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114	26.05.2026	Oral retinoid products (Isotretinoin and Acitretin)	oral retinoid products (Isotretinoin and Acitretin) shall be restricted to prescription-only use and that their sale shall be limited to State Pharmaceuticals Corporation (SPC) outlets
114	26.05.2026	Anti-tuberculosis (TB) medicines	marketing of anti-tuberculosis (TB) medicines shall be restricted and that such products shall be supplied and used exclusively through the National Anti-TB Campaign
114	26.05.2026	Topical skin preparations	Maximum pack size limitation of 30 g shall apply only to topical corticosteroid preparations. Other topical skin preparations, including emollients and aqueous creams, may be considered for larger pack sizes based on their therapeutic use, clinical justification, and the relevant classification in the British National Formulary (BNF).
114	26.05.2026	Montelukast Tablet 5mg	Not to register new products of Montelukast Tablet 5mg and not to renew registration and import license of existing products. Chewable and dispersible dosage form of Montelukast 5mg tablets are allowed for registration.
114	26.05.2026	Netilmicin Sulphate Injection	Not to register new products of Netilmicin Sulphate Injection and not to renew registration and import license of

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			existing products
115	23.06.2026	Nipple head pack types	Not to accept intravenous dosage form products presented in nipple head pack types
115	23.06.2026	Orciprenaline Tablets	The product Orciprenaline Tablets accepted for registration and approved indications shall be limited to cardiac indications, and no asthma-related indication shall be included in the product information.
116	28.07.2026	Radioactive pharmaceutical products	Grant approval for a period of one (01) year for the importation of radioactive pharmaceutical products, subject to the submission of the relevant registration dossier within the said one year period.
116	28.07.2026	Contract manufacturing	Contract manufacturing arrangements between local manufacturers and foreign manufacturers may be accepted by the NMRA, considering international regulatory practices and the potential benefits to the local pharmaceutical manufacturing industry, including technology transfer, knowledge sharing, strengthening of local manufacturing capabilities, and ensuring the

			availability and continuous supply of quality-assured medicines. Such arrangements shall be facilitated subject to the following conditions: 1. Both the contract-giving foreign manufacturer and the local contract manufacturing facility shall obtain the relevant approvals from the NMRA. 2. A valid Letter of Authorization issued by the foreign contract-giving manufacturer, authorizing the local manufacturer to apply for registration of the relevant product, together with a valid contract manufacturing agreement and other relevant supporting documents, shall be submitted to the NMRA. 3. The local manufacturer shall be the applicant for registration of the product in accordance with the applicable medicines regulations and shall submit the required Letter of Authorization issued by the foreign manufacturer. 4. Where the relevant product is already registered in Sri Lanka under the foreign manufacturer, the existing

			registration shall, where applicable, be cancelled/withdrawn when granting registration to the local manufacturer under the contract manufacturing arrangement. 5. The maximum limitation of 15 brands/generic products shall apply to products registered under contract manufacturing arrangements. However, this limitation shall not apply where: • the product was previously registered under the foreign manufacturer in Sri Lanka and such registration is cancelled/withdrawn when the product is registered under the local manufacturer through the contract manufacturing arrangement; or • the contract-manufactured product is intended solely for export and is not intended to be placed on the Sri Lankan market; or 6. Where the local manufacturer declares that the product is the same as a product/brand or generic product already registered with the NMRA by the local manufacturer,

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			except for the brand name, the application may be processed through the applicable second-brand pathway, subject to fulfillment of the relevant requirements. Where such sameness is not established or declared, the application shall be processed through the normal registration pathway.
116	28.07.2026	Hydrogen Peroxide Solution	Hydrogen Peroxide Solution 400 mL BP 6% w/v is not accepted for registration as a medicine in Sri Lanka due to the absence of a recognized clinical use or clinical requirement for the product.
117	25.08.2026	Single-Entity Sofosbuvir Phase-Out	Not to register new products of Sofasbuvir Tablet 400mg and not to renew registration and import license of existing products. (phasing out standalone formulations in favor of fixed-dose combinations)
117	25.08.2026	Oro-dispersible tablet formulation of Aspirin 100 mg	Accept the oro-dispersible tablet formulation of Aspirin 100 mg
117	25.08.2026	Labeling of medicinal	1. The labeling of medicinal products approved by the

		products	NMRA shall not be altered in a manner that changes, obscures or contradicts the approved product labeling. 2. Procurement related information may be added to the product packaging for government procurement and supply purposes, provided that such additions do not affect, obscure or contradict the NMRA approved information. 3. For medicinal products supplied exclusively through government procurement, details relating to the market authorization holder, local agent, marketing authorization holder or distributor may be removed or omitted, subject to maintaining the identification, authenticity, traceability and regulatory status of the product. 4. Any change to the approved product labeling, particularly regulatory and safety related information, shall be made only with the prior approval of the NMRA.
117	25.08.2026	QR Code / 2D Barcode Packaging Variation	where the only change to the approved product labeling is the addition of a QR code/2D barcode and the statement

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			"NMRA Registered", required in accordance with NMRA labeling requirements, submission of a variation application or a separate request letter to the NMRA shall not be required
117	25.08.2026	Personnel User Authorization	The process for issuance of Personal User Authorization Letters shall require a prescription issued by a Consultant. Accordingly, PUALs shall be issued only upon submission of a valid prescription issued.
117	25.08.2026	Sunscreens Regulation (SPF > 30)	Sunscreen products with an SPF above 30 shall be considered and regulated as cosmetic products and shall not require registration as medicines.
117	25.08.2026	Timeline for the submission of additional documents and renewal applications	Period of one (01) year shall be allowed for submission of documents requested under an "Awaiting Data" decision for New, Renewal and Re registration (RR) applications.
117	25.08.2026	Submission of new applications	Dossiers may be submitted within two (02) years from the date of issue of the sample license.

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118	22.09.2026	Brimonidine Tartrate Eye Drops 0.2% w/v	Register only Brimonidine Tartrate Eye Drops 0.2% w/v, in accordance with the available BNF strength.
118	22.09.2026	Medical Gases / Medical Oxygen	Decided that all medical gases, including oxygen, shall be registered as medicines. Applicants were instructed to submit registration dossiers within one year.
118	22.09.2026	In vivo diagnostic preparations	In vivo diagnostic preparations, including radiopharmaceuticals, computed tomography (CT) contrast media, magnetic resonance imaging (MRI) contrast agents, and other diagnostic agents administered to patients for diagnostic purposes, shall be regulated as medicinal products and shall be subject to the applicable registration requirements of the NMRA.