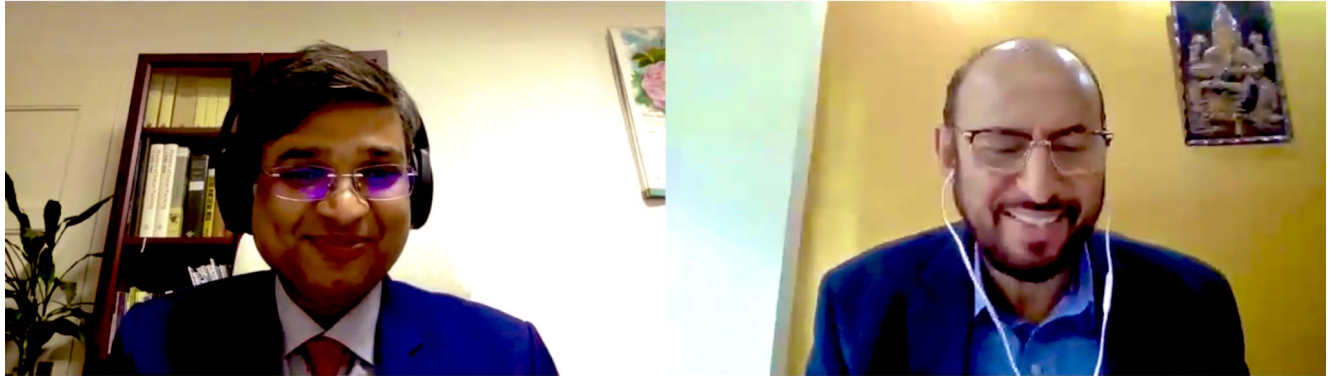


**Momentum in India- Swiss SMEs Program (MISSP 2.0):** The Embassy of India, Berne's organized MISSP 2.0 Webinar on 'Opportunities in Indian Medical Technology Sector' on 27 May 2020. EEPC India participated as guest speaker providing supplier ecosystem perspective. The Webinar was attended by Swiss & Indian companies and experts from the Medical Technology Sector followed by an interactive Q&A.

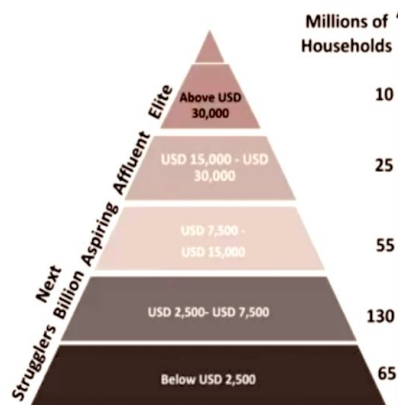


## India's Consumption Story

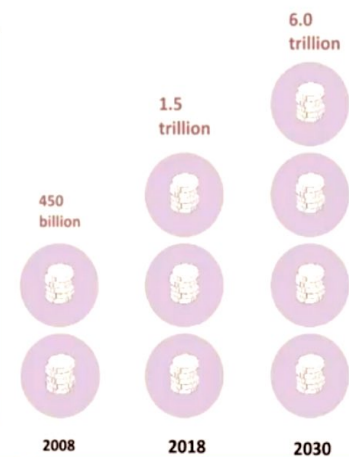
Middle class consumption (PPA constant 2011 trillion USD and global share)

	Country	PPP	Share
2015	USA	44.7	13
	China	4.2	12
	Japan	2.1	6
	India	1.9	5
2020	USA	6.8	16
	China	4.7	11
	India	3.7	9
2030	China	14.2	22
	India	10.7	17

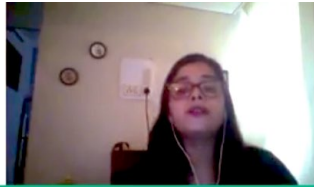
Middle class consumption (PPA constant 2011 trillion USD and global share)



India's Private Consumption Expenditure indicates increasing disposable income



Source: Brookings Institution, BCG



# 1. LEGAL UPDATE

## Recent Medical Device Regulatory changes in India 2020

### Overview of India's legal and regulatory framework for medical devices

- The main regulatory framework for the import, manufacture, sale of medical devices in India is the Drugs and Cosmetics Act, 1945 and the Medical Device Rules, 2017.
- Earlier only 37 categories of medical devices, notified by the Government of India under the regulatory framework.
- Risk based classification of all the medical devices - Class A (low risk), Class B (low moderate risk), Class C (moderate high risk) and Class D (high risk) as decided by the Central Drugs Standard Control Organization (CDSCO).
- Product standards for medical devices and Market entry for foreign manufactured medical devices through import license.

### Recent amendments

- Revised definition of Medical Devices under the Drugs Act notified to include all medical device intended for use in human beings or animals would qualify as drugs under section 3(b)(iv) of the Drugs Act with effect from 1<sup>st</sup> April 2020.
- The revised definition of medical device would result in bringing medical equipment such as knee implants, CT scan, MRI equipment, defibrillators, dialysis machine, PET equipment, X-ray machine etc.
- New registration requirement of medical devices under the Medical Devices (Amendment) Rules, 2020
  - Medical devices which have been additionally notified as drugs effective from 1<sup>st</sup> April 2020
  - Registration on voluntary basis for a period of 18 (eighteen) months
  - Exemption and relaxations for the medical devices falling within the newly notified definition
  - To meet certified quality standards



# 2. TAX UPDATE

## 2.3 TAX INCENTIVES FOR MEDICAL TECHNOLOGY SECTOR

### 35(2AB)

- Weighted tax deduction of 150% of In-house R&D expenditure (including on capital expenditure except on the expenditure in the nature of cost of any land or building), if the amount is spent on or before 31 March 2021 (subject to conditions)
- Deduction of 100% of In-house R&D expenditure (including on capital expenditure except on the expenditure in the nature of cost of any land or building), if the amount is spent on or after 1 April 2021 (subject to conditions)

- Deduction of an amount equal to 30 per cent of additional employee cost for 3 years
- Conditions prescribed for "Additional employees"

### 80J A

### GST / Customs

- Conditional exemptions / concessional rates of duty under customs for import of specified medical devices
- Export of manufactured medical devices would be entitled for export incentives under various export promotion schemes such as "Duty Drawback", "Merchandise Exports from India Scheme", "Export Promotion Capital Goods Scheme", etc.
- The unutilised balance of Input Tax Credit of GST paid on various inputs and input services can availed as refund

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