INDIA MEDICAL AND HEALTH TECHNOLOGY FACTSHEET

Opportunities for Icelandic Exporters under the Trade and Economic Partnership Agreement (TEPA)

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Embassy of Iceland
New Delhi

Nordic Council of Ministers

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Iceland

Disclaimer

What is the TEPA?

The India–EFTA Trade and Economic Partnership Agreement (TEPA) — between India and Norway, Iceland, Switzerland and Liechtenstein — entered into force on 1 October 2025, and covers services, investment, mobility, and regulatory transparency.[1]

Tariff liberalisation

- The EFTA removes duties on 92.2% of India's tariff lines, while India phases out tariffs on 82.7% of EFTA tariff lines over the transition period.[2]
- For Iceland, duty-free access applies to 39.5% of current tariff lines immediately, rising to 76% within a decade.[3]

Beyond tariffs

The TEPA encompasses 14 comprehensive chapters beyond tariffs, including investment promotion under an automatic route, intellectual property, government procurement, and sustainable development provisions.[4]

Trade positioning

- Iceland's merchandise exports to India were estimated at ~USD 7.2 million in 2025.[5]
- These exports were led by Ferrosilicon, edible fats and oils, fish oils, and some food preparations.

Indian MedTech & HealthTech landscape

India is the fourth-largest medical-device market in Asia and is projected to reach a market value of ~USD 30 billion by 2030.[6]

India has manufacturing scale in generic medicines, consumables and selected medical devices. However, it continues to import approximately 70–80% of its medical-device requirements, particularly specialised and high-value technologies.[7]

For Icelandic firms, the relevant gaps in India's Medtech are concentrated in:

- advanced prosthetics, orthotics and rehabilitation
- complex biologics and development services
- genomic analysis and precision-health tools
- digital screening and patient-management platforms
- advanced wound care and marine-derived health products

India's requirement is therefore, not for broad medical-equipment supply, but for specialised technologies supported by Indian clinical, commercial and research partners.

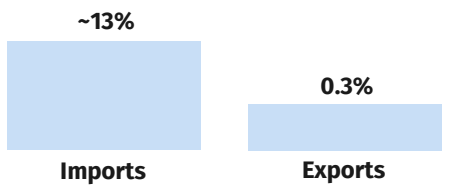
India imported ~USD 1 billion of orthopaedic, prosthetic and assistive products in 2025.[8]

India imported ~USD 1.6 billion of vaccines, blood products and biologicals in 2025.[9]

GenomeIndia has created a reference dataset of 10,074 individuals from 83 population groups.[10]

India medtech and healthtech landscape- Uneven trade growth (import growth outpaces exports)

FY 2025–26 year-on-year growth rate



The widening growth gap indicates continued dependence on overseas technology and specialised products.

1. Ministry of Commerce and Industry, Government of India
2, 3. Ministry of Commerce and Industry, Government of India
4. Press Information Bureau, Ministry of Commerce and Industry, 'India-European Free Trade Association Trade and Economic Partnership Agreement (TEPA) to come into effect on 01 October 2025'
5. Data extracted from ITC Trade Map, accessed in July 2026
6. PIB, Union Minister of State for Health and Family Welfare, Smt. Anupriya Patel addresses 21st CII Health Summit 2024, December 2024
7. EPCMD, Medical Devices trade analysis for the period of April-February 2025-26, April 2025 to February 2026
8, 9. Data extracted from ITC TradeMap, accessed in July 2026
10. Department of Biotechnology, 'Genome India', accessed in July 2026

Iceland's MedTech landscape

Specialised technology base
Biomechatronics and regenerative biomaterials: Icelandic firms develop sensor-controlled prosthetic knees and ankles, load-shifting orthotic braces, and cod-skin matrices for tissue regeneration.

Core strengths
Microprocessor-controlled prosthetics, orthotic braces, biosimilar development, fish-skin wound grafts, sleep diagnostics, AI-enabled screening, genomic analytics and digital patient-support platforms.

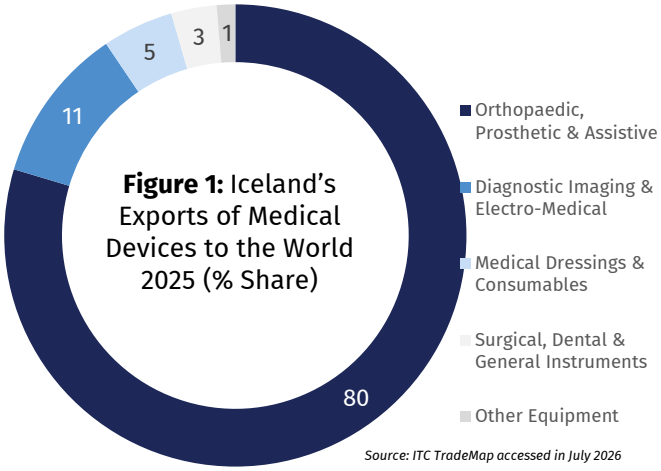


Figure 1: Iceland's Exports of Medical Devices to the World 2025 (% Share)

Source: ITC TradeMap accessed in July 2026

Iceland's presence in India

- **Advanced mobility — direct subsidiary:** Össur supplies microprocessor-controlled knees, powered feet and orthotic braces through Össur India. Its local operation supports fitting, clinician training and after-sales servicing.
- **Biosimilars — development and commercial partnerships:** Alvotech and Dr. Reddy's are collaborating on a pembrolizumab biosimilar. For adalimumab, Alvotech handles development and manufacturing, while Cipla supports registration and commercialisation in the agreed markets.
- **AI-enabled eye screening — clinical partnership:** RetinaRisk's risk-assessment software has been used with Indian technology and hospital partners, including Remidio and Sankara Nethralaya, for local validation and integration into screening workflows.
- **Regenerative wound care — parent-company channel:** Coloplast's established Indian operation could support the registration, clinician engagement and distribution of Kerecis fish-skin grafts. Current commercial availability in India has not been confirmed.

India's challenge-a specialisation gap

India is expanding medical-device manufacturing, biopharma research and genomic infrastructure. The remaining gap is in clinical validation, specialist training, data analysis and post-market support.

Intelligent mobility systems: Powered knees, adaptive ankles and sensor-controlled braces require patient assessment, device programming, gait training and continuing technical support. India's requirement therefore extends beyond importing a component to establishing fitting, rehabilitation and servicing capacity around the technology.

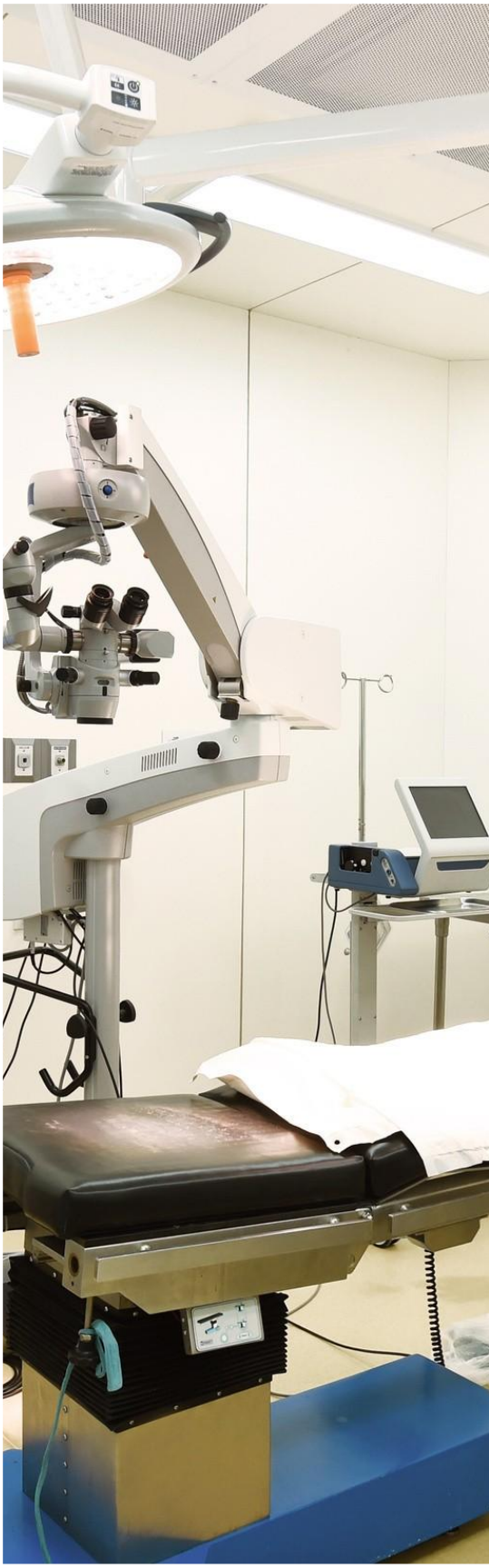
Biologics translation: India is strengthening research in complex generics, biosimilars, monoclonal antibodies and other precision biotherapeutics. Commercialisation requires cell-line development, physicochemical and functional analysis, formulation, process scale-up, fill-finish, and clinical development.

Clinical translation of genomics: GenomeIndia has established a national reference dataset and is funding translational research. The next requirement is to connect genetic variants with phenotype, disease cohorts and treatment outcomes through statistical genetics, structural-variant analysis, pharmacogenomics and target validation.

The strategic fit

India's opportunity for Iceland is concentrated in specialised technologies that require clinical integration, regulatory support and local delivery. TEPA supports software, engineering and selected mobility products, while biologics, wound care and genomics remain primarily partnership-led.

India's implementation requirement	Icelandic technology and operating fit
Clinical deployment of advanced mobility systems	Sensor-controlled knees, powered feet and orthotic braces, supported by local fitting, gait training, clinician education and after-sales servicing.
Development of complex biological products	Cell-line and process development, analytical testing, scale-up and fill-finish, combined with Indian registration, manufacturing or commercialisation partners.
Specialised treatment for chronic wounds	Acellular cod-skin matrices for diabetic, burn and surgical wounds, introduced through clinical validation, specialist hospitals and wound-care distribution.
Screening and patient management beyond specialist centres	Retinal-risk assessment, sleep diagnostics and digital patient-support platforms integrated with Indian clinical workflows and health-data systems.
Clinical use of population-genomics data	Variant interpretation, statistical genetics and disease-association analysis linked with approved Indian datasets, disease cohorts and research institutions.



Iceland's strongest fit is not in broad equipment supply. It lies in combining specialised products and analytical platforms with Indian clinical, pharmaceutical and research partners.

TEPA provides the clearest direct support for cross-border software delivery under Mode 1, Indian commercial presence under Mode 3, and temporary entry of eligible specialists under Mode 4. Goods access remains selective, making local partnerships central to most opportunities.

Service categories with export potential

The TEPA provides Icelandic suppliers with committed access in selected computer, engineering, technical-testing and advisory services. It supports remote delivery, establishment of an Indian operation and temporary entry of eligible specialists, but does not replace Indian licensing, medical-device, data, tax or visa requirements.

- Software, analytics and engineering services have the clearest cross-border access under Mode 1 or through an Indian operation under Mode 3.
- On-site delivery depends on the applicable Mode 4 personnel category, the service contract and Indian professional requirements.

Icelandic service strengths	The TEPA provision and advantage
Digital health, health IT and AI diagnostics	• Software, hosting and analytics may be delivered remotely under Mode 1. • An Indian operation may be established under Mode 3. • Medical-device approval, clinical validation and data rules continue to apply.
Clinical engineering, calibration and quality assurance	• Remote performance monitoring, quality review and calibration oversight may be delivered when classified under committed engineering, technical-testing or computer services. • On-site specialists may enter as contractual service suppliers; they are not covered as independent professionals.
Device and systems engineering	• Engineering services may be supplied remotely or through an Indian entity. • Eligible engineers may enter under Mode 4 for contracted project work.
Regulatory and clinical-development advisory	• Advisory work is covered only when it falls under a committed category such as management consulting, engineering, computer services or specified natural-science R&D. • Medical biotechnology and access to Indian biological resources remain outside the R&D commitment.
Cold-chain and supply-chain analytics	• Temperature monitoring, reporting and cloud analytics may be supplied under Modes 1 and 3. • Sensors, loggers and other hardware remain subject to the applicable goods tariff and product rules.
Personnel movement under Mode 4	• Intra-corporate transferees: initially up to one year, with extensions allowing a total stay of up to five years. • Contractual suppliers and independent professionals: up to one year or the contract period. • Installers and servicers: up to three months or the contract period.

Key restrictions:

- Clinical services are narrowly committed: cross-border delivery is generally limited to provider-to-provider research or second-opinion arrangements.
- National treatment is limited to scheduled services: Indian licensing, qualification, taxation, data-protection and immigration rules continue to apply.

Product categories with export potential

India's tariff commitments to Iceland cover a wide range of medical and health-technology products, but the treatment is selective and varies at the tariff-line level. Immediate or phased duty elimination applies to selected mobility aids, laboratory products, medical instruments, consumables and certain biological products.

However, several products that are more closely aligned with Iceland's established strengths, including artificial joints, other prosthetic body parts, selected immunological products and fish-skin grafts, receive only partial relief or remain outside the concessions.

The TEPA advantage

Immediate duty elimination (Day-1 zero duty)

- Selected tariff lines for nonwoven medical garments, made-up textile articles, wheelchairs and parts, laboratory glassware and corrective-lens blanks become duty-free from entry into force.
- **Implication:** These lines receive an immediate price benefit, although Iceland's demonstrated supply is limited in several categories.

Already bound at 0% (locked-in certainty)

- Selected chromatographs, electrophoresis equipment, spectrometers, mass spectrometers and physical or chemical analysis instruments already enter India duty-free.
- **Implication:** TEPA creates no immediate tariff saving but preserves zero-duty treatment for qualifying Icelandic products.

5 to 7-year track

- Selected cell-therapy product tariff lines reach zero duty within five years.
- Selected tariff lines for vision-care products, microscopes, microtomes, sterilisers, medical furniture, gloves, vaccines and certain instruments reach zero duty within seven years.
- **Implication:** Tariff relief is comparatively rapid, but product approval and commercial partnerships remain necessary.

10-year track

- Relevant lines include ultrasonic scanners, suture needles, ophthalmic instruments, orthopaedic and fracture appliances, selected wound dressings, surgical sutures, and selected medicaments.
- **Implication:** Orthopaedic appliances and selected wound-care products gain a gradual tariff advantage, with duties remaining during the transition period.

Partial reductions (not full elimination)

- Artificial teeth, artificial joints and other artificial body parts receive a 50% reduction in base duty over ten years.
- Selected medicaments, adhesive dressings, first-aid kits and X-ray generators also receive partial reductions.
- **Implication:** Several Iceland-relevant products remain dutiable after the transition period.

Key considerations:

- Best near-term tariff access: selected mobility aids, medical textiles, laboratory glassware and products already entering at zero duty.
- Limited relief for Iceland's stronger lines: artificial joints and body parts receive only partial reductions, while immunological products under selected tariff lines and fish-skin grafts under the classification used in this analysis remain excluded.
- Commercial effect: tariff treatment supports selected exports but does not replace Indian registration, product classification and distribution requirements.

Five prime opportunity areas

Advanced mobility systems: Microprocessor-controlled knees, powered feet and specialised orthotic braces supplied through prosthetic clinics, rehabilitation networks and hospitals, with local fitting, programming and servicing.

Biosimilar development and commercialisation: Cell-line development, process optimisation, analytical testing, scale-up and fill-finish for Indian pharmaceutical companies developing complex biosimilars or seeking regulated-market filings.

Regenerative wound care: Acellular fish-skin grafts for diabetic ulcers, burns and surgical wounds, introduced through tertiary hospitals, wound-care specialists and established surgical-product distribution networks.

AI diagnostics and sleep health: Retinal-risk assessment, image triage and sleep-testing systems integrated with Indian diagnostic chains, hospital workflows and locally generated clinical evidence.

Precision genomics and translational research: Variant interpretation, statistical genetics, pharmacogenomics and disease-association analysis delivered through research institutes, hospitals with disease cohorts and pharmaceutical partners.

Market entry routes

- **India is a long gestation market hence patience and perseverance is required.**
- **Select the regulatory pathway by offering.** Imported medical devices require product classification, an Indian authorised agent, an import licence and post-market compliance. Biologics, marine ingredients, digital-health products and genomics services follow separate Indian approval frameworks.
- **Use a segment-specific Indian partner.** Prosthetics require fitting and servicing partners; biologics require development, manufacturing or commercialisation partners; wound care requires specialist hospital access; genomics requires an Indian research institution.
- **Complete local validation and integration.** Digital diagnostics, sleep technologies and advanced wound-care products require clinical evidence acceptable to Indian regulators and users. Digital products must also align with Indian interoperability and data-protection standards.
- **Target the appropriate commercial channel.** Private hospitals, diagnostic chains, prosthetic centres and pharmaceutical companies are the main initial buyers for specialised products. Public procurement is more price-sensitive and may favour domestic value addition.
- **Monitor procurement and funding channels.** Tender opportunities are published through the Government e-Marketplace, Central Public Procurement Portal, state medical-services corporations and hospitals. Eligible Indian-led projects may also seek support under the PRIP and SMDI schemes.
- **Localise where commercially relevant.** Licensing, assembly, technology transfer or Indian manufacturing may improve pricing and procurement access for products facing residual duties or local-value requirements. Local production follows India's investment and manufacturing rules, not the TEPA services schedule.
- **Establish local delivery capacity where required.** An Indian entity or commercial presence under Mode 3 may support on-site service delivery, clinician training, technical support, adverse-event reporting and participation in institutional procurement.

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