approved by the CAA. The transition of regulation of pharmaceutical pricing from the CAA to NMRA, through the NMRA Act, has resulted in inconsistencies that need to be resolved in terms of the position and jurisdiction of the CAA on pharmaceutical pricing. While there is pricing of the 48 scheduled drug formulations listed in Gazette No. 1989/61 of 21st October 2016 is clearly established, it is not clear if the price freezes and price approvals are still applicable on drug formulations not included in the regulation. (i.e. drugs apart from the 48 scheduled drug formulations). The NMRA Act is an improvement of the previous legislative and institutional structure where even though the CDDA was responsible for pharmaceuticals, pricing was regulated by the CAA. With the NMRA Act, all regulatory aspects, including pricing, registration, licensing and quality assurance are under the purview of one institution, i.e. the NMRA, making it better a place to implement policies which are holistic and complement each other. The improved structure needs to be complemented by clarification of the mandate of the CAA, and the relationship between CAA and NMRA in terms of pricing of pharmaceuticals.
	Consistency in framework for updating pricing structure: Even though Gazette No. 1989/61 of 21st October 2016 provided that the MRPs for the 48 scheduled drug formulations are to be reviewed and updated once every two years, prices were revised in one year, through Gazette No. 2049/31 of 14th December 2017. Further, Gazette No. 2049/31 does not set a timeframe for revision of pricing, by stating that MRPs would be 'valid and effectual until revised'. Acting inconsistent to provisions on timeframes, and the subsequent failure to set a framework for frequency of revisions and time period for revisions, creates the potential for arbitrary decisions, making it difficult for the industry to plan ahead, and possibly affecting availability of drugs for consumers. Setting a timeframe for updates and revision of prices of pharmaceutical drugs, with strict exceptions in which it is possible to act outside this timeline would help facilitate a more consistent framework. If it is not possible to have set timeframes, a grace period can be provided for price revisions to come into action.
	Detailing timelines for passing and updating regulations passed under the Act: Section 142 of the NMRA Act provides for a list of regulations to be effected by the Minister on aspects dealing with quality, registration, and pricing, essential for effective functioning of the pharmaceutical sector. It has been three years since the NMRA Act came into effect, and regulations on aspects such as the terms and conditions for licenses and registrations; registration and regulation of pharmacies; and conditions relating to importers and market authorization holders, are yet to come into effect.

	Prescribing time frames in which such regulations are to be published and revised is important to prevent further delays and ensure that the stakeholders have access to required information.
Fairness and Objectivity	**Selection of drug formulations covered by pricing mechanism:** While the National List of Essential Medicines Sri Lanka 2013-2014 lists out 419 essential medicines, Gazette No. 1989/61 of 21st October 2016 is applied on 48 drug formulations identified as essential medicines. There is no official information detailing the reasons for selecting these specific drug formulations and excluding other essential medicines in the National List. Even if Sri Lanka chooses to not apply the MRPs to all essential medicines, it is necessary to provide to the public the basis for selection of these medicines. Failure to have such a basis suggests arbitrary decision-making without any factual basis.
	Evidence based decision making for pricing mechanisms: WHO Guidelines on pricing policies provides that countries should use a combination of different policies based on the objective, context and health systems; and address supply and demand issues. Currently, Sri Lanka seems to employ a combination of pricing mechanisms for pharmaceuticals, i.e. price ceilings applicable on the 48 scheduled drug formulations and price freezes for other drugs. It is necessary to ensure that pricing strategies used are suitable for the local context, achieve the relevant objectives, and address all demand and supply issues. Pricing strategies which are unsuitable for the local context can undermine adequate supply of medicines. Thus, there needs to be an evidence-based justification for application of these pricing mechanisms. Verification of this evidence based process is not possible, however, as the study on which the existing pricing mechanism is deemed to be based on is not accessible, raising concerns as to whether the pricing formula was actually based on research.
Openness/ Visibility	**Publication of mechanisms relating to registration:** While the legislation outlines the process to be effected for registration, the details have yet to be updated onto the NMRA website, which would be the first point of reference for stakeholders. At the time of writing this report, the website had details of forms and fees for registration, along with a detailed procedure, but still referred to the CDDA as the main institution, indicating that the website had to be updated. Further, the fees listed in Gazette No. 2023/30 of 14th June 2017, for registration and licensing of medicines, are different from the fees displayed on the website page. It is also not possible to discern if guidelines or procedures are in existence or are revised, as the information is either not available online, or information available is outdated. Given that several guidelines have still not been published through Gazette Notification, it is possible for procedures to be subject to arbitrary revisions, and there may be other guidelines or procedures which are not uploaded on the website. This makes it difficult for the industry to access guidelines and information required for their activities. These procedures need to be available in a format which is easily accessible to stakeholders.
	Assisting consumers to make informed decisions on accessing good quality drugs: Given the lack of knowledge in the sector, patients rely on instructions provided by medical professionals, which may not always be in the best interests of the patient (such as in the case where expensive branded products are prescribed, even with the availability of lower priced generic drugs). Further, consumers should

	also be able to trust the pharmacies dispensing drugs, to be assured that pharmacies are regulated and are dispensing drugs according to the price range and are of good quality. In this respect, the NMRA has taken steps to provide some information such as lists of registered medicines with corresponding manufacturers, details of drugs which have been withdrawn or withheld, and details of registered pharmacies in the country. It may be possible to improve existing information, by making it more user friendly, ensuring information available is up-to-date, and providing other useful data. For instance, while details of registered medicines are available, it may be useful to add corresponding prices, and connect to the relevant pharmacy/facility supplying the relevant drugs, making the process smoother and more accessible for consumers.

Monitoring and Review: *WHO Guidelines provide that policies should be regularly reviewed, monitored and evaluated and amended as necessary. The 'monitoring and review' section is an assessment of the structures in place to monitor existing design and implementation and effect reviews and revisions as necessary.*	
Tangibility	**Monitoring impact and updating pricing design:** The legislation is silent on reviews and updates to the pricing design. Given that the pharmaceutical market is susceptible to exchange rate fluctuations and changing demand for products, it is important to have mechanisms in place to monitor the impact of the existing price design to ensure key objectives are met. Provisions to conduct impact assessments of the pricing design, and updating the pricing design are necessary to ensure that good quality medicines continue to be available and are affordable.
	Assessing quality of drugs in the post-market context: While the NMRA Act identifies post-market surveillance as a key objective, the provisions to effect this form of surveillance are limited. Divisions such as the pharmacovigilance division', and 'inspectorate and enforcement division' are set up under the Act, but there is no other specific guidance on implementation of post-market surveillance activities, as is done in Section 58 to 60 of the NMRA Act for pre-market surveillance activities. Assessment of drug efficacy and safety are mostly only partially completed at the stage of registration, with more unknown effects likely to manifest at a later stage. Post-marketing surveillance has continuously been a rather weak aspect in the Sri Lankan framework, and is the case in the NMRA Act as well. It is necessary to clarify (i) the functioning of specific divisions dealing with aspects of post-marketing surveillance; and (ii) aspects pertaining to regular quality inspections, adverse drug monitoring and a consumer complaint mechanism. Clearly defining the aspects and functions to be fulfilled for these quality assurance mechanisms can also help with defining the technical and human resource capacity required for these activities, and form the basis for developing a strategy in this regard.
Fairness and Objectivity	**Oversight of actions of main decision making bodies in the pharmaceutical sector:** The NMRA Act provides for a means of oversight through the establishment of an Appeals Committee. The issue, however, is this oversight is limited to actions of the Authority and does not extend to actions of the Minister of Health under the

	NMRA Act. As noted in the 'Design' section, the Minister has significant powers under the Act, including prescription of a pricing mechanism. The lack of provisions for public consultations or review of pricing mechanism further impedes oversight which can have implications on ensuring fair and objective decision making. Given that the Minister of Health appoints members to the Appeals Committee and pass relevant regulations, this committee may not be the feasible option for independent oversight of ministerial decisions. However, it is necessary to effect other mechanisms, such as through the Parliament, to monitor and review actions of the Minister.
Openness/ Visibility	**Publication of guidelines for mechanisms to facilitate quality assurance:** Several regulations prescribed under Section 142 have yet to be effected. These include regulations specifying guidelines for Good Manufacturing Practices (GMP) and Good Review Practices (GRP); and functioning and procedure of the Appeals Committee, among others. These guidelines are essential for ensuring medicines imported into and manufactured in the country are of good quality. For instance, publishing information relating to GMP and GRP guidelines are useful for the manufacturer and importer to ensure they meet conditions necessary for supplying medicines to the country. Failure to pass and publish such guidelines may result in informal procedures or arbitrary decision-making on these matters. In this context, making procedures, guidelines and decisions publicly available is a means of public oversight, as it can invite review and comments from the public; and ensures that required information is easily accessible for the industry.