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IPASA Comments on Bill6	
Section	**Comment**
General:	Regulations to this Act need to be published for comment immediately post-publication of the Act for simultaneous implementation. Ensure that references to other Acts within the Medicines Act include an indication of 'as amended' if appropriate e.g. Act 72 of 2008, as amended Consider the amendments to regulations of Section 18A that are currently under consideration and under comment. Clarify the terminology used throughout the Act with respect to Medicines, Scheduled Substances. Clarity is required on the applicability of use of these terms in the various sections as there is an inconsistency of use where some sections only refer to 'medicines', while others refer to 'medicines and scheduled substances'.
ACT Introductory paragraph	Delete paragraph: 'To amend the Medicines and Related Substances Act, 1965 so as to delete and insert certain words in certain definitions; to insert certain definitions and to effect certain technical corrections; to provide for certain transitional matters; and to provide for matters connected therewith' Introductory paragraph must be an integrated preface containing the purposes of Act 101, Act 72 and Amendment Bill 6
Section 1: Definitions	**Complementary Medicine**: definition must align with the finalised Complementary Medicines guideline **Biosimilars:** A definition for 'Biosimilars' must be included and must align with the definition provided in the Biosimilars Guideline **Medical device:** Ensure alignment of definition to Medical Device regulations Consider inclusion of definitions for Chief Executive Officer and Registrar (refer to our comments in Section 2)
Section 2: General	The roles and responsibilities of the members and committees of the Board, meeting frequencies, committee structures and functions must be clarified in the Regulations to the Act. It is not clear whether this term relates to administrative committees or to technical committees.
Section 2A: Objects of Authority	Recommend that this section should read: 'The objects of the Authority are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials, medical devices and IVDS and related matters in the public interest.

	Add a section stating: The objects include regulatory oversight of foodstuffs and cosmetics.
Section 2B	(1)(b) A definition for 'timeously' must be included in the Regulations to the Act. (1)(f) Definitions for 'prescribed ethical and professional criteria and defined standards' (3) Clarify the difference between 'evaluation and registration' (of medicines...) and 'regulatory oversight' (of cosmetics and foodstuffs).
Section 3	Heading required. Propose: Appointment of Chief Executive Officer
Section 14:	(3) (a)(b): Propose deletion of subsection (b) as it contradicts the provisions of subsection (a) in terms of timelines for submission and timelines for the application of subsection 1.
Section 15	The timelines related to the evaluation process must be defined in the Regulations. (6)(b) Clarity on the process of licence renewals is required in the Regulations as reference is made to a 5 year registration validity period.
Section 15B:	(1) "Person' should be defined in terms of Act 54 of 1972 Recommend the addition of (4) to state: 'Nothing in this subsection prohibits the transfer of a product to another person during the registration process." Timelines must be defined in the Regulations