Role of Harmonized Standards in Promoting Manufacture and Trade of Medical Devices and Equipment in Africa

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African Organization for Standardization (ARSO) in Brief

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Values

Integrity
Excellence
Accountability
Inclusivity- People-centred
Reliability

Vision

To be an excellent standardisation institution that promotes a quality culture in support of trade, industrialization and sustainable development in Africa.

Mission

To facilitate African industrialization and intra-Africa and global trade by providing harmonized African standards and conformity assessment procedures that promote sustainable development

- **is an intergovernmental organization**
- Created by the African Union (AU) and the United Nations Economic Commission for Africa (UNECA) in **1977, Accra, Ghana**
- **43 African governments** represented by national standards bodies **(NSBs)**

Mission & Current ARSO Membership

Facilitate Intra-African & Global Trade

a. harmonize national and/or sub-regional standards as African Standards and issue necessary recommendations to member bodies for this purpose;

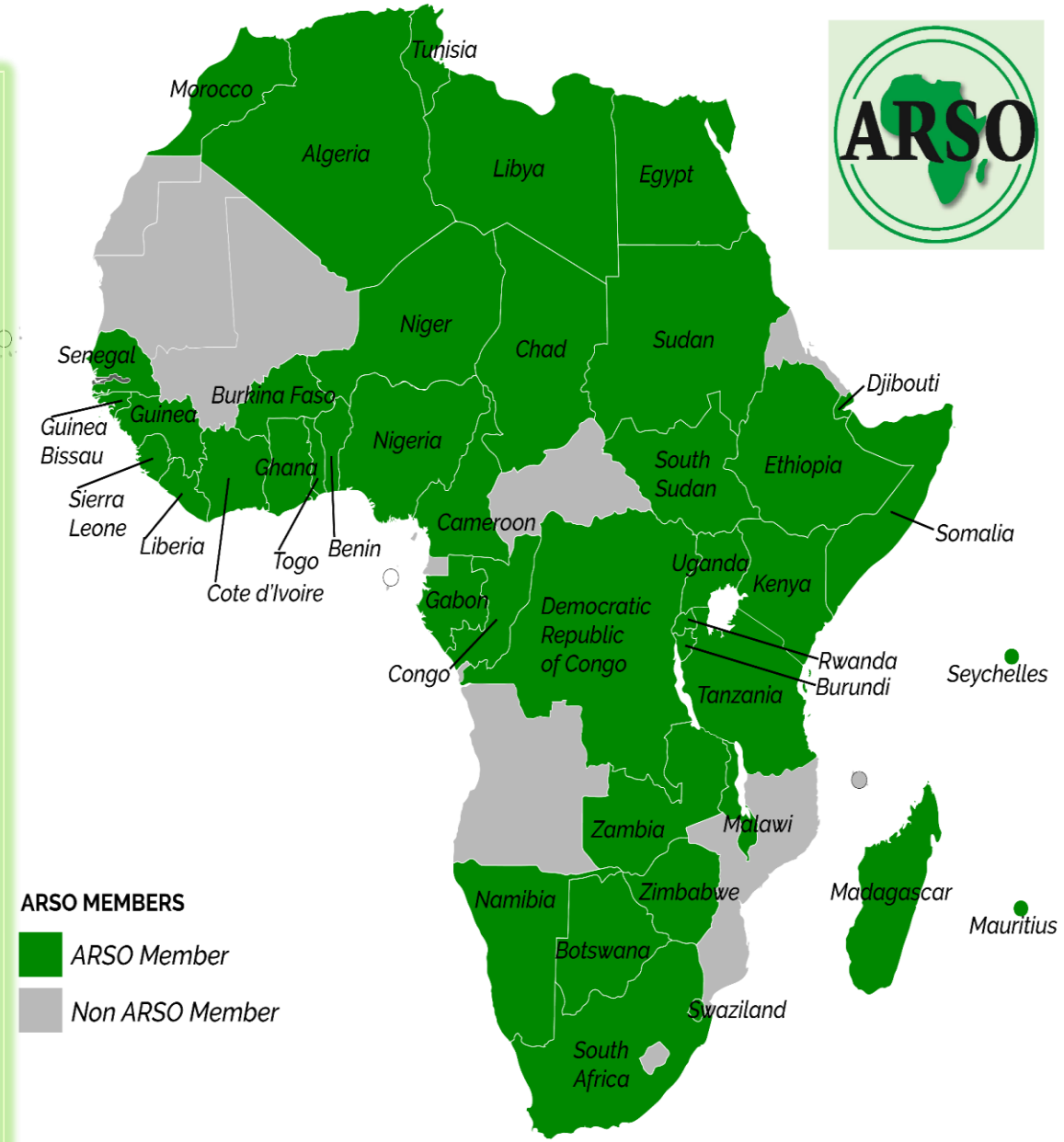
b. promote and coordinate standardisation and conformity assessment practices in Africa;

c. operate a regional certification marking scheme with a view to certifying the quality of and promoting African products;

d. encourage and facilitate the development by AU Member States of technical regulations to be based on African harmonised standards and/or international standards;

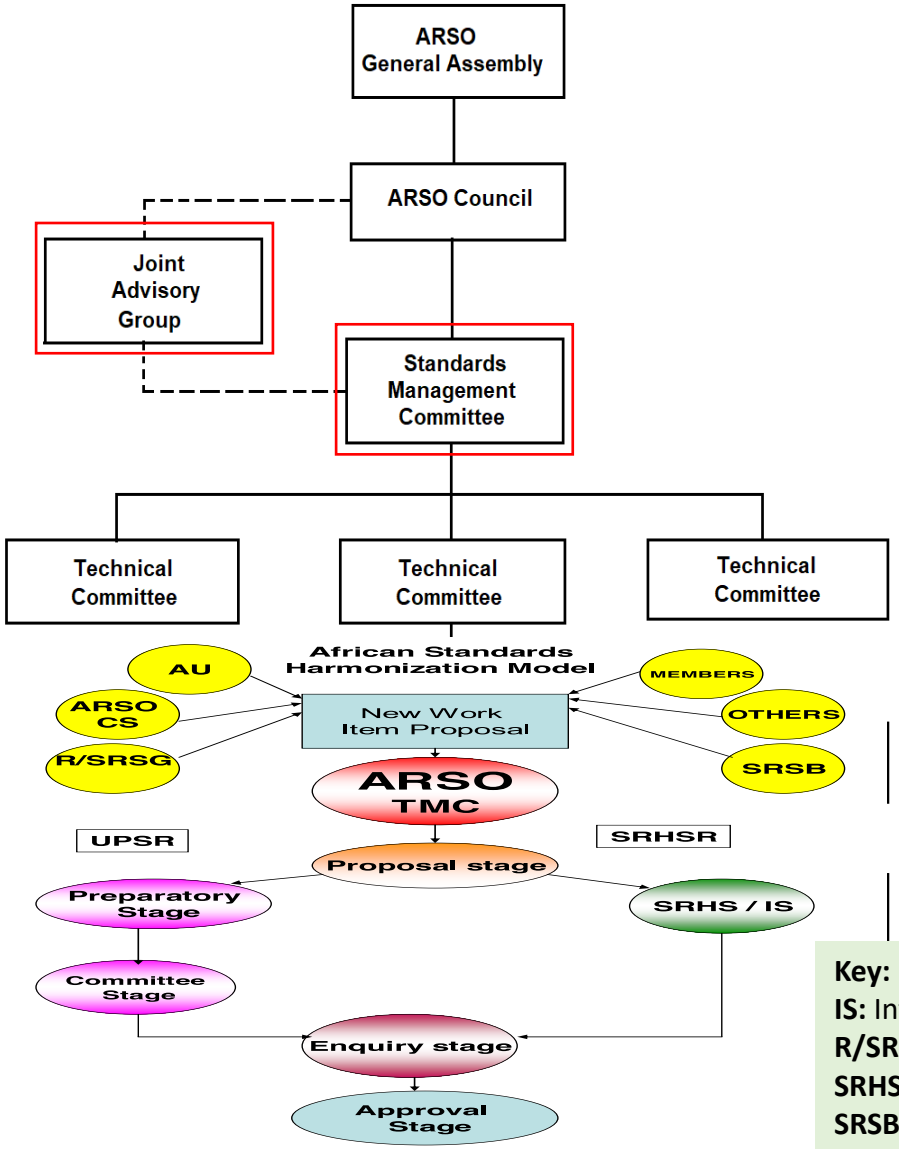
e. promote and facilitate exchange of experts, information and co-operation in training of personnel in standardisation activities;

f. create appropriate bodies in addition to the organs of the organization for the purposes of fulfilling its objectives.



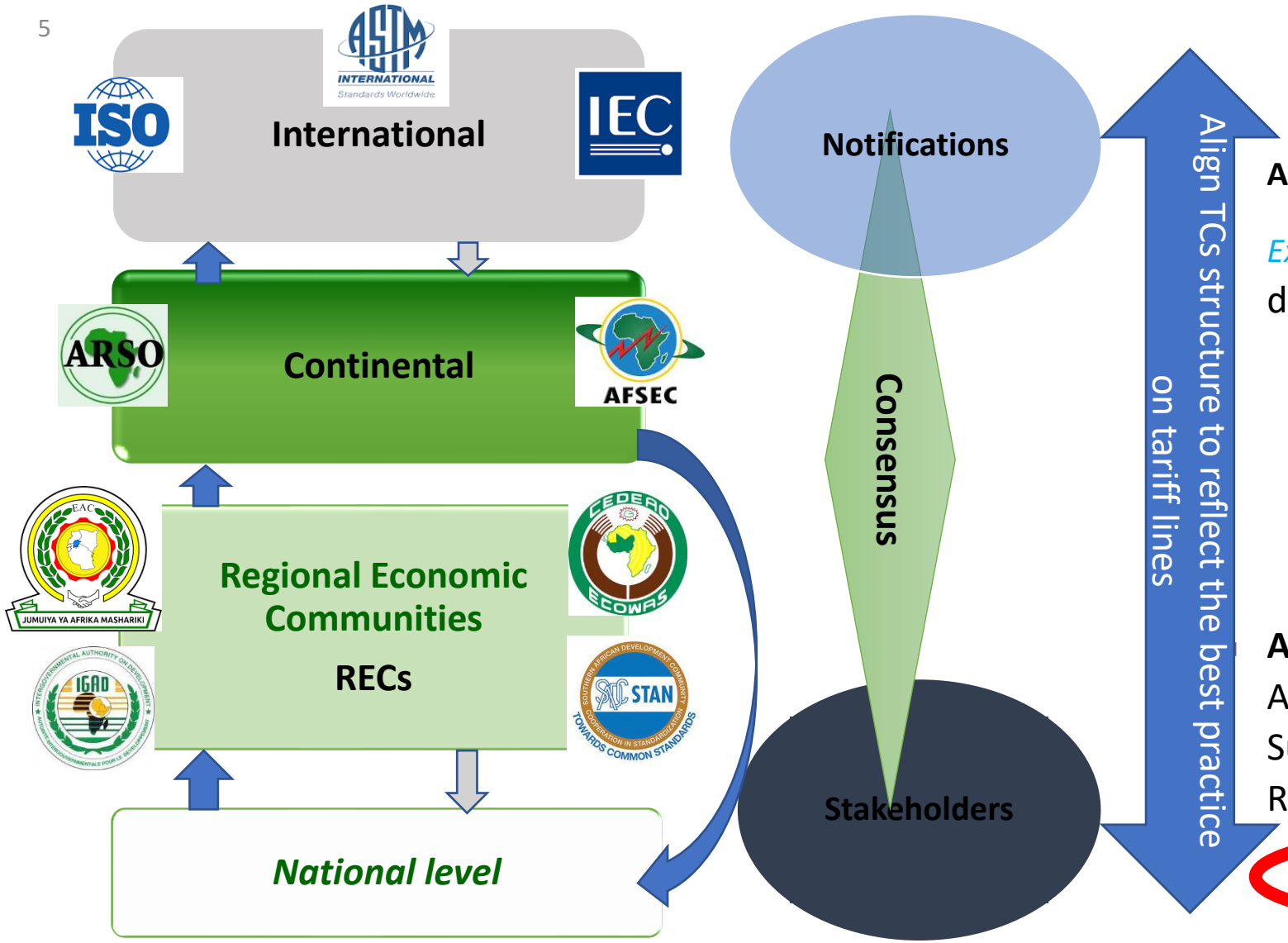
Priorities within RECs

EAC	COMESA	ECOW	IGAD	Frequency	TC
	ARSO/TC, Leather, leather products and accessories	ARSO prod	ARSO/TC, Leather, leather products and accessories	6	1
ARSO/TC, Tourism and Related Services	ARSO/TC, Tourism and Related Services	ARSO Servi		6	2
	ARSO/TC, Cereals, pulses and derived products	ARSO deriv	ARSO/TC, Cereals, pulses and derived products	5	3
ARSO/TC, Pharmaceuticals	ARSO/TC, Pharmaceuticals	ARSO	ARSO/TC, Pharmaceuticals	5	4
	ARSO/TC, Textiles, textile products and accessories	ARSO and a		5	5



Key:
IS: International Standard
R/SRSG: Regional/ Sub-Regional Stakeholder Groupings
SRHS: Sub-Regional Harmonised Standard
SRSB: Sub-Regional Standardisation Bodies
UPSR: Unique Product Standard Route

Institutional mandates to develop standards



Alignment: *Technical Committee*

Example **ARSO/TC 78,** Medical devices and Equipment

- **Equivalent Committees:** ISO/TC 84, Devices for administration of medicinal products and catheters
- ISO/TC 94, Personal safety -- Personal protective equipment
- ISO/TC 106, Dentistry

ARSO/CACO SC TR, Conformity Assessment Committee, Subcommittee on Technical Regulation

- *National level?*

- **Standard:** *Document **approved by a recognized body**, that provides, for common and repeated use, rules, guidelines or characteristics for **products or related processes and production methods**, with which **compliance is not mandatory (**WTO-Definition,* *TBT Agreement, Annex 1, par. 2)*

Does Africa Need to Manufacture Medical Devices?

- Medical devices are essential to the diagnosis and treatment of many diseases, particularly within surgical specialties, radiology, and critical care.
- A medical device is any instrument, apparatus, machine, appliance, implant, reagent for in vitro use, software, material, or related article used for a specific medical purpose.
- Most existing medical devices were built for the demands and resources available in high-income countries and are not adapted to the challenges often present in many countries in Africa.
- Most medical devices are designed by western firms from efficient innovation systems with a focus on their home markets. A disproportionately high percentage of imported medical devices in low resource settings become non-functional
- Therefore, there is an urgent need to develop medical devices that are specifically designed to address these challenges to improve African patients' access to medical care.

Pharmaceuticals & Medical devices Status

Current status

About 95.9% of Africa's imports of medicinal & pharmaceutical products

Drivers of Growth

1. Increased population
2. Dependence on importation
3. AfCFTA promoting Africa's industrialisation and export diversification

Needs for developing the sector

Less than 2% of drugs are produced locally

The demand for safe, effective and affordable medicines in Africa

Standards Harmonisation priorities

1. Pharmaceutical & medicinal products
2. Medical devices &Equipment
3. African traditional medicine
4. Healthcare services

(1) ensuring the quality of medicines, (2) avoiding stock outs, (3) supporting local incomes and jobs, (4) triggering technology spillovers, (5) addressing new challenges like non-communicable diseases, and (6) helping the sustainability of government medical schemes (UNIDO, 2015).

Harmonization of Standards for Medical Devices in Africa: Role

(1) Strategic selection of essential medicinal products for local production

(2) Pricing of locally produced products that governments and people could afford

(3) Strict compliance to quality and safety standards by the manufacturers

(4) Health security – an uninterrupted supply of essential medicines and medical devices

(5) Innovation for development of formulations that are suitable for local conditions

(6) Facilitation for development of medical products for diseases which are neglected at the international level but are of significant interest at national, sub-regional and continental levels

(7) Gaining competitiveness and recognition for international accreditation of local industries in the manufacture of medical products.

(8) Create the basis for harmonization of medicines regulations and mutual recognition of regulators to facilitate intra-African trade in pharmaceuticals and medical devices.

(9) Form the basis for governments to formulate public procurement contracts with producers.

Pharmaceuticals & Medical devices Status

in some African countries, the availability of essential medical products is potentially delayed by disparities in legal provisions of key regulatory functions (including standards, Technical Regulations and Conformity Assessment)

Resulted in

the need for Regulatory Oversight and policy frameworks and regulatory convergence towards a common/unified continental regulatory framework, leading to the some initiatives:

one of them is

Harmonizing the standards of pharmaceutical products and medical devices in Africa

State of Production of Medical Devices in Africa

- In most African countries, more than 90% of the medical devices in public hospitals are imported, with very limited local production
- Moreover, most medical devices cannot be serviced and maintained locally, given the lack of local infrastructure
- There is limited local manufacturing capacity and design mechanism to incentivise manufacturers to engage in the production of priority medical devices
- Local medical device manufacturers not starting up due to the high capital investment required, the prohibitive and unaligned regulatory framework, brand representation and the unwillingness of end users to switch to smaller brands, and cash flow and liquidity problems
- MNCs' dominance in the medical device industry; lack of funding and incentives for manufacturers; high cost of regulatory compliance; import duties on components which are often higher than the price of finished goods; and unavailability and unreliability of raw materials from local suppliers

ARSO's interventions

Membership (23 countries)

Algeria, Botswana, Burkina Faso, Cameroon, Cote d'Ivoire, Congo Brazzaville, Chad, Democratic Republic of Congo, Egypt, Ethiopia, Eswatini, Gabon, Ghana,, Kenya Madagascar, Malawi, Mauritius, Morocco, Namibia, New State of Libya, Niger, Nigeria, Rwanda, Senegal, Seychelles, Sudan, South Sudan, South Africa, Tanzania, Togo, Tunisia, Uganda, Zambia, Zimbabwe and Zanzibar

AFRICAN ORGANISATION FOR STANDARDISATION (ARSO)

Facilitate **intra-African and global trade**

through **harmonized standards and conformity system**

ASHAM

Harmonisation process

- *Technical Committees (TCs)*
- *Standards Management Committee (SMC)*
- *National Mirror Committees (NMCs), WTO*
- *ARSO Council (12 ARSO members)*

A few of the harmonized standards & technical guidelines

African Standards

1. ARS 1692:2021, Medical devices — Medical face masks — Specification
2. ARS 1693:2021, Community face coverings — Guide to minimum requirements, methods of testing and use
3. ARS 1694:2021, Medical respirators — Specification
4. ARS 1695-1:2021, Medical devices — Surgical gowns, drapes and clean air suits — Part 1: General requirements
5. ARS 1695-2:2021, Medical devices — Surgical gowns, drapes and clean air suits — Part 2: Test methods
6. ARS 1693:2021 Disinfectants Sanitizers Specification
7. ARS 1709:2021 Disinfectants sanitizers based on iodophors Specification
8. ARS 1710:2021 Disinfectants sanitizers based on glutaraldehyde for general use Specification
9. ARS 1653:2021 Disinfectants Quaternary ammonium based Specification
10. ARS 1654:2021 Disinfectants Glossary of terms

- Over 200 standards
- 20 ARS/GL

Technical Regulations Guidelines

1. ARS GL 1705_2021, Guideline for regulation and conformity assessment for medical devices
2. ARS GL 1706_2021 Guideline for regulation and conformity assessment for in vitro diagnostic medical devices (IVDs)
3. ARS GL 1707:2021 Guideline for Setting up a temporary emergency medical facility.
4. ARS GL 1703:2021, Guideline for the regulation of African Traditional Medicine (ATM)
5. ARS GL 1704:2021, Guideline on marketing authorization of human pharmaceutical products

International standards (ASTM, IEC, EN & ISO)

1. ARS/ASTM F1862/F1862M:2017, Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity);
2. ARS/ASTM F2100:2020, Standard Specification for Performance of Materials Used in Medical Face Masks
3. ISO 11135:2018 Sterilization of health-care products — Ethylene oxide
4. ISO 11138-1:2017 Sterilization of health care products — Biological indicators — Part 1: General requirements
5. EN 14885:2015 Chemical disinfectants and antiseptics — Application of European Standards for chemical disinfectants and antiseptics
6. IEC 60601-1:2005+AMD1:2012 + AMD2: 2020 CSV Consolidated version, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Regulatory Environment in Africa

- The regulation of medical devices is still developing in many African countries, where regulatory controls are not yet well established to prevent the importation or use of sub-standard devices
- The regulatory approval process for medical devices in Africa is lengthy, opaque, and skewed towards controlling entry into the market of substandard imports, which pose a risk to health
- The regulatory environment, or lack thereof, is a key issue for manufacturers in Africa. It should be considered an issue of vital importance to be addressed for the development of the medical devices sector
- The WHO encourages the harmonisation of medical device regulation towards standardisation, to promote uniformity between national medical device bodies. In an era of globalisation, this facilitates cooperation among regulators and the industry, particularly with regard to audits, submission requirements, use of international standards and exchange of safety information, and also leverages experience gained over time

Global Trade in Medical Devices and Equipment

- From 2001 to 2020, the global trade volume of medical devices increased rapidly from US$112.963 billion to US$488.256 billion, representing an average annual growth of 7.23%.
- Changes in total trade volume are the combined result of changes in participating economies and trade volumes.
- With the continuous expansion of the global trade of medical devices, the number of participants in the trade has been increasing, and the structure of the trade network has become increasingly complex.
- From 2001 to 2020, the number of participants in the global medical device trade increased from 190 to 230, and the number of trade connections increased from 5,434 to 5,640, representing an increase of 17.39.0% and 6.65%, respectively.

Top 10 net import and export countries from 1990 to 2020 **(US$million)**

	Net export countries		Net import countries	
Rank	Country	Trade value	Country	Trade value
1	Sweden	1,401.12	Russia	996.02
2	US	1,358.32	South Korea	647.10
3	UK	1,112.55	China	503.80
4	Israel	856.62	Brazil	338.80
5	Germany	585.23	Japan	314.41
6	Netherlands	375.96	India	291.63
7	Belgium	246.29	Turkey	177.30
8	France	155.17	Italy	158.66
9	Canada	149.55	Australia	146.31
10	Switzerland	112.43	Thailand	133.94

- *Import-dependent medical equipment and supplies market tops US$3.2 billion as African countries rely on imported medical equipment and supplies*

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THANK YOU