SAHPRA
South African
Health Products
Regulatory Authority

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RE-ADVERTISEMENT

EXPRESSION OF INTEREST
Independent Expert Review of South Africa's Draft Medical Devices Regulations

Issued by: South African Health Products Regulatory Authority (SAHPRA)

CALL FOR EXPRESSIONS OF INTEREST FROM MEDICAL DEVICES REGULATORY EXPERTS

The South African Health Products Regulatory Authority (SAHPRA) is South Africa's national regulatory authority responsible for the regulation of health products, including medicines, medical devices, In Vitro Diagnostic (IVDs)medical devices, radiation-emitting products and related health technologies, with a mandate to ensure access to safe, effective and quality health products.

SAHPRA invites suitably qualified medical devices regulatory experts to submit an Expression of Interest to conduct an independent expert review of South Africa's revised draft Medical Devices Regulations.

This Expression of Interest is targeted at individuals with demonstrable expertise in medical devices regulation, particularly those affiliated with, or who have contributed to, the International Medical Device Regulators Forum (IMDRF), the African Medical Devices Regulatory Forum (AMDRF), or who are currently or previously employed by regulatory authorities responsible for the oversight of medical devices and in vitro diagnostic medical devices. The purpose of this process is to identify and appoint an independent expert or panel of experts who can provide an objective assessment of the draft regulations prior to their finalisation and implementation.

BACKGROUND

South Africa has revised its Medical Devices Regulations under section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965). The revised regulations are intended to replace the current Regulations Relating to Medical Devices and In Vitro Diagnostic Medical Devices published in Government Gazette No. 40480 of 9 December 2016. The draft regulations have undergone public consultation, including consideration of comments from industry, professional associations, public health stakeholders and other interested parties. The final regulatory package has also been supported by a Socio-Economic Impact Assessment (SEIAS) sign-off process.

PURPOSE OF THE ASSIGNMENT

The appointed expert will be required to provide an independent written review of the revised draft Medical Devices Regulations, and assess whether the regulations are globally aligned, contextually appropriate for Africa and South Africa, and capable of enabling a safe, competitive and sustainable South African medical devices industry.

SCOPE OF THE INDEPENDENT REVIEW

1. **Global alignment:** assess the extent to which the draft regulations align with IMDRF principles and related international good regulatory practices, including risk-based classification, essential principles of safety and performance, conformity assessment, vigilance, reliance, clinical evidence, software as a medical device, post-market surveillance and quality management systems.
2. **Regulatory reliance and convergence:** comment on whether the regulations create sufficient enabling provisions for reliance on trusted regulatory authorities, recognised conformity assessment bodies, WHO Prequalification, Medical Device Single Audit Program (MDSAP) /ISO 13485 evidence and internationally accepted technical documentation, while preserving SAHPRA's sovereign decision-making authority.
3. **Relevance to the African context:** assess the appropriateness of regulations for implementation in an African regulatory environment, including regional harmonisation, alignment with AMDF and African Medicines Regulatory Harmonisation (AMRH) objectives, scarce regulatory capacity, cross-border trade, public sector procurement realities and access to essential diagnostics and medical technologies.
4. **Relevance to the South African context:** review whether the regulations adequately address South Africa's health system realities, including public and private sector use, rural access constraints, digital access limitations, post-market vigilance, importation routes, local accountability, use of local authorised representatives, and the need for traceability and patient protection.
5. **Impact on industry enablement:** assess whether the regulations are likely to enable or constrain the South African medical devices industry, including local manufacturers, importers, distributors, wholesalers, service providers, diagnostic laboratories and innovators, and whether they support competitiveness, investment, innovation and regional export potential.
6. **Implementation feasibility:** provide an opinion on whether the requirements are proportionate and practically implementable, particularly in relation to product registration, call-up notices, transitional arrangements, labelling, instructions for use, electronic information, ISO 13485 certification, conformity assessment body recognition, timelines and regulatory capacity.
7. **Key risks and unintended consequences:** identify any provisions that may unintentionally restrict access to medical technologies, increase regulatory burden without commensurate public health benefit, create ambiguity in supply-chain responsibilities, duplicate international controls, or impede South Africa's role as a regional medical devices hub.
8. **Recommendations:** provide concrete recommendations on amendments, clarifications, guidance documents, transitional mechanisms or implementation sequencing that would strengthen the regulations prior to their finalisation.

ELIGIBILITY CRITERIA

Respondents should meet one or more of the following criteria:

- demonstrated expertise in medical devices and/or in vitro diagnostic medical devices regulation;
- current or previous affiliation with IMDRF, AMDRF, or related international or regional medical devices regulatory harmonisation initiatives;
- current or previous employment by a regulatory authority responsible for the regulation of medical devices or in vitro diagnostic medical devices;

- experience in regulatory reliance, convergence, conformity assessment, classification, clinical evidence, vigilance, post-market surveillance, quality management systems, or software as a medical device;
- understanding of regulatory implementation in low- and middle-income country contexts, preferably including African regulatory systems; and
- ability to provide an independent, evidence-based and practical written assessment within the agreed timeframe.

DOCUMENTS TO BE MADE AVAILABLE

For purposes of the review, SAHPRA will provide the revised draft Medical Devices Regulations, the consolidated responses to public comments, and the SEIAS sign-off documentation. These documents reflect the policy intent, stakeholder concerns and regulatory rationale underlying the current draft.

EXPECTED DELIVERABLES

We would appreciate a written independent review report that includes an executive summary, a high-level assessment of the overall regulatory approach, clause-specific or thematic comments where necessary, a view on readiness for implementation, and clear recommendations for strengthening global alignment and local applicability. Where appropriate, the report may distinguish between matters that should be addressed in the regulations themselves and matters that could be addressed through guidelines, transitional plans, implementation notices or operational procedures.

SUBMISSION REQUIREMENTS

Interested experts are invited to submit an Expression of Interest containing the following information: a brief motivation indicating suitability for the assignment; a curriculum vitae; details of relevant regulatory experience; a declaration of current or previous affiliation with IMDRF, AMDRF or a medical devices regulatory authority; confirmation of independence and absence of conflict of interest; availability to complete the assignment within four to six weeks from receipt of the full document pack; and an indication of proposed fees or remuneration expectations, where applicable.

EVALUATION OF EXPRESSIONS OF INTEREST

Expressions of Interest will be considered based on relevant medical devices regulatory expertise, demonstrated international or regional regulatory experience, familiarity with IMDRF and/or AMDF principles, understanding of African and South African public health and regulatory contexts, independence, availability, and ability to produce a clear and practical expert report.

INDEPENDENCE AND CONFIDENTIALITY

The review will be an independent expert assessment and should not be construed as an endorsement by IMDRF, AMDF or any regulatory authority unless formally authorised through the appropriate institutional processes. SAHPRA will treat the findings as expert advisory input to support evidence-informed regulatory decision-making. Any non-public documentation shared for purposes of the review must be treated as confidential and used only for the agreed purpose.

PROCEDURE

- This is a re-advertisement, candidates who previously applied need not to re-apply.

- Expressions of Interest must be submitted **online at** https://apply.sahpra.org.za:6006
- Only documents in pdf must be uploaded.
- Further communication will be limited to nominated candidates with appropriate skill sets.
- Closing date for nominations is Friday**, 25 September 2026 at 16h30. No late submissions will be accepted.**

Enquiries: Office of the CEO at CEOOffice@sahpra.org.za