Rödl & Partner

MISSP

DOING BUSINESS IN INDIA – INDIAN MEDICAL TECHNOLOGY SECTOR

Legal & Tax update

May 27, 2020

AGENDA

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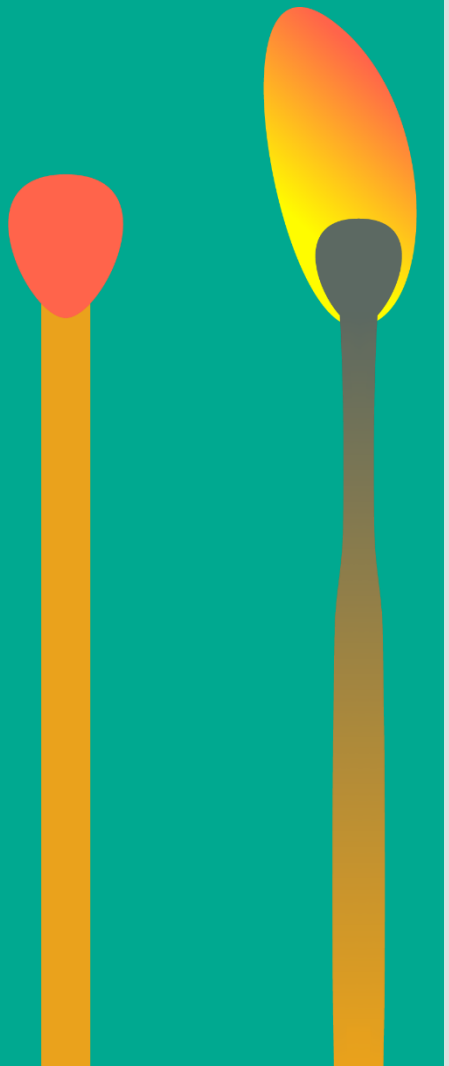

1. LEGAL UPDATE

By Apoorva Singh
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1. LEGAL UPDATE

Growth of Medical Technology Sector in India

Government Initiatives

- Medical technology is recognized as **"sunrise sector"** by the Indian Government.
- 100% FDI is permitted in "medical devices" and hospitals under the automatic route attracting lucrative investments.
- **'Make in India'** initiative by the Indian government to help boost domestic manufacturing and export competitiveness of this industry.
- Changes in its medical regulatory framework for medical devices in India towards ensuring quality and safety of these medical devices at par with the international standards.

Growth status

- The medical device sector of India in particular adds a sizeable contribution to the Indian health care industry and is expected to show a surge by crossing $11 billion threshold by 2022.
- At present India is one of the top 20 global market hub for medical devices and ranks 4th largest market for medical devices in Asia after Japan, China and South Korea.

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1. LEGAL UPDATE

Complex rules and guidelines

Lack of mandatory requirement of adhering to certain quality standards and obtaining proper approval from the government authority

KEY CHALLENGES FACED BY THE INDUSTRY IN THE MEDICAL DEVICE SECTOR

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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 1st 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 1st 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

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2. TAX UPDATE

By Anand Kankariya
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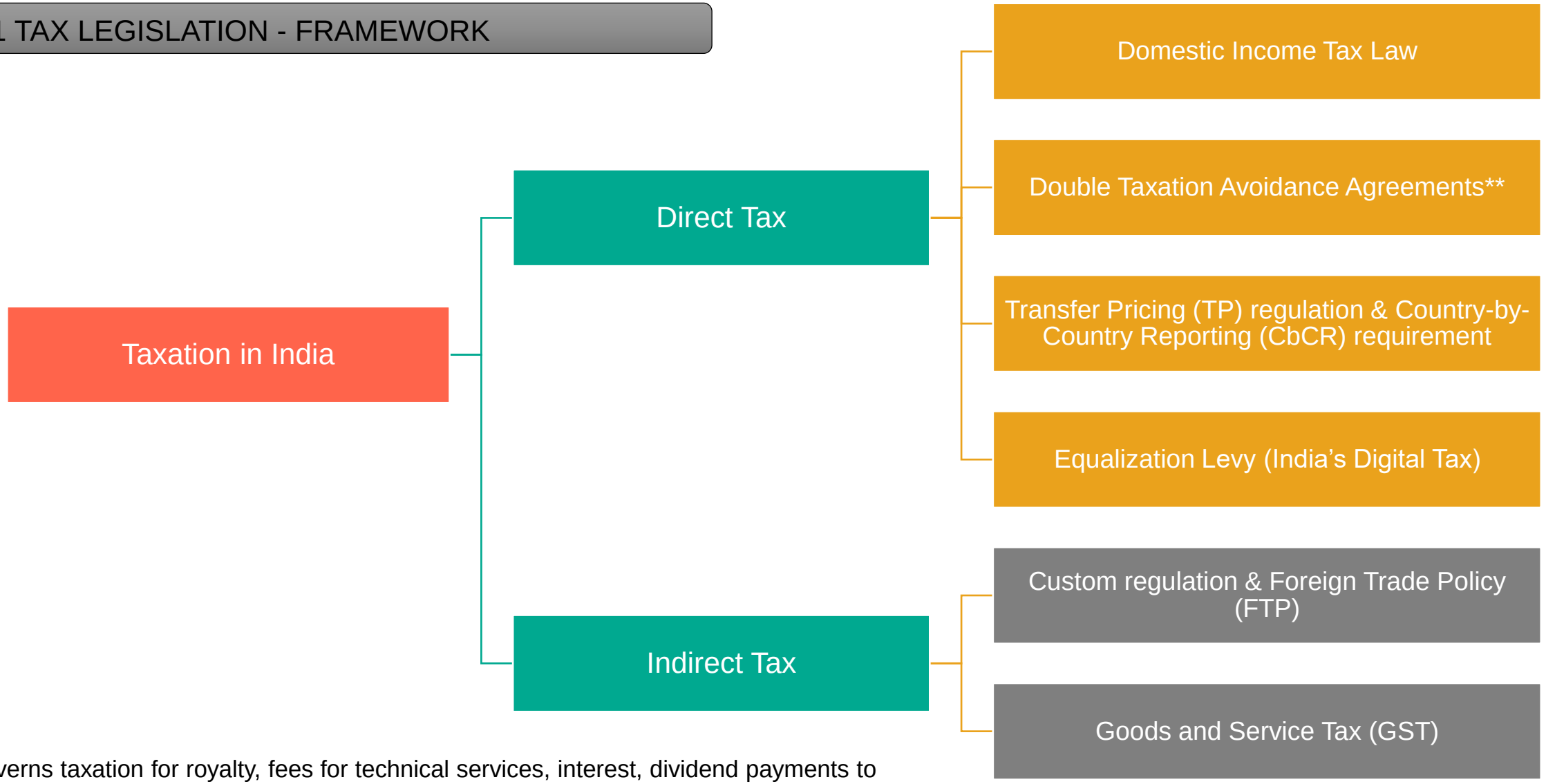
2. TAX UPDATE

2.1 TAX LEGISLATION - FRAMEWORK



**governs taxation for royalty, fees for technical services, interest, dividend payments to foreign parent companies

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2. TAX UPDATE

2.2 RECENT UPDATES – GENERAL

Base Corporate Income-tax (CIT) rate reduced to **22%** from FY 2019-20

Reduced CIT rate of **15%** for setting up a **manufacturing company** in India

Dividend Distribution Tax abolished w.e.f 01 April 2020

Digital tax (equalisation levy) scope widened from 01 April 2020

Interest on foreign currency loan subject to 5% withholding. Interest deduction allowed up to 30% of EBDITA

General Anti Avoidance Rules applicable from 01 April 2017

Other imp updates (POEM, MLI)

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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)

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

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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