Accessibility, Affordability of Medical Devices –South East Asia Regional perspective

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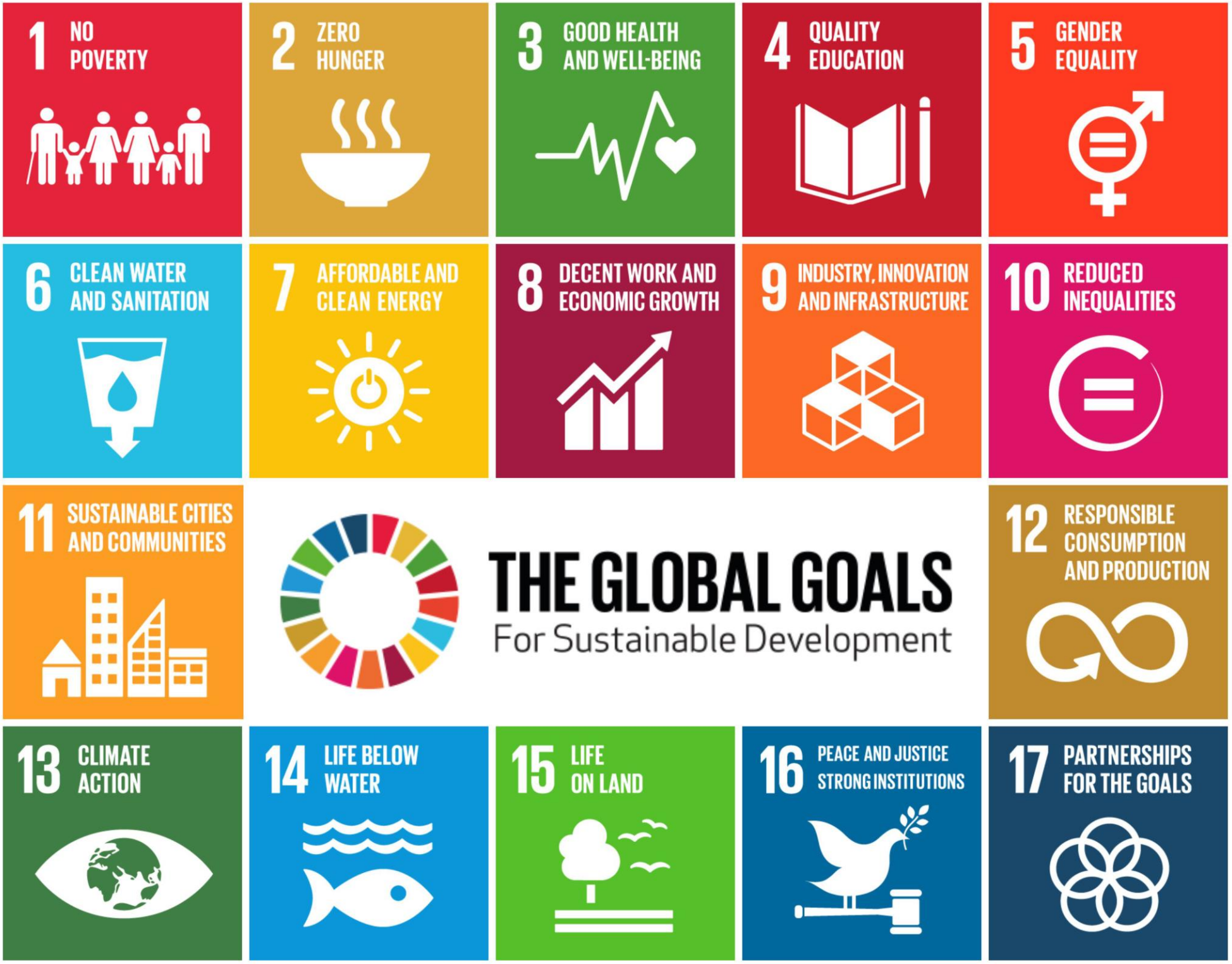
1 NO POVERTY
2 ZERO HUNGER
3 GOOD HEALTH AND WELL-BEING
4 QUALITY EDUCATION
5 GENDER EQUALITY
6 CLEAN WATER AND SANITATION
7 AFFORDABLE AND CLEAN ENERGY
8 DECENT WORK AND ECONOMIC GROWTH
9 INDUSTRY, INNOVATION AND INFRASTRUCTURE
10 REDUCED INEQUALITIES
11 SUSTAINABLE CITIES AND COMMUNITIES
THE GLOBAL GOALS
For Sustainable Development
12 RESPONSIBLE CONSUMPTION AND PRODUCTION
13 CLIMATE ACTION
14 LIFE BELOW WATER
15 LIFE ON LAND
16 PEACE AND JUSTICE STRONG INSTITUTIONS
17 PARTNERSHIPS FOR THE GOALS

13 Targets under SDG 3: “Ensure healthy lives and promote well-being for all at all ages”

Target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services, medicines and vaccines for all

MDG unfinished and expanded agenda

- 3.1: Reduce maternal mortality
- 3.2: End preventable newborn and child deaths
- 3.3: End the epidemics of HIV, TB, malaria and NTD and combat hepatitis, waterborne and other communicable diseases
- 3.7: Ensure universal access to sexual and reproductive health-care services

New SDG 3 targets

- 3.4: Reduce mortality from NCD and promote mental health
- 3.5: Strengthen prevention and treatment of substance abuse
- 3.6: Halve global deaths and injuries from road traffic accidents
- 3.9: Reduce deaths from hazardous chemicals and air, water and soil pollution and contamination

SDG3 means of Implementation targets

- 3.a: Strengthen implementation of framework convention on tobacco control
- 3.b: Provide access to medicines and vaccines for all, support R&D of vaccines and medicines for all
- 3.c: Increase health financing and health workforce in developing countries
- 3.d: Strengthen capacity for early warning, risk reduction and management of health risks

Interactions with economic, other social and environmental SDGs and SDG 17 on means of implementation

Medical devices are technologies indispensable to accomplish the health related 2030 SDG: *prevent, diagnose, treat, palliate, assist.*

Target	Example of health technology/ medical device
3.1 by 2030 reduce the global maternal mortality ratio to less than 70 per 100,000 live births	Blood pressure meters, pregnancy tests, surgical instruments, cord clamps..
3.2 by 2030 end preventable deaths of newborns and under-five children	Neonatal resuscitation devices, warming devices/ incubators, diagnostics
3.3 by 2030 end the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases and combat hepatitis, water-borne diseases, and other communicable diseases	In vitro diagnostics to initiate the right treatment.
3.4 by 2030 reduce by one-third pre-mature mortality from non-communicable diseases (NCDs) through prevention and treatment, and promote mental health and wellbeing	Diagnostics: in vitro, blood glucose meters, pathology; x rays…imaging , Treatment: surgical instruments, implants, radiotherapy, inhalers chemotherapy, cardiac support
3.7 by 2030 ensure universal access to sexual and reproductive health care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes	From condoms to contraceptive devices

Determinants in Medical devices

- From patients to people
- National and State Regulators: Guardians for quality, safely and efficacy of medial products

- Approvals
  - administrative requirements-
  - Technical approval of products/ processes

- Costs- to compliance (i) Regulators (National and state) and (ii) manufacturers
    - time cost
    - procedural costs

International Engagements

- 1st World Conference on Access to **Medical Products** and International Laws for Trade and Health in the Context of the 2030 Agenda for Sustainable Development, 21-23 November 2017, New Delhi, India
- 9-11 October 2018 2nd World Conference
  - Medical products – medicines, vaccines, medical devices, diagnostics

- SEARN – medical devices
  - To assist in development of science-based approaches to regulatory decision making for assessing manufacturing quality, extent of manufacturing related submissions,
  - better allocate resources to lower the regulatory burden on manufacturers and regulators.

Why a Regulatory Network for the Region?

- Complexity and range of medical products – medicines, vaccines, diagnostics, medical devices
  - 10,000 Types of medical devices , 500,000 different products commercially available
  - Even well-resourced authorities are hard-pressed to thoroughly evaluate new products and enforce existing regulations.
  - information sharing, collaboration and convergence of medical product regulatory practices across the Region for access to quality medical products
- Build speed in decision making
- SDGs 2030 Agenda

Getting the most from collaboration- SEARN

- Recognizing no one can work effectively and efficiently alone in very complex and rapidly changing global conditions
  - Trade-dominated environment where trade in goods, including medical products is increasing- **internet** ?
  - Complexity of technological medical product innovations, e.g. personalized therapies pose challenges for effective, efficient and suitable regulation.
  - Number of medical product manufacturers has increased rapidly, both domestically and internationally
    - challenges for regulatory authorities in guaranteeing the quality, safety and efficacy of the medical products and **conducting inspections of facilities**.
    - Contribute to **Institutional development Plans (IDPs)** of National and State regulatory agencies

Priority areas identified for action in SEARN

- Quality assurance and standards of medical products, including labs
- Good Regulatory Practices including GMP, GDP etc.
- Vigilance for medical product
- Information sharing platform

Formation of Steering Group in 2017 and Next steps

- **Steering group**
  - 3 members for continuity- India, Indonesia, Thailand + 2 Members – Sri Lanka (chair of the next meeting) and one member to be nominated by consensus – Bhutan
  - establish **Working groups**
  - **Co-opt regulators from provincial/ state governments?**
- Information in public domain: communication on SEARN website

  Information among regulators/focal points

- Venue of next meeting: **22-23 March 2018 in** Sri Lanka

- Work in progress: 4th Global Forum on Medical Devices 2018 New Delhi

Specific context in Medical devices-1

- **Challenge in production -**
  - Their design, evaluation , procurement, planning, training, maintenance and decommissioning usually done by **biomedical engineers**: relate to medical use
- **Pharmacists are to medicines as biomedical engineers are to medical devices!!.**
- Biomedical engineers study: math, calculus, chemistry, biology, pathology, physiology, electronics, mechanics, physics, biochemistry, biomechanics, transducers, optics, …

Specific context in Medical devices-2

- **Challenge in Use-**
  - The performance does not depend on the device itself but on the way they are used , this has to be safe and correct – certain devices – BP monitors being **used by the people themselves** - with little or no medical information- **instructions and labelling** requirements
  - Putting health decisions in the hands of the people – personalized medical devices

Movement in International Trade of Medical devices

- World Customs Organization- Harmonized System of Classification Section XXI
  - Chapter 30, **Pharmaceutical products**

Harmonized System of Classification – HS Code

Heading	HS Code	**Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices), impregnated or coated with pharmaceutical substances or put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes.**
30.05	3005.10	-Adhesive dressings and other articles having an adhesive layer
	3005.90	-Other
30.06		**Pharmaceutical goods specified in Note 4 to this Chapter.**
	3006.10	- Sterile surgical catgut, similar sterile suture materials (including sterile absorbable surgical or dental yarns) and sterile tissue adhesives for surgical wound closure; sterile laminaria and sterile laminaria tents; sterile absorbable surgical or dental haemostatics; sterile surgical or dental adhesion barriers, whether or not absorbable
	3006.20	-Blood-grouping reagents
	3006.30	-Opacifying preparations for X-ray examinations; diagnostic reagents designed to be administered to the patient
	3006.40	-Dental cements and other dental fillings; bone reconstruction cements
	3006.50	- First-aid boxes and kits

Thank You