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Post-pandemic shifts in medical electronics GVCs and changing value dynamics amidst new digitalisation:

An analysis based on Indian subsidiaries of EU-based corporations

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Post-pandemic shifts in medical electronics GVCs and changing value dynamics amidst new digitalisation:

An analysis based on Indian subsidiaries of EU-based corporations

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Abstract

Realignments of global value chains (GVCs) are occurring at a time when the technological dynamics in manufacturing industries, including in healthcare-related industries like medical electronics, is undergoing significant changes due to the wave of new digitalisation. This study examines post-pandemic changes in global medical electronics value chains through industry-level trade analysis and the GVC participation of selected Indian subsidiaries of medical electronics companies based in the European Union (EU), focusing on the implications of digitalisation and data-centric strategies for capturing value. The study finds that post-COVID-19 realignments in the industry proceeded gradually until 2023. Meanwhile, digitalisation is leading to a gradual expansion in operations by EU-based medical device multinational corporations (MNCs) in India. This is shown to be due to the increased role of software for product design and process optimisation in digitalising value chains. Leading EU-based medical device MNCs are found to be leveraging India's strengths in software design and data-analytics capabilities for co-developing their software-embedded 'health systems' and 'solutions'. However, even when software and services exports from India went up with increasing digitalisation, the shares of the EU-based lead firm groups in total revenue of the Indian subsidiaries were found to increase. This occurred through imports of software-embedded medical devices and equipment along with imports of higher-valued proprietary software platforms, health systems and the like, which are patented and marketed by the EU-based lead firms or their foreign subsidiaries back to India. It is stressed that, just like Big Tech, medical device lead firms' software platforms, when embedded in their proprietary devices and health systems, enable them de facto 'ownership' of data. Leveraging vast amounts of personal and non-personal data through different strategies enables them to keep refining and advancing the data-analytics algorithms and software platforms embedded in their health solutions and medical devices. Given the resultant monopolisation of data and intelligence enabled by the self-reinforcing first-mover advantages of these lead firms, we highlight the need for the EU to develop a rights-based regime for data in order to ensure greater competition and innovation as well as more equitable development across the various countries participating in medical device GVCs.

Keywords: digitalisation, GVCs, medical device industry, medical electronics, European MNCs, value distribution, digital value chains

JEL classification: F14, F23, L64, O14

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1. Introduction

With global value chains (GVCs) in many strategic industries (e.g. electronics and pharmaceuticals) heavily centred on China, the COVID-19 pandemic became a watershed moment for several countries to review the development strategies for their manufacturing sector. In many countries and blocs, including India and the European Union (EU), supply chain disruptions owing to the US-China trade-technology war had already prompted GVC lead firms to re-think their production network strategies. Lead firms' re- and near-shoring strategies to increase the resilience of their supply chains have been expected to reinforce GVC realignments in the post-pandemic years.

Importantly, these supply chain realignments are occurring at a time when the technological trajectories of manufacturing industries are undergoing significant changes due to the wave of new digitalisation, which involves the intelligentisation of value chains (Francis 2018). The progressive merging (or 'fusion') of the physical and digital spheres through data-centric processes enabled by increased softwarisation is transforming more and more value chains into digital value chains (Francis 2018, 2020). This has entailed a significant change in the technological dynamics in healthcare-related industries, including the pharmaceutical and medical electronics industries.

The medical electronics industry (alternatively referred to as MedTech or the medical devices industry) plays a significant role among EU-based high-tech industry groups by contributing high value-added employment and a significant share of the patents (MedTech Europe 2023).[1] It is also one of the key industries involving EU-based MNCs in India,[2] which is among the top 20 medical devices markets globally and the fourth-largest medical devices market in Asia (IBEF 2024).

In the drive towards more efficient and often personalised healthcare provision, medical equipment and personal health device makers have been using health and non-health data to make their products 'intelligent', giving rise to 'smart' networked medical equipment and wearable health devices. This increasing digitalisation has seen digital health 'solutions' become embedded in medical devices and equipment. These digital transformations are critically influenced by corporate strategies for value appropriation (Francis 2018). Software-embedded products with proprietary algorithms and platforms for data capture and data analytics are being used for process and product optimisation and innovations as well as for value-added services as part of the anticompetitive strategies pursued by industry leaders (Francis 2018, 2020). This changing nature of new product development and process innovations is of critical significance in the context of the distribution of value within digital value chains. The evolving value chain dynamics is also significantly influenced by national policies in the electronics industry, the health sector and the data-governance space.

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[1] The industry directly employs more than 8.5 million people, compared with 8.65 million people employed in the European pharmaceutical industry, and it accounts for 8.1% of the total number of patent applications, the second-highest among all industrial sectors in Europe. The industry is also very important for the innovation dynamics among the small and medium-sized enterprises (SMEs), which comprise around 92% of the medical technology industry (MedTech Europe 2023).

[2] During the 2015-2020 period, European MNCs were among the key investors in the Indian medical devices industry, along with Singapore, the US and Japan (FMC 2023).

Against this backdrop, this study seeks to examine post-pandemic GVC realignments of the medical electronics industry and how the GVC engagement of EU-based MNCs are being influenced by digitalisation and associated data-centric corporate strategies for value appropriation. The study builds upon the propositions in Francis (2020, 2023), using the analytical framework laid out in Francis (2025). We show that through data-centric process and product innovations within digitalising value chains, the largest part of the value in medical electronics value chains is captured by EU-based lead firms within their group network outside India. This is due to the self-reinforcing nature of data-based innovations, wherein lead firms are able to continuously derive intellectual property (IP) premiums through their patented software-embedded equipment and software systems/platform solutions, which are systematically improved through data analytics-based insights and artificial intelligence (AI) generated and trained on local and other data. Consequently, the dominant market positions occupied by the EU-based lead firms (and other lead firms in medical device GVCs) are likely to become further entrenched. On the other hand, evidence on production shifting and diversification to increase supply chain resilience may only be partially observable through industry-level goods trade data as of 2023.

Globally, the medical technology industry comprises different segments broadly categorised as medical devices, in-vitro diagnostics (IVDs); and consumables and disposables. Among these, the present study focuses on the medical devices industry. However, in India, the term ‘medical devices’ is commonly used broadly to cover all three of these segments together, namely, medical equipment and surgical instruments; in-vitro diagnostics (IVD); and consumables and disposables.[3] The medical equipment and surgical instruments segment of India’s medical devices industry, which is among the most capital- and technology-intensive segments, may be considered the equivalent of the global medical devices industry.

Taking cognizance of the significant role of information and communication technologies (ICTs) within the medical equipment segment, India’s 2023 National Medical Devices Policy (Government of India 2023) has separated out surgical instruments and recently introduced the following broad classification: (i) electronic equipment (ii) implants; (iii) surgical instruments; (iv) IVD reagents; and (v) consumables and disposables. Although digitalisation has implications for all of these segments to varying extents, this study focuses on the medical electronic equipment segment.

Empirically, the study involves the following two components:

(i) industry-level trade analyses to capture any changes in the aggregate trade patterns of the global and Indian medical device industries from post-Covid-19 GVC re-alignments; and

(ii) firm-level analyses of GVC engagement of selected Indian subsidiaries of leading EU-based medical device MNCs to capture the impact of digitalisation on the distribution of value within GVCs.

[3] See, for instance, James and Jaiswal (2020), Datta and Selvaraj (2018), FMC (2023) and IBEF (2024). This difference must be kept in mind in the ensuing discussion of the overall characteristics of the Indian medical devices industry.

Industry-level analyses of global and Indian medical electronics trade were carried out using trade data from the UN COMTRADE database and the Government of India's Ministry of Commerce and Industry, respectively. Under the Harmonised System (HS) of tariff nomenclature whose Chapter 90 covers Optical, medical and other scientific and professional instruments and apparatus as well as their parts and accessories, we consider the following set of four-digit product categories to focus on the MedTech industry:

1. 9018 – Electro-cardiographs (ECGs), magnetic resonance imaging (MRI) apparatus, ultrasonic scanning apparatus, surgical instruments, etc.;
2. 9019 – Mechano-therapy appliances, oxygen therapy apparatus, etc.;
3. 9021 – Hearing aids, pacemakers and other portable aids; and
4. 9022 – Computed tomography (CT) apparatus, X- ray and other radiation machines

The diagnostic imaging equipment segment, which combines the product categories HS 9018 and HS 9022, has remained the most important segment in the global trade of medical devices in terms of value. Thus, the second part of the study involves standardised in-depth case studies of two leading EU-based players in the global diagnostic imaging equipment segment.[4] The case studies involve detailed analyses of how these EU-based lead firms' value chain dynamics has been evolving since the 2018/2019 financial year (FY) – that is, the year before the pandemic – using company-level financial data and customs trade data for examining their intra- and inter-firm transactions.

Intra-firm networks of the EU-based lead firms are captured comprehensive analyses of related party transactions in goods and services. This follows the methodology developed in Francis (2021), which built upon the analysis in Verma (2019) of related party transactions to study the foreign exchange (forex) transactions of foreign manufacturing subsidiaries in India. Related parties of an Indian foreign affiliate include its holding company (HC) and ultimate holding company (UHC), along with fellow subsidiaries, associate firms, and its own joint ventures/subsidiaries in India and abroad. Analyses of overall company financial statements, along with related party transactions in both financial statements and customs trade data, were used to arrive at a comprehensive understanding of the revenue share captured by the EU-based lead firms within their group firms abroad. The data sources for the case study analyses were the company annual financial reports available from the Government of India's Ministry of Corporate Affairs (MCA). The source of the firm-level customs trade data was the commercial market research firm, The Trade Vision.[5]

The rest of the paper is organised as follows. Section 2 analyses the trade trends of the global medical device industry to examine whether there have been significant changes in trade patterns in the post-pandemic years. Section 3 provides a brief overview of the Indian medical device industry and its trade trends to provide a backdrop to the case study analyses in Section 5. Section 3 also discusses the domestic production support policies adopted by India since 2020. Section 4 discusses the analytical framework to examine the implications of new digitalisation for the medical device industry, emphasising

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4 A larger number of case studies of European medical device affiliates in India could not be undertaken given the dependence of the methodology on the availability of company financial statements for at least five years as well as due to the nature of the Indian operations of some of the originally considered EU-based affiliates that were only involved in the wholesale trading of medical devices.

5 The Trade Vision, www.thetradevision.com

the significantly increased role of software in digital value chains. It highlights the principal difference in this framework when compared to the existing literature exploring the impact of digitalisation on GVCs. Section 5 presents the standardised in-depth case studies of two leading EU-based medical electronics subsidiaries in India to verify the central propositions on the implications of digitalisation for value distribution within GVCs. Following a discussion of the results in Section 6, Section 7 concludes by discussing the major implications and providing policy suggestions.

2. Changing trends in the global trade of medical devices

Global trade in medical devices had been growing steadily since 2015, including through the decline in total global trade in 2019 and 2020 (Table 1). While the product category including non-radiation imaging equipment and electro-diagnostic equipment consisting of ECG, MRI, ultrasound and surgical instruments (HS 9018) – followed by those of hearing aids, pacemakers, etc. (HS 9021) – had contributed to the growth in medical devices trade in 2019, growth in 2020 was aided by the jump in demand for oxygen therapy apparatus (HS 9019) during that first year of the pandemic. On the other hand, in 2021 and 2022, all four product categories of the medical devices industry recorded a significant increase. Total trade in medical devices only dropped in 2023 following the global economic and trade slowdown triggered by new geopolitical conflicts.

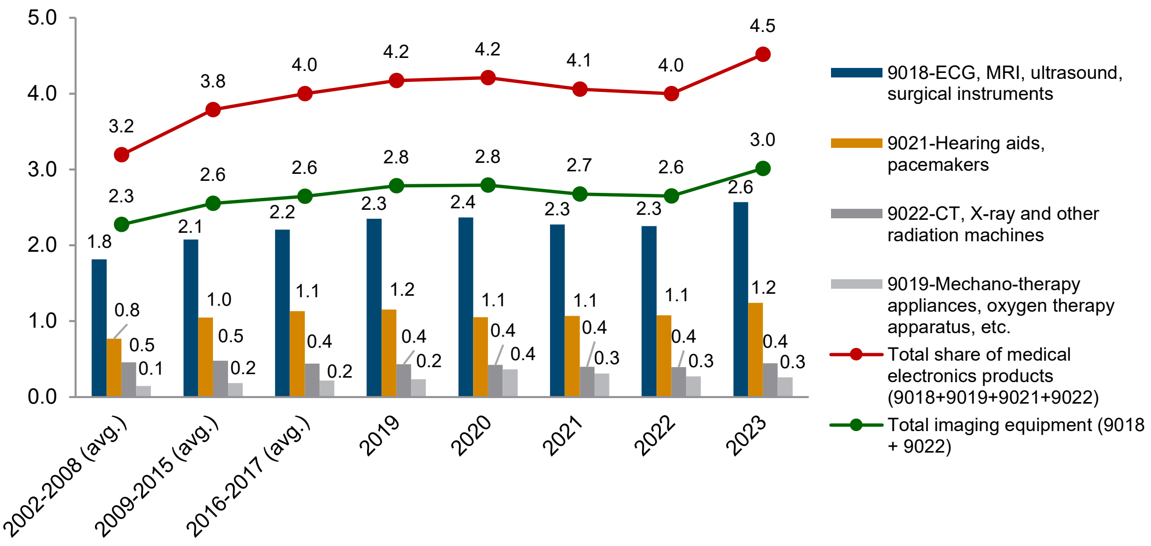
Table 1 / Global trade in medical devices (in USD m)

Product category/sector	Average for 2009-2015	Average for 2016-2017	2018	2019	2020	2021	2022	2023
9018 – ECG, MRI, ultrasound, surgical instruments	349.8	403.7	458.8	489.4	489.3	561.3	566.2	563.3
9021 – Hearing aids, pacemakers, etc.	176.6	207.6	231.5	240.2	217.3	264.0	270.4	272.1
9022 – CT, X-ray and other radiation machines	80.8	80.7	90.4	90.3	88.1	98.7	99.1	97.7
9019 – Mechano-therapy appliances, oxygen therapy apparatus, etc.	31.2	40.2	46.4	48.7	75.8	76.7	68.2	57.5
Total imaging equipment (9018 + 9022)	**430.6**	**484.4**	**549.2**	**579.7**	**577.4**	**660.0**	**665.4**	**661.0**
Total medical electronics products (9018+9019+9021+9022)	**638.3**	**732.2**	**827.1**	**868.6**	**870.4**	**1000.6**	**1003.9**	**990.6**
Chapter 90 – Optical, medical and other prof. apparatus & their parts (USD tn)	1.76	1.99	2.31	2.31	2.27	2.66	2.34	2.15
Total global trade (USD tn)	**16.9**	**18.3**	**21.2**	**20.8**	**20.7**	**24.7**	**25.1**	**21.9**

Source: Author's calculations based on the WITS Comtrade database

It must be noted that the combined imaging equipment segment has remained the most important segment in the global trade of medical devices (Figure 1). Within this, the non-radiation imaging equipment (HS 9018) segment dominated, and its share in global trade increased from 2.2% in 2018 to 2.6% in 2023. Even though its share in global trade is lower in comparison, the radiation-based imaging and therapy equipment segment (HS 9022) – which covers CT, X-ray and other radiation machines – has maintained a steady share since the late 2010s.

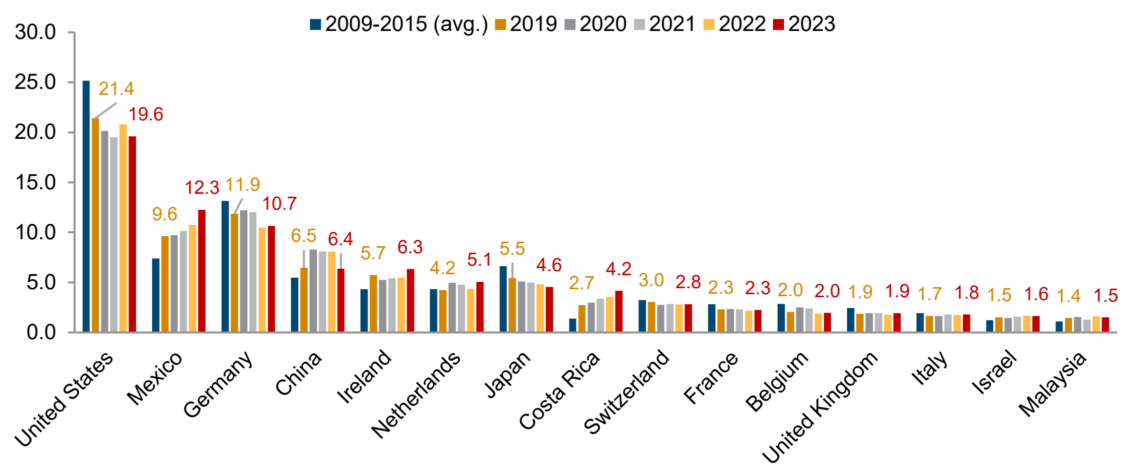
Figure 1 / Composition of global trade in medical devices (% share in total global trade)



Note: The value for a period is the annual average share for that period.
Source: Author's calculations based on the WITS Comtrade database

The US has remained the single largest global exporter of non-radiation imaging equipment (HS 9018), even though its share declined between 2019 (i.e. the year before the pandemic) and 2023 (Figure 2). Significantly, Mexico has overtaken Germany as the second-largest global exporter in this segment. While Germany slipped to third place owing to drops in its shares in 2022 and 2023, China's export share only registered a drop in 2023, allowing it to remain in fourth place (Figure 2). Among European countries, the global export shares of Switzerland and Denmark also dropped between 2019 and 2023. In fact, Mexico registered the largest gain in global export share in this segment between 2019 and 2023, followed by Costa Rica, the Netherlands, Ireland and the Dominican Republic. Others with increases in export shares in this period were Poland, Taiwan, Czechia, Italy and Israel.

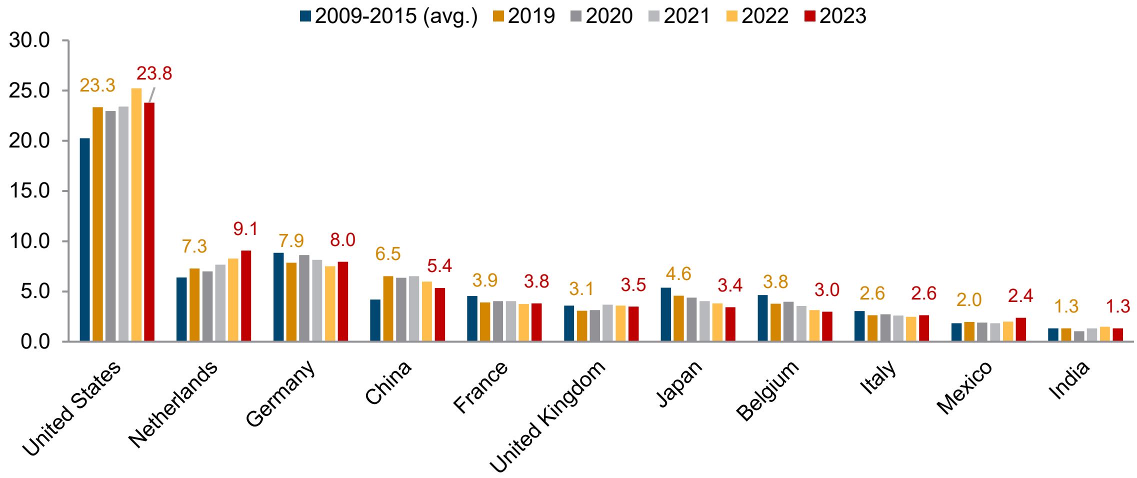
Figure 2 / Top global exporters of non-radiation imaging equipment (% share)



Source: Author's calculations based on the WITS Comtrade database

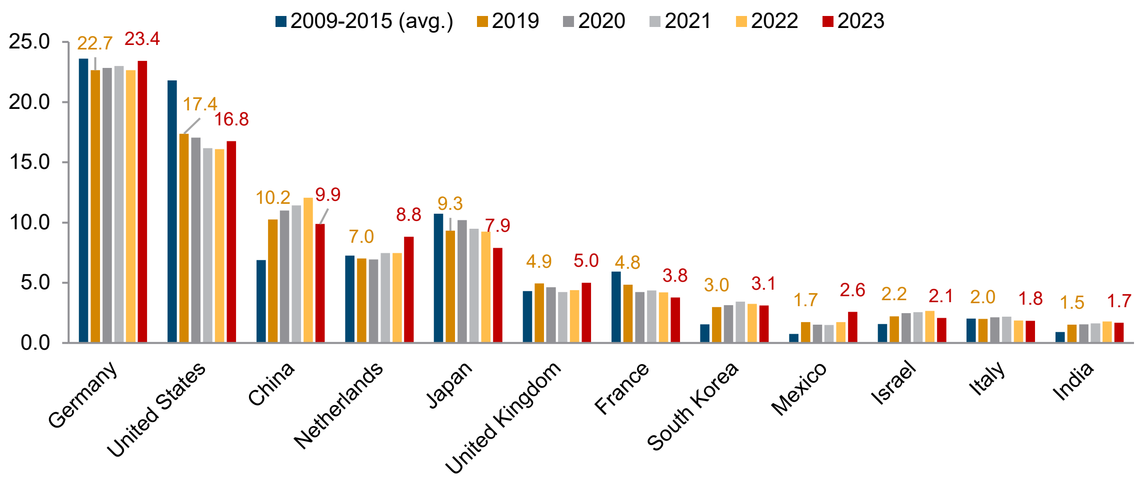
In the case of global imports of non-radiation imaging equipment (HS 9018), the US has also remained the single largest import market, while the Netherlands and Germany occupied the next two ranks, followed by China (Figure 3). Other top EU importers in this segment were France, the UK, Belgium and Italy. Further, the Netherlands – followed by the US, Mexico, the UK, Costa Rica and others – registered the largest increase in import shares. While India was not a major exporter, its significance as an import market for non-radiation imaging equipment increased. Importantly, the import shares of China and Hong Kong dropped between 2019 and 2023, along with those of Japan and Belgium.

Figure 3 / Top global importers of non-radiation imaging equipment (% share)



Source: Author's calculations based on the WITS Comtrade database

Figure 4 / Top global exporters of radiation-based imaging equipment (% share)

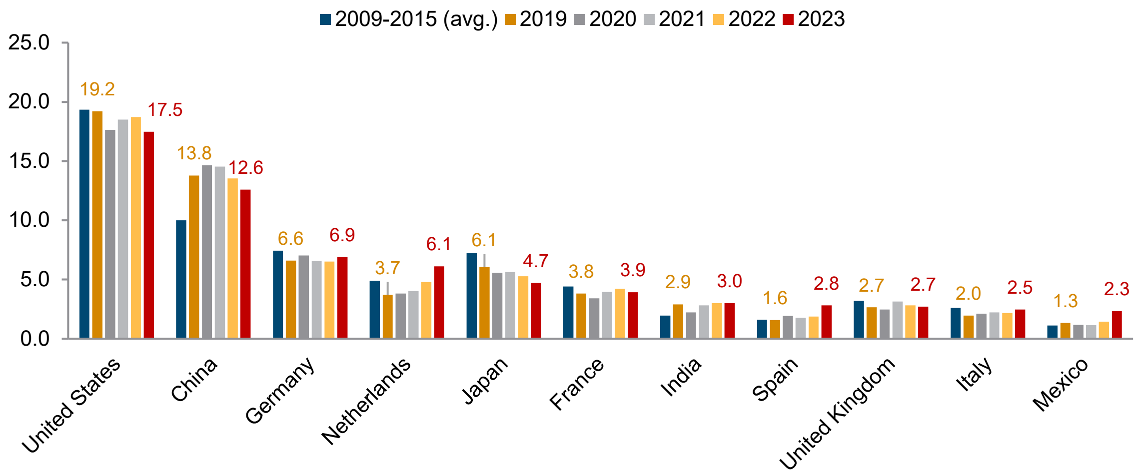


Source: Author's calculations based on the WITS Comtrade database

In the case of the radiation-based imaging equipment segment (HS 9022; Figure 4), Germany, followed by the US, have remained the top global exporters, followed by China and the Netherlands. Countries with the largest gain in global export shares between 2019 and 2023 were the Netherlands, followed by Mexico, Germany and Sweden. Interestingly, along with Gambia, Poland, Czechia and some other countries, India also registered positive growth in its share of global exports between 2019 and 2023, although its share only increased marginally, from 1.5% to 1.7%, during the interim period. On the other hand, Japan, France, the US and some other countries saw their shares of global exports drop between 2019 and 2023, while China's share also dropped in 2023.

In the case of global imports of radiation-based imaging equipment (HS 2022), the US was the largest market in 2023, followed by China (Figure 5). However, in the pandemic years starting in 2020, China's share of global imports declined. Germany and the Netherlands were the third- and fourth-largest importers in 2023, with the latter's share of global imports increasing beginning in 2019. Apart from those of the Netherlands and Germany, the global import shares of other EU countries (e.g. Spain, Italy, Germany, Poland and Czechia) also went up. India's share of global imports increased throughout the period except in 2020 (i.e. the first year of the pandemic), and it was the seventh-largest global importer of radiation-based imaging equipment in 2023. Along with China, the major countries that saw drops in their shares in global imports between 2019 and 2023 were the US and Japan, followed by Russia, all of which saw their shares decline in 2023.

Figure 5 / Top global importers of radiation-based imaging equipment (% share)

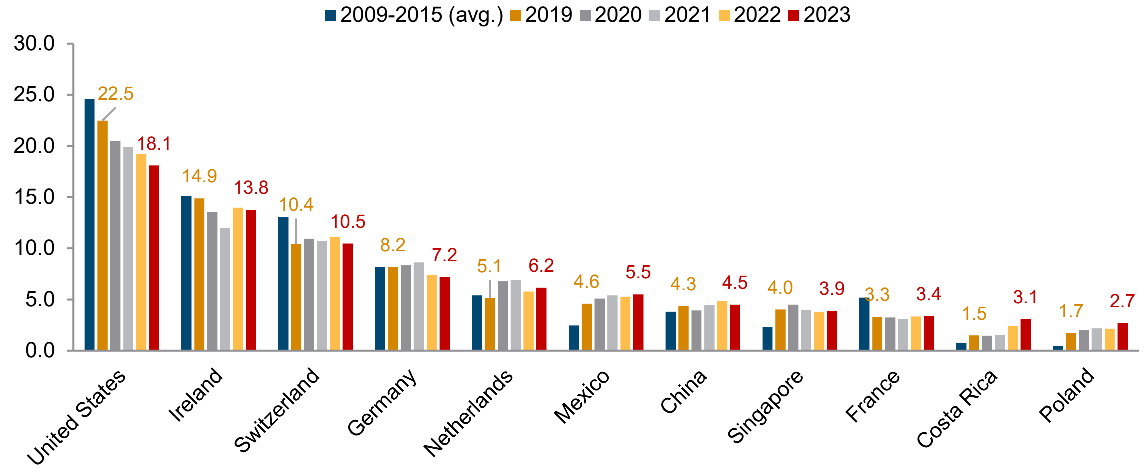


Source: Author's calculations based on the WITS Comtrade database

The US remained the top global exporter and importer in the product group including hearing aids, pacemakers, etc. (HS 2021) (Figure 6). While Ireland, Switzerland, Germany and the Netherlands were among the top exporters, the Netherlands and Germany were also the top importers in this segment, along with Belgium (Figure 7). Apart from Mexico and Turkey, all the other major importers were also EU member countries.

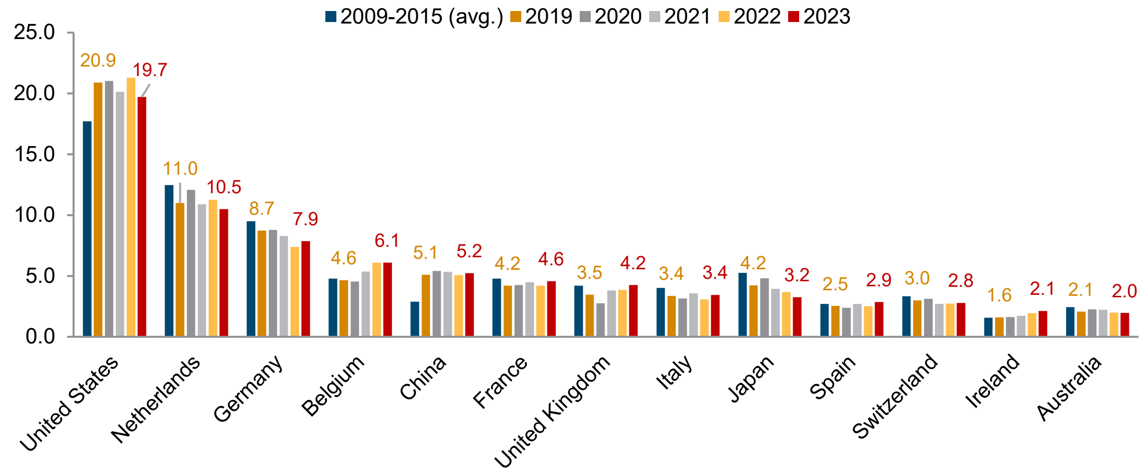
It is evident that there has been significant two-way trade in the industry, which captures the presence of intra-firm trade within GVCs. This was also the case with India, which has seen increased foreign direct investments (FDI) into its medical device industry in recent years, as we will discuss in the next section.

Figure 6 / Top global exporters of hearing aids, pacemakers, etc. (% share)



Source: Author's calculations based on the WITS Comtrade database

Figure 7 / Top global importers of hearing aids, pacemakers, etc. (% share)



Source: Author's calculations based on the WITS Comtrade database

3. Overview of the Indian medical devices industry

Despite having a large domestic market, India has traditionally had a small indigenous medical devices manufacturing industry (Datta and Selvaraj 2018), and the large majority of domestic medical device production has often involved assembly (or repackaging) (James and Jaiswal 2020). A comparatively small R&D base has been one of the major weaknesses of the Indian medical devices manufacturing industry (Datta and Selvaraj 2018). Consequently, recent reports also point out that most medical devices manufactured in India continue to be in the low-value and high-volume segment of disposables, such as catheters, perfusion sets, extension lines, cannulas, feeding tubes, needles and syringes. At the same time, there is significant production of implants, such as cardiac stents, drug-eluting stents, intraocular lenses and orthopaedic implants (IBEF 2024).

In the case of the higher-priced, more sophisticated medical devices (e.g. diagnostic imaging equipment), one of the major issues facing the industry has been the abysmally low level of government health expenditure in the country. As a result, usage of advanced medical devices and their coverage within healthcare organisations has remained low.[6]

Given that domestic companies have largely been involved in manufacturing low-end products for local and international consumption (FMC 2023), India continues to have an overall import dependency in the medical devices industry of between 70% and 80% (IBEF 2024).[7]

3.1. TRENDS IN INDIA'S TRADE IN MEDICAL DEVICES

Non-radiation-based imaging equipment has also dominated India's medical device trade, accounting for roughly 55% of imports (Table 2) and 65% of exports in FY 2023/2024 (Table 3).

However, India has witnessed a steady rise in its share in global imports of medical devices, except in 2020 (Figure 8). The country has been the most import-dependent when it comes to radiation-based medical equipment (HS 9022), in which its global import share continued to rise until 2023, followed by oxygen therapy apparatus (HS 9019; Figure 8). On the other hand, non-radiation imaging equipment was the only segment in which India enjoyed a share of global exports of more than 1% (Figure 9).

[6] This has also meant that there is a significant market in the country for refurbished medical devices, which also depend on imports for their replacement and other parts in the absence of a strong local production ecosystem.

[7] This is despite the industry's strengths in specific segments. For instance, during the COVID-19 pandemic, the Indian medical devices sector's contribution was very prominent, as it supported the domestic and global battle against the pandemic through the large-scale production of medical devices and diagnostic kits, such as ventilators, rapid antigen test kits, reverse transcription polymerase chain reaction (RT-PCR) kits, infrared thermometers, personal protective equipment (PPE) kits and N-95 masks (NMDP 2023).

Table 2 / Composition of India's imports of medical devices (% share)

Product group	Average for 2009/2010-2014/2015	Average for 2015/2016-2016/2017	2018/2019	2019/2020	2020/2021	2021/2022	2022/2023	2023/2024
9018 – ECG, MRI, ultrasound, surgical instruments	58.5	53.5	53.8	53.7	53.5	45.4	54.9	54.9
9022 – CT, X-ray and other radiation machines	19.7	23.0	24.3	23.5	22.7	17.9	20.2	20.0
9021 – Hearing aids, pacemakers, etc.	17.5	17.9	16.1	16.9	12.3	11.8	19.0	19.7
9019 – Mechano-therapy appliances, oxygen therapy apparatus, etc.	4.2	5.5	5.9	5.8	**11.5**	**24.9**	5.8	5.4
Total (USD bn) (9018+9019+9021+9022)	2.1	2.7	3.3	3.3	2.7	4.9	4.3	4.7

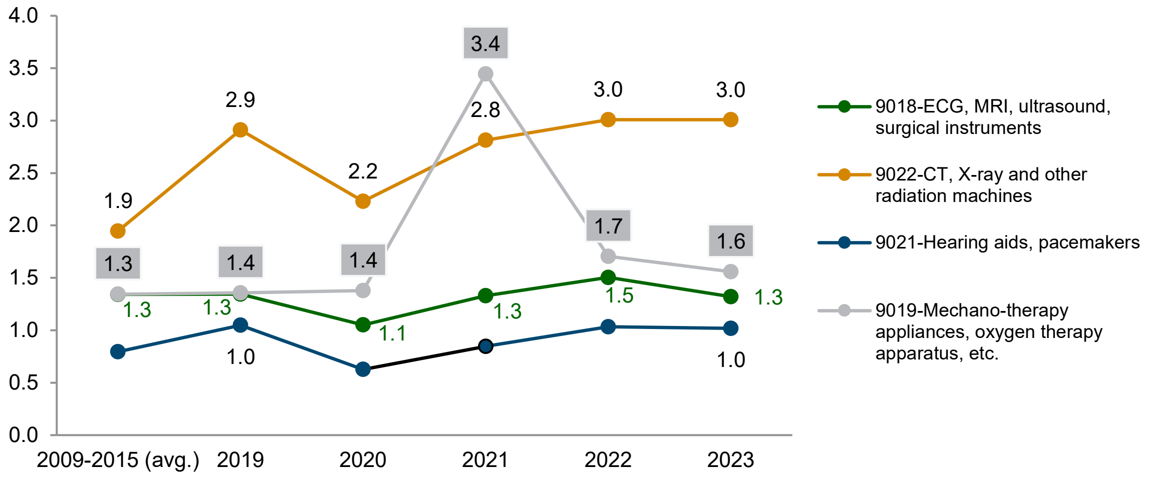
Source: Author's calculations based on EXIM database, Department of Commerce, Government of India

Table 3 / Composition of India's exports of medical devices (% share)

Product group	Average for 2009/2010-2014/2015	Average for 2015/2016-2016/2017	2018/2019	2019/2020	2020/2021	2021/2022	2022/2023	2023/2024
9018 – ECG, MRI, ultrasound, surgical instruments	67.5	65.3	64.8	68.6	66.7	65.4	66.2	64.9
9021 – Hearing aids, pacemakers, etc.	6.5	9.9	10.5	11.1	11.8	12.7	14.7	18.0
9022 – CT, X-ray and other radiation machines	25.5	24.0	23.9	19.5	20.4	19.8	17.9	15.8
9019 – Mechano-therapy appliances, oxygen therapy apparatus, etc.	0.5	0.8	0.8	0.9	1.1	2.0	1.1	1.2
Total (USD bn) (9018+9019+9021+9022)	0.7	1.0	1.3	1.4	1.4	1.7	1.9	2.2

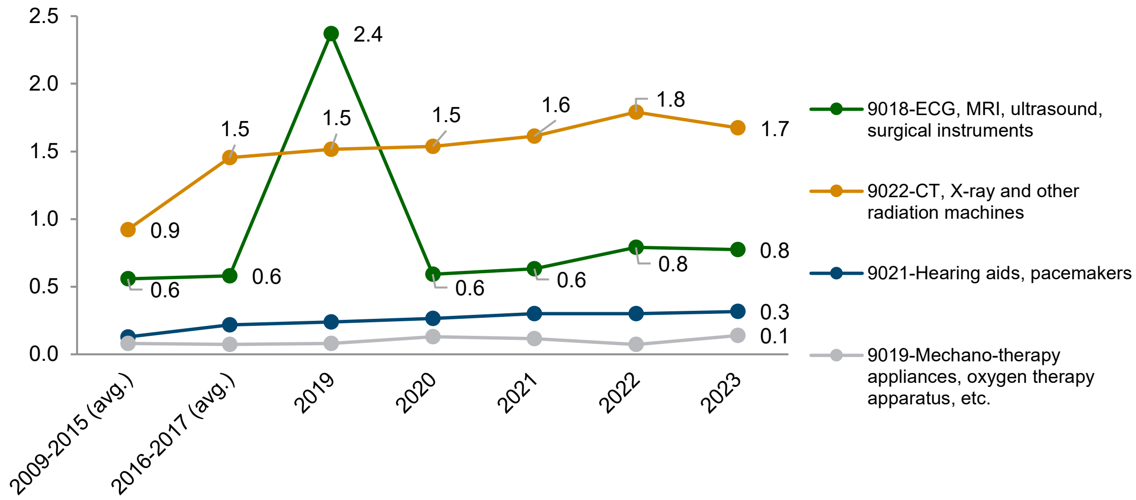
Source: Author's calculations based on EXIM database, Department of Commerce, Government of India

Figure 8 / India's shares in global imports of medical devices (% share)



Source: Author's calculations based on the WITS Comtrade database

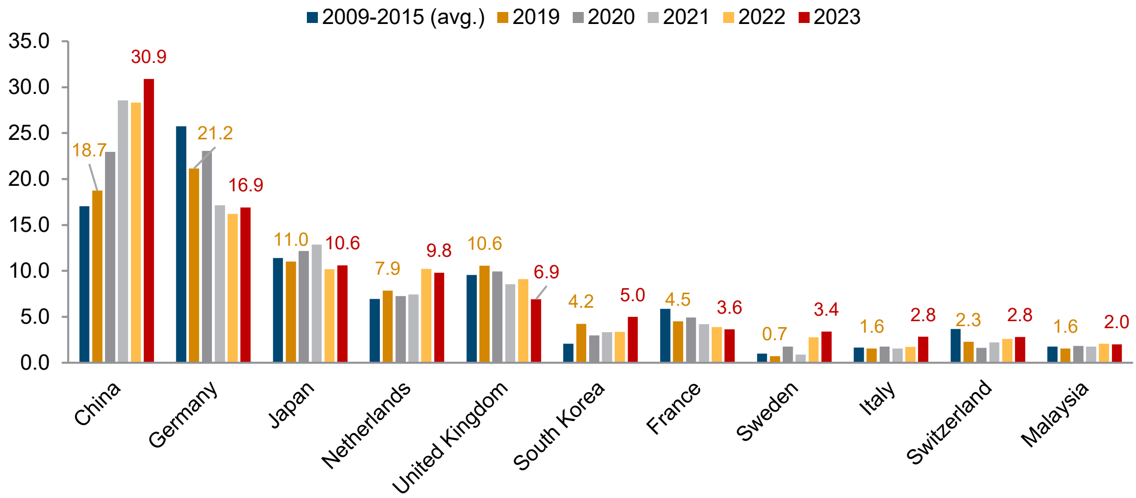
Figure 9 / India's shares in global exports of medical devices (% share)



Source: Author's calculations based on the WITS Comtrade database

In radiation-based imaging equipment (HS 9022), in which India's import dependence has been the highest, China's share in Indian imports increased dramatically, from about 19% in 2019 to about 31% in 2023 (Figure 10). Even as Germany remained the second-largest supplier, it lost market share, along with the UK, Japan, France and Belgium. In fact, despite the increase seen for some EU members, the share of the EU27 (i.e. excluding the UK), which had dropped from nearly 70% in 2002 (i.e. at the time of China's entry into the World Trade Organization (WTO) to about 43% in 2019, declined further in 2023 to 38.6%.

Figure 10 / Changes in the origin distribution of India's imports of radiation-based imaging equipment (% share)

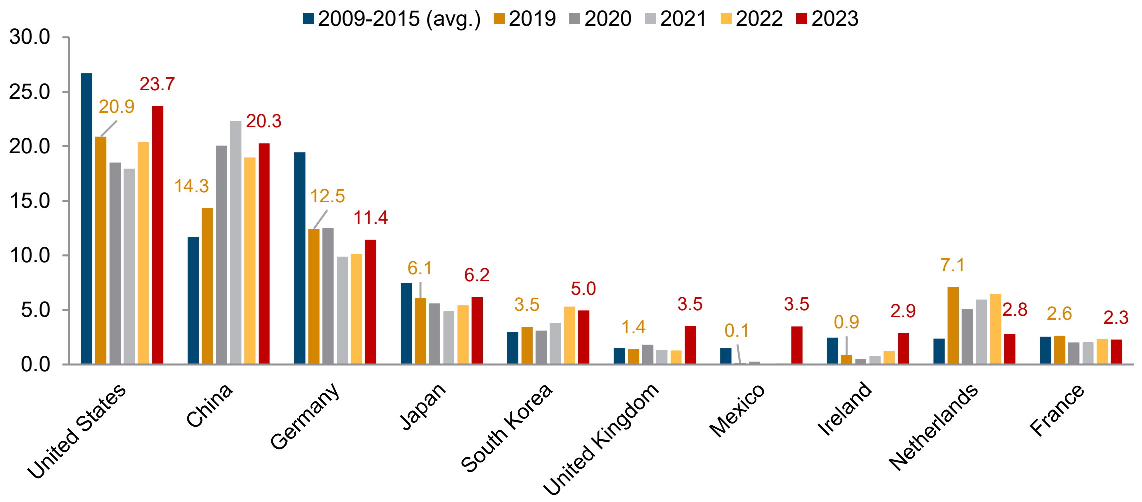


Source: Author's calculations based on the WITS Comtrade database

In the case of India's non-radiation equipment imports, the US was the largest supplier, followed by China, with the latter catching up rapidly with the former (Figure 11). Between 2019 and 2023, Germany and the

Netherlands also lost market share in India in this category. Thus, it is clear that China has significantly boosted its share in the Indian market for imports of imaging devices at the EU's expense.

Figure 11 / Changes in the origin distribution of India's imports of non-radiation imaging equipment (% share)



Source: Author's calculations based on the WITS Comtrade database

Notably, China's share of exports of radiation-based imaging equipment from India also increased, followed by those of Germany and the Netherlands (Table 4). Significant export volumes went to France and Singapore, too. In the case of India's exports of non-radiation imaging equipment, the US, followed by Germany and the Netherlands, dominated and increased their shares, while exports to the United Arab Emirates (UAE) also registered a significant jump in 2023 (Table 5).

Table 4 / Changes in the market distribution of India's exports of radiation-based imaging equipment (% share)

Destination country	Average for 2009-2015	2018	2019	2020	2021	2022	2023	% Change between 2019 & 2023
China	16.3	11.1	11.2	16.3	18.0	14.8	17.0	**5.9**
France	1.5	5.2	8.1	10.1	10.9	10.8	8.7	**0.6**
Singapore	21.8	22.7	17.3	9.6	7.8	5.9	7.7	**-9.5**
Germany	9.7	4.4	6.3	5.7	5.7	5.3	6.9	**0.6**
Japan	7.6	8.9	4.8	4.1	4.4	4.4	4.7	**-0.1**
Netherlands	1.7	1.9	2.2	1.4	1.5	3.0	2.7	**0.5**
Thailand	0.2	0.5	0.6	0.4	0.4	0.8	1.0	**0.3**
Brazil	0.5	1.6	0.9	0.8	1.2	1.1	0.8	**-0.1**
Bangladesh	0.5	0.6	0.8	0.5	0.6	1.2	0.7	**-0.1**
Nepal	0.5	0.7	0.6	0.5	0.9	1.5	0.7	**0.1**
EU25 members	**14.1**	**15.4**	**18.5**	**19.9**	**19.8**	**21.1**	**20.0**	**1.5**
EU27 members (excl. the UK)	**14.0**	**14.7**	**18.0**	**19.4**	**19.4**	**20.7**	**19.6**	**1.6**
India's total exports of HS 9022 (USD m)	220	364	350	323	397	406	407	**56.8**

Source: Author's calculations based on the WITS Comtrade database

Table 5 / Changes in the market distribution of India's exports of non-radiation imaging equipment (% share)

Destination country	Average for 2009-2015	2018	2019	2020	2021	2022	2023	% Change between 2019 & 2023
United States	20.7	26.2	25.1	22.7	22.7	23.1	20.6	**-4.5**
Germany	4.5	5.8	7.2	7.5	5.8	5.8	6.1	**-1.1**
United Arab Emirates	2.2	1.1	1.0	1.7	1.8	2.2	6.1	**5.1**
Netherlands	1.9	2.2	1.9	1.8	3.7	4.5	6.0	**4.2**
Brazil	4.0	5.5	3.7	3.7	4.4	5.1	4.7	**1.0**
China	3.8	6.1	6.3	6.2	5.7	4.8	4.2	**-2.1**
Turkey	2.2	2.1	2.3	3.2	2.7	3.8	3.5	**1.2**
Singapore	8.7	2.0	2.5	3.4	2.8	3.5	3.0	**0.5**
Belgium	2.2	1.4	1.9	1.8	2.5	2.1	2.7	**0.9**
France	3.0	2.6	2.8	2.2	2.0	1.7	2.3	**-0.5**
Italy	1.5	1.6	1.6	1.9	1.8	2.1	2.0	**0.4**
Russian Federation	1.0	1.1	1.2	1.1	1.1	1.8	1.8	**0.6**
Mexico	0.7	0.6	0.7	0.9	0.9	1.1	1.6	**0.8**
United Kingdom	1.1	1.3	1.4	1.5	1.4	1.7	1.5	**0.2**
Nepal	1.6	1.5	1.4	1.3	2.4	1.6	1.2	**-0.2**
Bangladesh	2.1	1.9	1.6	1.2	1.3	1.3	1.2	**-0.4**
Spain	0.6	0.8	0.8	1.2	1.2	1.1	1.1	**0.3**
Sri Lanka	1.3	1.1	1.0	1.3	1.0	0.4	1.0	**0.0**
EU25 members	17.8	19.6	20.8	22.5	23.1	23.1	25.6	**4.8**
EU27 members (excl. the UK)	17.3	18.8	19.9	21.6	22.1	22.0	24.7	**4.8**
India's exports of HS 9018 (USD m)	506	787	964	918	1065	1232	1388	**424.1**

Source: Author's calculations based on the WITS Comtrade database

These trade patterns appear to reflect intra-firm trade of the EU-based (and US-based) MNCs with their production bases in China, India and other countries apart from their home countries.

It must be remembered that FDI has been permitted in the Indian medical device manufacturing sector without any prior approval from the government ('automatic route') since 2014. Many MNCs have also established local presences by acquiring established domestic companies (FMC 2023). Despite the ease of entry for foreign investments for scaling up operations and for acquisitions, as well as several policy measures aimed at increasing local manufacturing,[8] India's medical device industry received only USD 600 million in FDI during the 2015-2020 period, with key investments from Singapore, the US and Japan as well as from Europe (IBEF 2024). The low level of FDI, despite the liberal FDI policy regime and the presence of low wages, reflected the fact that India's trade liberalisation under the multilateral route as well as through free trade agreements (FTAs) with the Association of Southeast Asian Nations (ASEAN), Japan and South Korea had incentivised foreign original equipment manufacturers (OEMs or lead MNCs) to continue to maintain their value chains centred around China, ASEAN countries and other locations. In other words, in the absence of a coherent, federally supported industrial policy to build up its local production capabilities, India's FTAs with countries deeply integrated into both regional and global electronics value chains had created perverse incentives for foreign OEM investments to engage in tariff-jumping FDI for local production in India (Francis 2016, 2019).

8 See FMC (2023) for a review of these policies at the national and state levels.

However, the supply chain shocks during and after the pandemic that reinvigorated US- and EU-based MNCs' search for greater supply chain resilience, combined with changing policies in India to support local production, appear to be leading to increased interest by medical device MNCs to expand operations in India. This, in turn, could pave the way for some shifts in trade patterns through intra-firm trade associated with MNCs.

3.2. RECENT POLICIES TO PROMOTE LOCAL MANUFACTURING

India has unveiled a number of policies to promote the local manufacturing of medical devices through both firm-level and horizontal fiscal support and other policies. Here, we focus on the post-COVID-19 policies that have direct implications for foreign investors into the industry.

The Production-Linked Incentive (PLI) scheme for medical devices introduced by the Indian government in 2020 has a total outlay of funds of INR 34.2 billion (approximately EUR 412 million[9]) and production tenure from FY 2022/2023 to FY 2026/2027. To compensate for the manufacturing weaknesses in selected medical device segments, the scheme provides a 5% incentive on incremental sales of medical devices manufactured in India by selected companies for a period of five years (as compared to a base year). The four target segments[10] covered by investment incentives are:

1. Cancer care/radiotherapy medical devices;
2. Radiology and imaging medical devices (both ionising & non-ionising radiation products) as well as nuclear imaging devices;
3. Anaesthetics and cardio-respiratory medical devices, including catheters of the cardio-respiratory category as well as renal care medical devices; and
4. All implants, including implantable electronic devices

As of December 2024, 19 greenfield projects had been commissioned under the PLI scheme for the production of 44 products, including critical high-end medical devices – including CT scans, MRI machines, mammogram equipment, C-arms, linear accelerator (LINACs), ultrasound machines, cath lab products, anaesthesia, dialysis and patient monitoring equipment – that were previously imported (Government of India 2024).[11]

The PLI was followed by the Phased Manufacturing Programme (PMP) for medical X-ray machines and related sub-assembly/parts/sub-parts published in January 2021. Under the PMP, a roadmap of tariff changes was announced that came into effect on 1 April 2021 with the objective of progressively increasing domestic value addition in the local manufacturing of medical X-ray machines. The roadmap covers tariff changes at an increasing rate on a range of products, including high frequency X-ray generators, medical-grade monitors, X-ray tubes and flat panel detectors. However, after industry

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9 The Reserve Bank of India (RBI) annual average exchange rates for the respective launch years were used for the rupee-euro (INR-EUR) conversions.

10 Any key component that constitutes a major part of the finished medical device and has a distinct HS code for itself (e.g. rotating anode tube, stationary anode tube, MRI magnet, flat panel detector and similar components) is also considered as belonging to the corresponding target segment.

11 There are two EU-based medical device affiliates among these PLI beneficiaries: Philips Global Business Services LLP, with a committed investment for producing MRI coils, and Siemens Healthcare Pvt. Ltd., with a commitment for producing CT scan and MRI machines.

representatives said that boosting local manufacturing capacity would take more time, the customs duties on X-ray tubes and flat panel detectors were reduced in the 2024/2025 budget to synchronise them with domestic capacity addition.

Simultaneously, the government announced the Scheme for Promotion of Medical Device Parks to develop common infrastructure facilities (CIFs) for a period of five years (from FY 2020/2021 to FY 2024/2025) in order to further reduce the production costs of medical devices manufactured in the country. The scheme has a total outlay of about INR 4 billion (approximately EUR 46.2 million).

In January 2024, another new scheme, the Assistance to Medical Device Clusters for Common Facilities (AMD-CF), was announced. The scheme aims to provide financial incentives to medical devices clusters to develop common infrastructure facilities (e.g. testing labs, e-waste treatment facilities and logistic centres). The scheme will provide financial assistance to national- or state-level public and private institutions interested in establishing or enhancing facilities for testing medical devices. Micro, small and medium enterprises (MSMEs) are eligible to receive the incentive under the scheme.

Before these schemes were announced, India's Central Drugs Standard Control Organisation (CDSCO) had published the Medical Devices Rules 2017, which require importers and manufacturers of medical devices to obtain registrations and licenses. The rules, which came into effect in 2018, represented a clear mandate to bring the entire medical devices sector under regulation in a staggered manner[12] by classifying medical devices under four categories based on their risk levels. Both domestic companies and MNCs had to go through the registration processes within the same time periods, which reportedly led to some churning in the domestic segment. With around 2,500 companies having submitted applications for registration between 2018 and 2023, the medical device manufacturing industry is expected to experience changing dynamics.[13] In fact, there was a quantum jump in FDI into India's medical devices industry in the post-pandemic years (FMC 2023). During the three years between April 2000 to March 2023, FDI inflows into the Indian medical and surgical appliances sector stood at USD 2.8 billion, as compared to USD 3.26 billion during the April 2000-December 2023 period as a whole (IBEF 2023, 2024). Meanwhile, the 2023 National Medical Devices Policy (Government of India 2023) was approved to effect the highly warranted coordination among ongoing policy efforts at multiple levels.

However, India's health expenditure has yet to see an increase large enough to adequately support the various schemes. Further, the lack of skill availability for the multidisciplinary areas relevant to the medical devices industry is likely to continue to create significant hurdles to expanding actual local manufacturing in the country (FMC 2023).

At the same time, the expanding roll out of India's national digital health infrastructure may lead to implications that are not yet anticipated or understood. In September 2021, the Ayushman Bharat[14] Digital Mission (ABDM) was launched to develop the backbone necessary to support the integrated digital health infrastructure of the country. It seeks to connect digital health solutions across hospitals, labs, pharmacies, wellness centres, insurance providers and other players in the health ecosystem. The

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12 In February 2020, two new amendments were introduced: first, a new chapter for registration of medical devices by their respective manufacturers and importers and, second, an exemption of the 37 categories of already regulated or notified medical devices from the requirement of registration introduced by the new chapter.

13 Based on an interview.

14 It translates as 'Live Long India'.

components of the ABDM are: the Ayushman Bharat Health Account (ABHA) number; the ABHA Mobile App (a personal health record); the Health Facility Registry; the Healthcare Professionals Registry; and the Unified Health Interface. The ABDM stands to increase digitalisation of the entire heath sector within the country (although it has been criticised for not featuring adequate data protection rights).

At the same time, transformation of the medical device industry that can leverage healthcare digitalisation has already been advanced by the efforts of industry lead firms to digitalise the industry's production spheres. In what follows, this paper discusses how digitalisation is changing the nature of goods trade and services transactions within medical device GVCs.

4. Impact of new digitalisation

4.1. DIGITAL VALUE CHAINS, INTELLIGENT PROCESSES AND SMART PRODUCTS

The previous phase of the transformation of how businesses are organised – from the old, rigid internal hierarchical pyramids of the mass production age into flexible organisations and adaptable networks, which led to the spread of GVCs, was itself intrinsically linked to advances in ICTs (Perez 2001). Advances in ICTs drove the initial wave of digitalisation of business services, which enabled MNCs to make value chain segments more fragmented, even though the specific drivers, patterns and phases of organisational reconfigurations within GVCs may have been different across different global industries.

Thus, digital technology systems have been around for many decades, underpinned by the use of hardware and software technologies belonging to the ICT techno-economic paradigm that was embraced beginning in 1971 (Perez 2001, 2009).[15] As originally argued in Francis (2018), all the new digital technology systems since the 2000s that became dominant in the 2010s – such as cloud computing, advanced telecom and network technologies (e.g. 4G and 5G), digital platforms, artificial intelligence (AI), machine learning (ML) and the Internet of Things (IoT) – have built upon the earlier ICT technology systems.[16] They are all fundamentally mediated by ICT hardware and software as well as other software-embedded and electronic products, all of which belong to the ongoing ICT techno-economic paradigm (Francis 2020, 2023).

However, it needs to be emphasised that today's ICT technology systems, or the new digital technology systems (sometimes referred to as Industry 4.0 technologies), involve a drastically closer intertwining of hardware and software than the earlier ICT technology systems did (Francis 2020, 2023). Furthermore, with tremendous amounts of digital data being generated through the deployment of these enabling technologies, intelligentisation based on data analytics has become the hallmark of this phase (Singh 2018; Francis 2018, 2020, 2023).

As discussed above, the digitalisation of business services has been central to the servicification trends in manufacturing value chains even before the ongoing platform phase of digital services (Francis 2018). However, the new digital technology systems and platformisation of services have together been leading to further radical innovations in product development and production processes as well as business processes and organisation in manufacturing firms. In the ongoing new digitalisation, devices, machinery and infrastructure are connected and interlinked via sensors and embedded technologies (i.e. IoT) to integrate physical objects, people and processes across the value chain – from product design and development, to procurement and production lines, and to logistics, sales and marketing.

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15 This is the fifth technology revolution in neo-Schumpeterian models. See Perez (2001, 2017), Freeman and Louca (2001) and the detailed discussion in Francis (2018, 2020).

16 For more discussion on the extension of the ICT techno-economic paradigm to the current set of digital technology systems, see Francis (2018).

The capturing of real-time data at the sources through IoT, along with data mobility and data analytics enabled by advanced telecom/networking technologies and cloud-based software architectures and platforms, are together enabling automated machine-to-machine (M-to-M) communication and new forms of human-to-machine interfacing – at the factory level, at the enterprise level and across entire value chains (Francis 2023). Digital transformation of the manufacturing sector is thus leading to networked, automated and intelligent (and, therefore, predictive) cyber-physical production systems and digital value chains (Francis 2020b, 2023).[17]

It can be noted that Germany's High-Tech Strategy 2020 described Industrie 4.0 as seeking a 'fusion' of the online world and the world of industrial production. According to GTAI (n.d.), cyber-physical production systems made up of smart machines, logistic systems and production facilities are to enable ICT-based integration for vertically integrated and networked manufacturing. Thus, the original conceptualisation of cyber-physical production systems clearly acknowledged that the fusion of the world of the internet and the physical world is enabled by ICTs.

However, it must be highlighted that although the new wave of digitalisation is an extension of the automated processes that the manufacturing sector has seen before, the crucial differentiator is that ICT networking and automation technologies are now involved in the real-time collection of data, which then becomes the resource for generating digital intelligence (Francis 2023). Thus, apart from networking technologies, data-analytics software for the generation of intelligent insights is a central tenet in the applications that are built and used by companies participating in and accelerating the digital transformation.

Meanwhile, cloud computing, which provides the infrastructure for data storage and computing/data-analytics services, along with networking and data transfer enabled by advanced telecom and networking technologies, have become the foundational enablers/digital infrastructural layers that digitalising industries and their value chains depend upon (Francis 2020, 2023, 2025).

The implications of this framework are broader than the impact of the technologies of Industry 4.0 or the Fourth Industrial Revolution (4IR) on supply chain digitalisation as typically discussed in the literature. The latter does discuss how supply chain resilience requires real-time, predictive intelligence for businesses through the continuous processing of all data relating to raw materials and other supplies and inventories, production processes, maintenance, finances, sales and so on. Thus, the possibilities of improving operational performance based on insights and intelligence derived through data analytics across digital/digitalising value chains have been acknowledged widely in different strands of the literature. This is expected to lead to a significant increase in operational efficiency and productivity at the firm level.

In the context of this study, however, the study by Brun et al. (2019), which analyses the impact of the adoption of Industry 4.0 technologies on GVC lead firms, is more relevant. They viewed 'digital economy MNEs' as leading the disruption and disintermediation characterising the change in global manufacturing and service GVCs due to digitalisation. The study's authors divided digital economy MNEs into the sub-categories of digital MNEs and ICT MNEs. Digital MNEs are characterised by the use of the internet as

17 See the detailed discussions in Francis (2023, 2025). At the factory level, it is often called 'smart factory' or 'smart manufacturing'.

their central operating and service delivery model.[18] On the other hand, ICT MNEs include legacy telecom providers, device and component manufacturers, and software development firms.[19] Posing the question from the standpoint of value chain governance as to whether digital economy MNEs will complement, displace or lead to the adaptation of existing GVC lead firms, they discussed three scenarios: complementary, displacement and adaptation. In the complementary scenario, digital economy MNEs create dynamic new additional value, employment and investment across industries, but they do not replace existing lead firms. The displacement scenario occurs when digital economy MNEs disrupt existing industries, challenging existing lead firms' business models. In the third scenario (i.e. adaption), Industry 4.0 technologies are successfully adopted by the existing lead firms to improve the efficiency of production.

While the complementary and disruption scenarios continue to prevail to varying degrees, our framework on the impact of new digitalisation on manufacturing straddles all three scenarios. We argue that the adoption of digital technologies by manufacturing sector GVC lead firms is leading to disruption and displacement. More importantly, as we argued earlier, moving beyond production efficiency, the deployment of advanced digital technologies by existing lead firms in different product and allied markets across sectors (and not just by digital or ICT MNEs) is driving a new dynamic in self-reinforcing product innovations. This dynamic, in turn, is the biggest change impacting the creation and distribution of value within manufacturing-sector GVCs. We have also argued that manufacturing sector digital transformations are being driven by existing lead firms, and that this is increasing the role of software in firms in the traditionally non-electronic/non-ICT industries (Francis 2018, 2020, 2023).

In addition to the electronics industry, the manufacturing industries undergoing advanced digitalisation also include the machinery industries (including MedTech), the automotive industry, the pharmaceutical and chemicals industries, and the food and beverage industry. For instance, the global engineering machinery giant Siemens AG has transformed itself into a provider of digitalised equipment, software and tools. Among its offerings of automation systems and software for factories, Siemens has a business platform that includes IoT-enabled hardware, software and digital services for the entire value chain.

We also argue that, in addition to the efficiency gains from improved production and business processes, digitalising lead firms garner IP premiums by carrying out new product design/product development on top of data-based insights and digital intelligence/AI to create new value. All kinds of personal and non-personal data are used for analytics-based innovations in the product-development stage itself. This changing nature of new product development and innovations is of critical significance in the context of the distribution of value within digital value chains.

Singh (2018) has shown in the context of digital/platform MNEs that the large amount of metadata generated over their clouds/platforms/networks and offer useful business insights is employed by these digital infrastructure providers to improve their own product offerings as well as to generate additional revenue through its sale to third parties.[20] We argue that, in a similar manner, manufacturing firms

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18 In our understanding, these are essentially all the digital platform companies (especially Big Tech), including the ones that provide cloud computing, network connectivity and similar digital/software infrastructural platforms (including e-commerce).

19 It may be noted that ICT MNEs defined in this manner are the conventional lead firms in the traditional electronics industry, but they also include all software providers.

20 Also see the detailed discussions and literature cited in Francis (2018, 2020).

undergoing advanced digitalisation are coming up with innovative ways to merge the physical and digital worlds involving a continuous flow of data by incorporating AI, edge computing, software-defined control and software-as-a-service (SaaS), among other advanced ICT technologies.

Innovations that encode intelligence are based on data analytics-driven insights and predictive pattern recognition (often marketed as AI), which in turn are derived from real-time data obtained from the networked/connected entities, along with data from other domains (Francis 2023). In the current phase of technological development – including in the large language models (LLMs) used to train advanced AI algorithms – large amounts of data are required to train algorithms as well as to draw data-based insights and (artificial) intelligence. The greater the volume of data, the greater the innovation potential and predictive ability.

Thus, the ability to turn digital data into intelligence that will create analytical (and predictive) power for new generic and customised products and applications is increasingly becoming the core competitive advantage and innovation advantage. As discussed above, data collection and storage, data analytics and data porting are carried out through a combination of software and embedded technologies. This implies that manufacturing corporations and existing lead firms undergoing advanced digitalisation and owning advanced algorithms for data mining and analytics will also increasingly own the intellectual property rights (IPRs) for the new digitalised goods and services they develop on top of the data itself (Francis 2020, 2023, 2025).

The GVC literature tells us that the largest shares of the value within GVCs accrue to firms engaged in product innovation/R&D and product design (as well as to those in the post-production segments). Thus, the largest share of the efficiency gains from digitalising value chains will accrue to companies owning the IP for data-analytics software as well as to those able to develop new proprietary software-embedded products based on digital intelligence (Francis 2023).

5. New digitalisation in the MedTech industry

The use of digital intelligence or AI in medical devices is widely expected to increase operational efficiency in the healthcare sector as well as to help to reduce operational risks through machine learning (see Greenlight Guru 2024). Over and above these efficiency gains, building upon the discussion in the previous section, we argue that the health-related and other data generated and gathered through the use of advanced digital technologies and the equipment embedded with them have become value-generating assets for the medical devices companies that extract and gather them.

Medical device companies often buy data from healthcare organisations that use their equipment and services. They also use such data in combination with public data sets in order to find ways to generate new value through innovative medical device products/systems and value-added services embedded with software/AI solutions. The absence of holistic national data-governance frameworks and the nature of IPR regimes for software and AI across countries[21] implies that firms obtain de facto control over data extracted via their IP-protected products and solutions.

Gaining access to expanding and quality data sets helps these firms to keep refining and advancing the training of their data-analytics algorithms, which in turn helps them to design better and more 'intelligent' healthcare products, including both devices/equipment and the software platforms that operate and control them. In other words, the unilateral access to data through digitalised devices enables them to keep improving their software and AI solutions dynamically as well as to gain IP premiums by selling products and platforms/systems embedded with increasingly more sophisticated and innovative software or AI. This gives these lead firms immense first-mover advantages in newer and newer product segments.

Meanwhile, manufacturing-sector lead firms face intense competition from the Big Tech firms (e.g. Apple, Microsoft and Amazon), which use their platform-based access to humongous amounts of data to build new product ecosystems in various industries, including in the healthcare space. For instance, a quarter of the deals that Alphabet, Google's parent company, made between 2019 and 2021 were in the healthcare and life sciences space to support its product offerings across wearables, health-related records and AI, and futuristic projects (e.g. DeepMind). Not far behind in their ecosystem ambitions are Apple, Microsoft and Amazon, the last of which was to reportedly launch a health referral service (The Economist 2022).

In this competitive dynamics, lead firms in such digital value chains are pursuing various strategies to maintain their competitive advantages and consolidate their leading positions in specialised product segments. Building upon Francis (2018, 2020), such lead firm strategies may include engaging in the following activities:

(i) Integration of embedded technologies/software in networked products to create new data-centric product/platform ecosystems, which will help to entrench the innovator's monopoly position through continuous advancement of data-based intelligence;

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21 This is discussed in further detail below.

(ii) Acquisition of competitors and innovative startups to buy up new technologies related to digital capabilities and/or to gain access to wider data-collection means (e.g. health, wellness and fitness apps as well as hardware startups in niche areas);

(iii) Mutually beneficial strategic collaborations with Big Tech firms (e.g. Apple, Microsoft and Amazon) to gain access to their humongous amounts of platform-based data as well as to thwart such firms' own ecosystem ambitions (as is discussed below in more detail);

(iv) Collaboration with healthcare-related facilities (e.g. hospitals, clinical labs, educational institutions and research organisations) that expand access to different types of relevant data sets;

(v) Expansion of IP protection into new spheres through (i), (ii), (iii), and (iv), and strategic patenting by innovators, leading to 'patent thickets'[22] that block innovation by competitors and new entrants; and/or

(vi) Pricing practices for products that integrate platform-based software offerings to increase the network effects of data-centric innovations.

As the research on electronics industry GVC dynamics has shown, apart from capturing the bulk of industry profits through IPR rents, platform firms in the ICT industry play crucial roles within their GVCs by exerting tight control over the innovative trajectory of the industry (Borrus 2000; Sturgeon and Zylberberg 2016; Ernst 2016a; Nathan and Sarkar 2014). We argue that new data-driven software and software-embedded hardware platforms being created by medical device lead firms have started playing a similarly crucial role within digitalising medical device value chains.

Further, while digitalisation stands to boost efficiency at the firm level, the extent of value addition that accrues in the host countries of lead firm subsidiaries is likely to be low (Francis 2020, 2023). This is because foreign exchange (forex) outflows from these subsidiaries in countries like India can become much larger than in the pre-intelligentised era owing to payments for technology and services. In other words, even when the smart products may be domestically produced in subsidiaries across the lead firm's network nodes, subsidiaries in countries like India are likely to witness increased payments through the services account. Such payments will include ones for proprietary AI and embedded technologies and software-embedded equipment and solutions in addition to technology payments to foreign-owned digital infrastructural layers, such as telecom networks, cloud storage providers and platforms (Francis 2023).

This analytical framework offers the context for the analysis of the value chain distribution of two major EU-based medical device subsidiaries in India. Given that diagnostic imaging equipment spread across HS 9018 and 9022 is the largest segment within the global and the Indian medical devices industry, two leading EU-based players in the diagnostic imaging equipment segment (identified as Indian subsidiary A and Indian subsidiary B) have been selected for the standardised in-depth case studies.

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22 Innovation often requires the use of currently existing IP. Anticompetitive strategies by first movers to broaden and leverage the monopoly power granted through patents lead to long and costly negotiations by competitors and followers to obtain the multiple permissions needed before they can innovate. Baker et al. (2017) used the term 'patent thickets' to refer to such blocks that delay and reduce innovation.

6. Standardised case studies

6.1. CASE STUDY 1

The EU-based lead firm of Indian subsidiary A has been undergoing digital transformation for over two decades now, and its digitalised healthcare provision is evident from its product offerings:

- Diagnostic imaging, ultrasound, image-guided therapy, monitoring and enterprise informatics as well as personal health products; and
- Other services (e.g. system support, financing, consulting and further training)

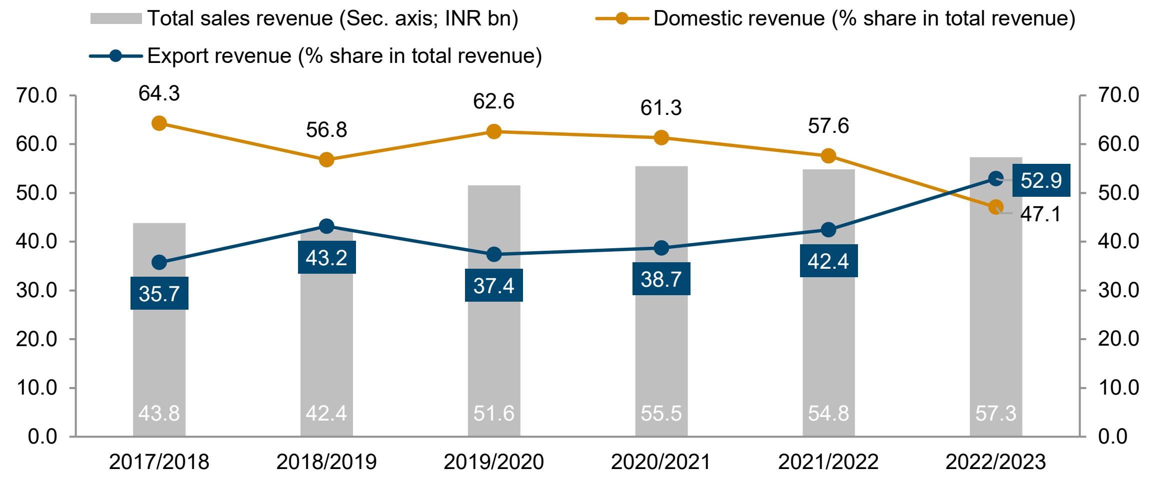
The increasing impact of the lead firm's digitalisation strategies is reflected in the Indian subsidiary's operations, which have become significantly focused on health equipment since it divested its domestic appliances businesses in July 2021. The Indian subsidiary's business segments are: Health 'Systems,; Personal Health Products and Innovation Services. Among these, the highest turnover-contributing product or service has been Health Systems (Figure 3). The latter includes imaging equipment such as computed tomography (CT), intervention-guided therapy (IGT), magnetic resonance imaging (MRI), ultrasound and patient monitoring. The businesses in the second product segment (i.e. Personal Health Products) continue to play an important role in the company's integrated health continuum approach through connected products and solutions. The third segment (i.e. Innovation Services) involves the development of embedded software and design, with the latter comprising software development, architecture, and platforms & innovation.

In FY 2022/2023, 54.8% of the company's turnover originated from the broad product category 'publishing of computer operating systems, system software, application software, games, etc.' (broadly, the software category), while 'retail trading' accounted for the rest of the turnover. The share of the former was only 27% in FY 2017/2018 and 31% in FY 2019/2020. This jump in the software category's share in turnover between FY 2019/2020 and FY 2022/2023 is a clear reflection of the increased role being played by the Indian subsidiary's software development centre within the parent firm's digital value chain strategies in the post-COVID-19 years.

Interestingly, while the subsidiary used to be significantly oriented towards the Indian domestic market, exports started increasing continuously beginning in FY 2019/2020 (Figure 12). In particular, there was a distinct decline in the share of domestic market in total revenue in FY 2022/2023. Exports constituted 53% of total revenue in FY 2022/2023, up from 37.4% in FY 2019/2020.

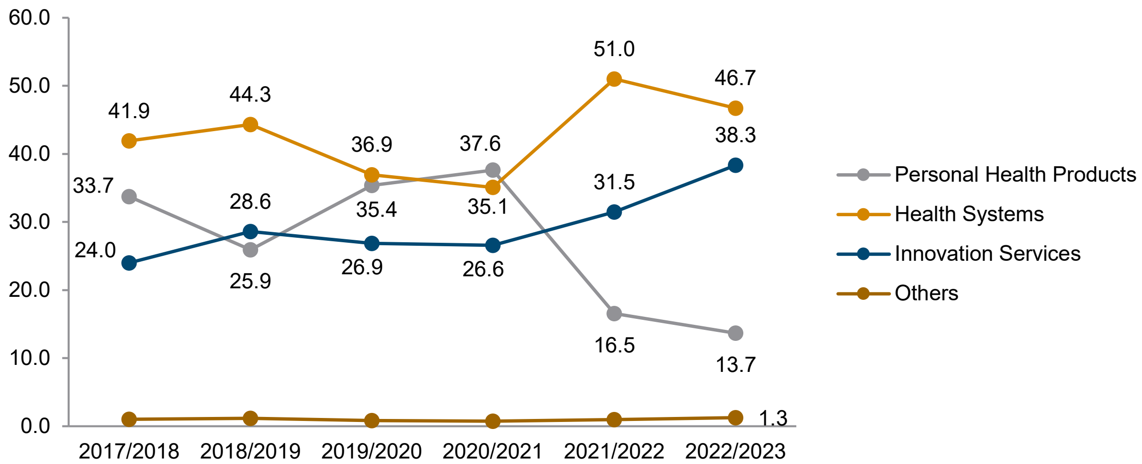
Trends in segment-wise revenue distribution (Figure 13) showed that even though there was an increase in the share of Personal Health Products in the Indian subsidiary's revenue during the pandemic years, it subsequently dropped, and Health Systems continued to dominate in FY 2022/2023. On the other hand, the share of Innovation Services in total sales revenue rose and stood at more than 38% in FY 2022/2023. This confirms the increasing role of India as a software development centre for the parent firm's digitally transformed product portfolio, which is further corroborated by the fact that revenue from Innovation Services is totally comprised of services exports (Table 6).

Figure 12 / Indian subsidiary A's market orientation



Source: Author's calculations based on data from annual financial statements

Figure 13 / Indian subsidiary A's revenue distribution (% share)



Source: Author's calculations based on annual financial statements

Analysis of the market orientation of the various segments revealed that while India's domestic market was the most important for the Personal Health Products segment dominated by goods, its revenues fell in nominal (and share) terms in both FY 2021/2022 and FY 2022/2023 (Table 6). The substantial increase in demand for personal health devices during the pandemic had led to a satiation of demand, which subsequently tapered off.

Health Systems, accounting for a revenue share of about 47% in FY 2022/2023, was also dominated by the sale of goods (Table 6). However, the share of services became more significant within Health Systems revenue, making up more than 30% of total revenue in FY 2022/2023 (compared to 25.2% in FY 2017/2018). Such services are provided for software-related systems within the health systems segment dominated by imaging equipment.

Table 6 / Indian subsidiary A's product segments in terms of goods, services and market orientation

Product segments	2017/2018	2018/2019	2019/2020	2020/2021	2021/2022	2022/2023
Personal Health Products (INR bn)	**14.8**	**11.0**	**18.2**	**20.9**	**9.0**	**7.7**
Sale of goods (% share in segment)	99.8	99.3	99.6	99.8	99.9	100.0
Domestic revenue (% share in segment)	98.1	99.1	98.0	97.6	99.9	99.9
Health Systems (INR bn)	**18.4**	**18.8**	**19.1**	**19.5**	**27.7**	**26.5**
Sale of goods (% share in segment)	67.3	66.0	63.3	59.9	70.8	67.6
Domestic revenue	74.8	70.1	75.5	69.8	79.2	69.6
Export revenue	25.2	29.9	24.5	30.2	20.8	30.4
Innovation Services (INR bn)	**10.5**	**12.1**	**13.9**	**14.7**	**17.1**	**21.7**
Sale of services (% share in segment)	99.7	100.0	100.0	100.0	99.8	100.0
Export revenue (% share in segment)	100.0	99.9	100.0	99.8	100.0	99.9
Others (INR bn)	**0.4**	**0.5**	**0.4**	**0.4**	**0.5**	**0.7**
Sale of services (% share in segment)	100.0	100.0	100.0	100.0	97.4	100.0
Export revenue (% share in segment)	75.8	96.1	95.5	97.3	79.8	81.0

Source: Author's calculations based on annual financial statements

At the same time, an analysis of the Indian subsidiary's imports during FYs 2018/2019, 2019/2020 and 2022/2023 revealed that all the major imaging equipment items were being imported (Table 7). While the significance of CT systems and X-ray equipment (9022) increased between FYs 2018/2019 and 2022/2023, the shares of MRI apparatus with accessories (9018), ultrasound scanning apparatus (9018), CT systems for radiation oncology (9022), and other devices showed some decline despite remaining significant.

Several parts – particularly for the C-arm image intensifier system (e.g. touch monitor, PCB assembly and cable assembly) – as well as systems and solutions (e.g. the portal solution and the CT upgrade package system) were also significant imports. This pointed to semi-knocked-down (SKD) assembly operations related to the start of local production under the PLI scheme (see Section 3.2 above). On the other hand, imports of several personal/consumer health products were also important with increasing shares for various products, including a personal groomer for men and a hair-styling product.

Table 7 / Indian subsidiary A's top imported products

S. No.	Product description	2018/2019	2019/2020	2022/2023	% change between 2019/2020 & 2022/2023
1	Medical equipment with accessories (CT system)	13.9	9.0	12.8	3.8
2	X-ray equipment	5.9	8.2	11.8	3.6
3	Hair-styling product	0.7	1.9	3.3	1.4
4	Touch monitor for C-arm image intensifier system	0.1	0.1	1.3	1.3
5	Rechargeable battery for portable oxygen concentrator	0.7	0.6	1.7	1.1
6	Defibrillator	1.2	1.5	2.5	1.0
7	Personal grooming product	0.3	0.3	1.3	1.0
8	Field replaceable units – PCB/PCB assembly	0.2	0.2	1.0	0.8
9	Intra-vascular ultrasound catheter	-	-	0.8	0.8
10	Glass baby bottles	0.6	0.5	1.2	0.7
11	Blood pressure monitor	0.1	0.1	0.6	0.5
12	Glass baby bottles	0.5	0.2	0.7	0.5
13	Part of X-ray-radiography system	3.5	4.4	4.8	0.4
14	Intellispace portal solution (parts used in medical equipment)	0.1	0.1	0.6	0.4
15	Incisive CT upgrade package system	0.1	0.2	0.6	0.4
16	Advanced CT system and spare parts	0.2	0.5	0.9	0.4
17	Cable assembly for C-arm image intensifier system	0.7	0.7	0.8	0.2
18	Diagnostic ECG system	0.4	0.5	0.6	0.1
19	Diagnostic sleep system	0.5	0.7	0.8	0.1
20	Part of MRI system	1.1	1.4	1.3	-0.1
21	Personal grooming product	0.7	1.1	0.9	-0.2
22	Personal grooming product	1.2	1.8	1.5	-0.3
23	Patient monitors	5.6	7.5	6.9	-0.6
24	CT scanner for radiation oncology	6.6	4.2	3.5	-0.7
25	Server with accessories	3.6	3.5	2.5	-1.0
26	Ultrasound scanning system with accessories	9.6	9.1	8.0	-1.1
27	Personal groomer for men	11.8	11.6	9.8	-1.9
28	MRI apparatus with accessories	13.7	12.5	9.3	-3.2
29	**Total share of the above in total imports by the Indian subsidiary (%)**	**83.4**	**82.4**	**91.8**	**9.4**
30	**Total imports (USD m)**	**219.0**	**229.5**	**257.1**	**27.5**

Source: Author's calculations based on customs trade data

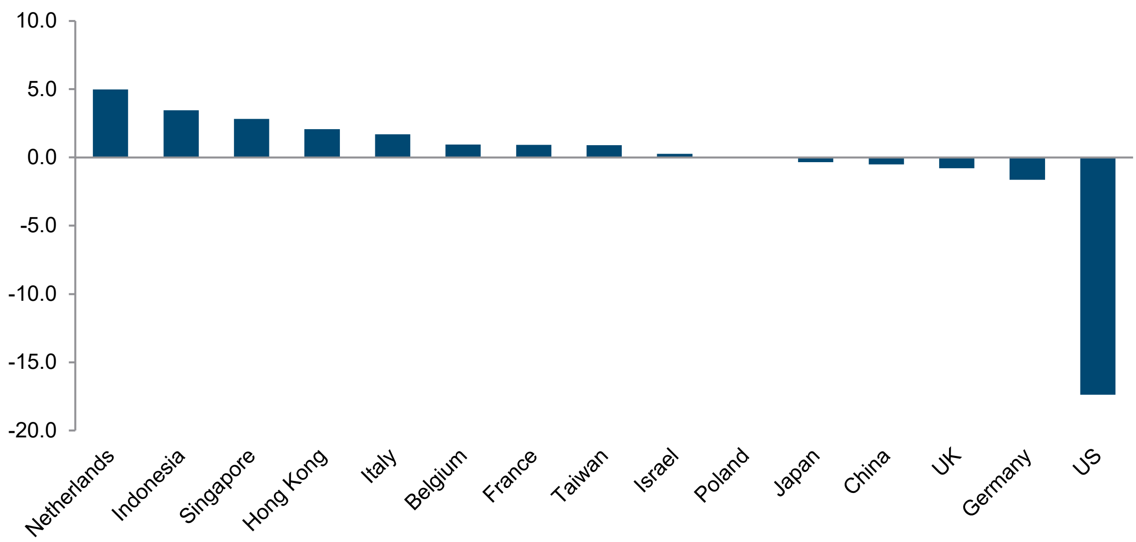
The top supplier in FY 2022/2023 was the Netherlands (i.e. the EU home country), followed by China, Singapore and Indonesia, along with other European countries, including Germany, Italy, France and the UK (Table 8). There was distinct increase in the shares of the home country, which became the largest import supplier, while the US share fell drastically in FY 2022/2023 (Figure 14), causing it to fall from its top rank in the pre-COVID-19 year to fifth place. Notably, despite a slight drop in its share between FYs 2019/2020 and 2022/2023, China became the second-largest supplier because of the dramatic drop in the US share. Furthermore, the import share of Hong Kong increased between these two financial years, more than compensating for the slight decline in China's import share. Two non-EU suppliers that saw a rise in their shares were Indonesia and Singapore.

Table 8 / Indian subsidiary A's top supplier countries

S. No.	Foreign country of imports	% share in total imports (FY 2019/2020)	% share in total imports (FY 2022/2023)
1	US	28.5	11.1
2	Netherlands	20.6	25.6
3	China	16.2	15.7
4	Singapore	11.6	14.4
5	Indonesia	8.8	12.2
6	Germany	6.6	4.9
7	Italy	2.0	3.6
8	France	1.2	2.2
9	UK	0.8	0.0
10	Hong Kong	0.7	2.7
11	Israel	0.5	0.8
12	Japan	0.4	0.0
13	Poland	0.4	0.4
14	Belgium	0.3	1.3
15	Taiwan	0.3	1.2
16	Total share of the above	98.7	96.2
17	Total imports of the Indian subsidiary (USD bn)	229.5	257.1

Source: Author's calculations based on customs trade data

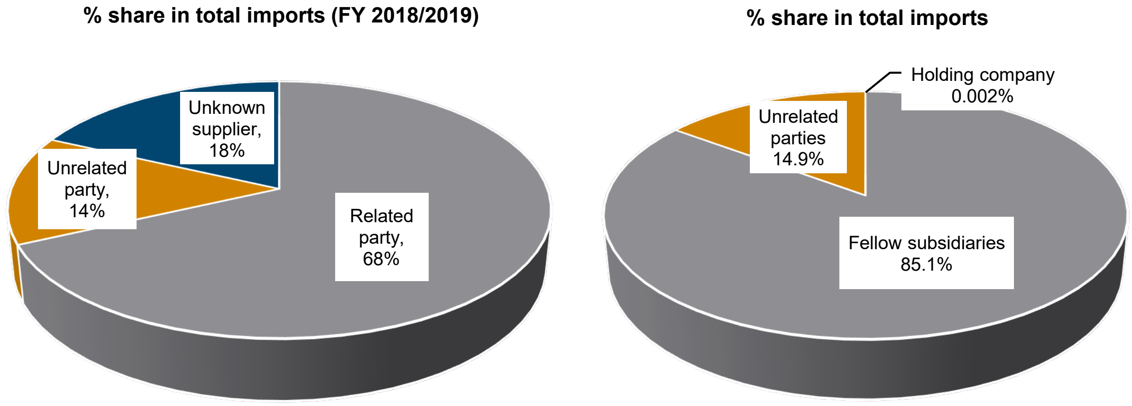
Figure 14 / Change in shares of Indian subsidiary A's top import suppliers (%)



Source: Author's calculations based on customs trade data

Despite the apparent diversification in terms of supplier countries, the large majority of import procurement of the Indian subsidiary in both FY 2018/2019 and FY 2022/2023 was from within the lead firm's group, reflecting high levels of intra-firm trade (Figure 15).

Figure 15 / Indian subsidiary A's import distribution by type of related party



Note: The supplier names were unavailable for more than 18% of the total import suppliers for FY 2018/2019. As a result, their nature (in terms of whether they were related parties or not) could not be ascertained.
Source: Author's calculations based on customs trade data

On the other hand, when it came to exports, the US was the single largest market (with a 28% share in FY 2022/2023), followed by the home country, the Netherlands (which, however, saw a drop in its share compared to FY 2019/2020). Apart from the latter, which absorbed a quarter of the subsidiary's exports even in FY 2022/2023, other major export markets were all non-EU countries (with the exception of Poland) (Table 9). Further, the shares of Thailand, Singapore, Brazil, Poland and Turkey registered increases, especially at the expense of the Netherlands.

Table 9 / Indian subsidiary A's top export markets

S. no.	Export market	% share in total exports (2019/2020)	% share in total exports (2022/2023)
1	US	29.2	28.1
2	Netherlands	33.6	24.9
3	Thailand	3.7	5.6
4	Singapore	3.5	4.9
5	Japan	5.0	4.2
6	Brazil	1.4	4.1
7	Poland	0.1	3.8
8	Turkey	0.4	3.6
9	Canada	3.2	3.0
10	UK	-	2.8
11	Russia	1.2	2.5
12	Australia	2.8	1.8
13	South Africa	0.6	1.1
14	Indonesia	0.2	1.0
15	Malaysia	0.5	0.9
16	China	1.8	0.4
17	Hungary	4.2	0.2
18	Sri Lanka	3.3	0.0
19	**Total share of the above (% in total exports)**	**94.9**	**92.8**
20	**Total exports (USD bn)**	**54.3**	**82.5**

Source: Author's calculations based on customs trade data

Given the high significance of the intra-firm trade transactions observed, the data on related party transactions from the annual financial statements of various years was analysed to capture the aggregate impact of intra-firm transactions covering both goods and services.

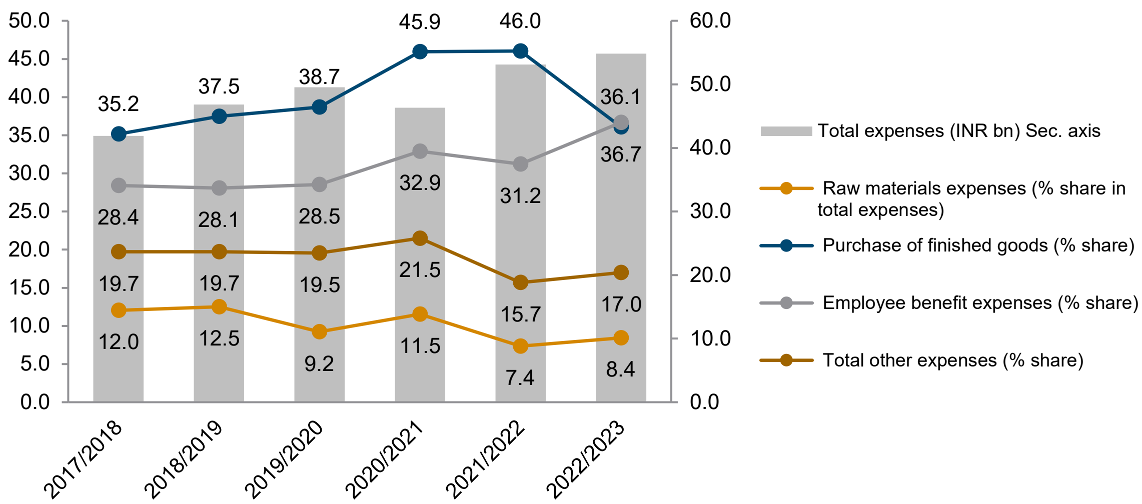
It was found that, in addition to imports of services from the UHC throughout these years (except FY 2021/2022), there were also imports of services from fellow subsidiaries in the Netherlands, followed by the US, in FYs 2021/2022 and 2022/2023 (Table 10). At the same time, along with the increased digitalisation discussed earlier, software exports from the Indian subsidiary increased significantly in these two post-pandemic financial years. These went mainly to the home country (i.e. to fellow subsidiaries and the UHC) followed by the fellow subsidiary in Israel. As a result, the company's net services receipts from related parties increased further during FYs 2021/2022 and 2022/2023.

Table 10 / Significance of services income within Indian subsidiary A's related party transactions

Financial statement values (INR m)	**2017/2018**	**2018/2019**	**2019/2020**	**2020/2021**	**2021/2022**	**2022/2023**
Import of services from related parties	217	171	30	31	1,155	901
Export of services to related parties	8,828	10,029	11,290	11,794	16,945	20,382
Net services receipts from related parties	8,611	9,858	11,260	11,763	15,790	19,481
	2017/2018	**2018/2019**	**2019/2020**	**2020/2021**	**2021/2022**	**2022/2023**
Total payments made to related parties	7,102	10,766	9,547	10,633	28,757	31,276
Total income from related parties	11,020	13,181	13,893	15,111	28,331	27,632
Net income from related parties	3,918	2,415	4,346	4,478	-426	-3,644

Source: Author's calculations based on annual financial statements

Figure 16 / Major components of Indian subsidiary A's expenses

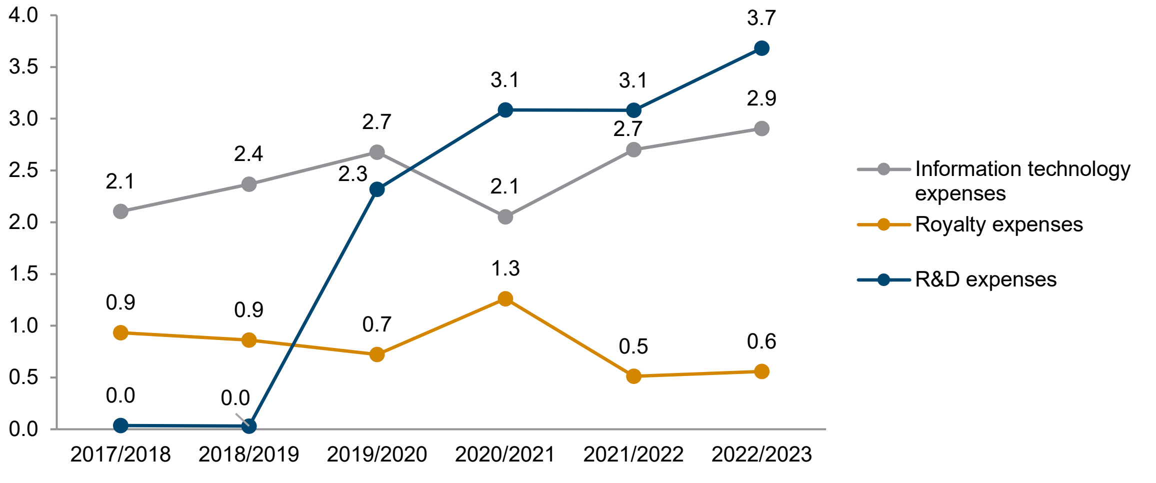


Source: Author's calculations based on annual financial statements

The increased role of R&D and software development is also captured in the trends in the composition of expenses (Figure 16 and 17). The share of total employee benefit expenses has been increasing since the pandemic years and accounted for nearly 37% of total expenses (equivalent to the share of 'purchase of finished goods') in FY 2022/2023 (Figure 16). The innovation centre's average workforce during FY 2022/2023 was 4,578, an increase from 3,946 in FY 2021/2022. Total employment at the centre stood at 5,000 in 2024. The rapidly increasing shares of R&D and IT expenses in the company's total expenses are also visible in Figure 18.

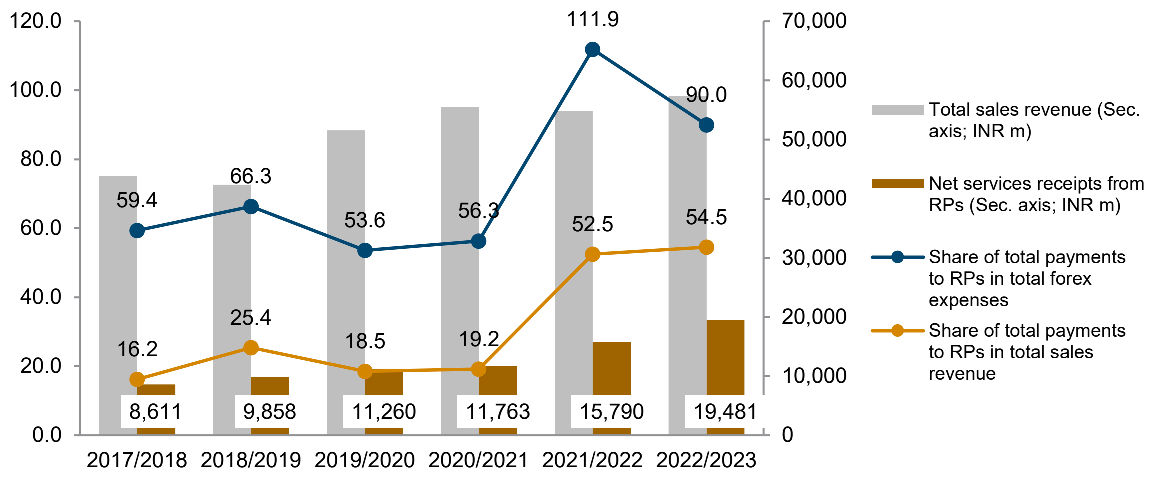
On the other hand, Figure 16 also reveals that expense shares of the purchase of finished goods declined significantly during FY 2022/2023 following the increase witnessed during the pandemic FYs 2020/2021 and 2021/2022. The start of domestic production in India under the PLI scheme (see Section 3.2 above) could lead to an increase in imports of parts and components for semi-knocked-down (SKD) assembly and cause a drop in the purchases of finished goods.

Figure 17 / Share of IT, royalty and R&D expenses in Indian subsidiary A's total expenses (%)



Source: Author's calculations based on annual financial statements

Figure 18 / Share of related party payments in Indian subsidiary A's total sales revenue and total foreign exchange expenses (%)



Source: Author's calculations based on annual financial statements

Overall, despite the clearly increased role of the Indian subsidiary in the software development and services segments of the parent firm's GVC as well as the resulting increase in its net service income from related parties,[23] its total net income from related parties abroad turned negative in FY 2021/2022 and declined further in FY 2022/2023 (Table 12). This was directly linked to the increase in the share of payments to the lead firm group (i.e. all related parties consisting of the UHC and all fellow subsidiaries abroad) in the total revenue of the Indian subsidiary, which increased beginning in FY 2020/2021 (Figure 18).

This proves that despite an increase in software exports from the Indian subsidiary with an increase in its role in the parent firms' GVC strategy as a software development centre following increasing digitalisation, the revenue share going abroad to the lead firm group increased rather than decreased. This is because the Indian market is served through imports of services/software solutions and equipment from the foreign related parties, which incorporate the premiums attached to patented software-embedded 'smart'/intelligentised equipment, devices, proprietary software platforms, etc.

6.2. CASE STUDY 2

Indian subsidiary B is a fully owned subsidiary of another major EU-based medical imaging lead firm, with its HC based in the Netherlands and its UHC in Germany. The Healthcare IT segment of the parent firm serves all the product segments of the company, which includes diagnostic and therapeutic imaging, laboratory diagnostics, and molecular medicine. The Indian subsidiary has been involved in developing digital health services and health enterprise services and has been principally engaged in two major activities since FY 2016/2017: (i) wholesale trading of medical equipment; and (ii) computer programming, consultancy and related activities. The second category is described as the provision of research, consultancy, product and software development services, and software solutions related to the healthcare business for its group companies (henceforth referred to as 'R&D and software development services'). In FY 2022/2023, wholesale trade accounted for 74% of the total turnover, with the remaining 26% contributed by the other major activity (i.e. R&D and software development). The latter's turnover share saw an increase from 21% in FY 2018/2019. We will show that the R&D and software development operations in the Indian subsidiary has been playing a significant role in the digitalisation trajectory of the parent EU firm.

Revenue from the sale of products (goods) accounted for the majority of total operational revenue of this Indian subsidiary (Table 11). However, its share went above 60% of total operational revenue in only two financial years, 2016/2017 and 2021/2022. In FYs 2019/2020 and 2022/2023 (i.e. pre- and post-COVID-19 years), the share of services revenue was quite high, ranging between 45% and 47% of total operational revenue.

[23] In the case of a fellow Indian subsidiary, as well – for which the financial statement data was only available for FYs 2018/2019 and 2019/2020 – it was seen that all forex earnings came from software exports in both financial years. Interviews revealed that the software operations in this unit principally related to optimising the lead firm's business transactions globally.

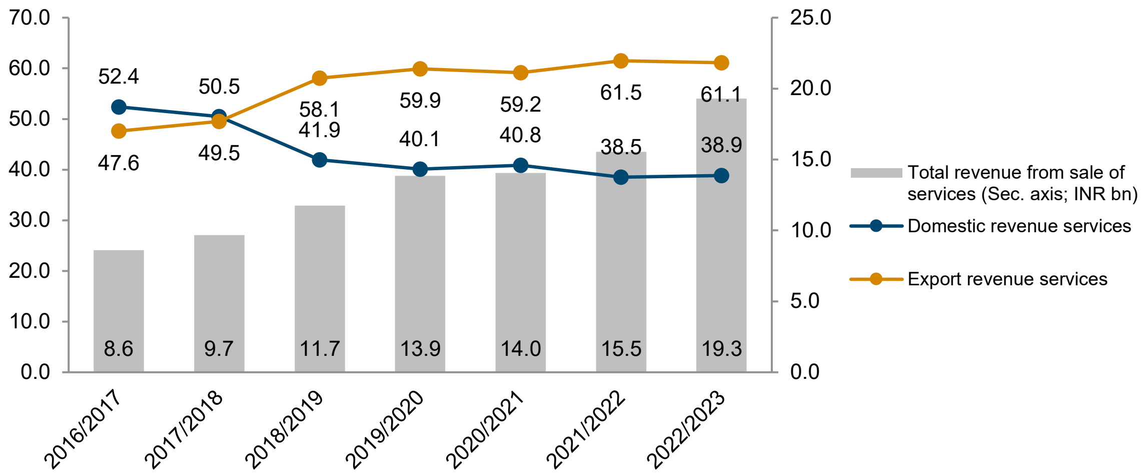
Table 11 / Indian subsidiary B's revenue composition

% share in total operational revenue	2016/2017	2017/2018	2018/2019	2019/2020	2020/2021	2021/2022	2022/2023
Revenue from sale of products	63.3	59.0	58.2	52.2	57.6	61.6	54.5
Revenue from sale of services	35.0	39.7	40.9	46.8	41.8	37.3	44.7
Other operating revenues	1.8	1.3	0.9	1.0	0.6	1.1	0.8
Total revenue from operations (INR bn)	**24.6**	**24.4**	**28.7**	**29.6**	**33.6**	**41.6**	**43.2**
Total operational revenue as % share in total income	99.1	99.2	99.6	99.4	98.3	99.3	98.7

Source: Author's calculations based on annual financial statements

While some manufactured goods were exported in FYs 2016/2017 and 2017/2018, the Indian subsidiary has been a domestic market-oriented company (Figure 19). All of its goods revenue came from the Indian domestic market beginning in FY 2018/2019. In contrast, services revenue arising from R&D and software development services was predominantly from exports. The share of exports in the Indian subsidiary's total services revenue increased beginning in FY 2017/2018 and has hovered around 60% since FY 2019/2020, with the rising trend continuing into the post-pandemic years.

Figure 19 / Indian subsidiary B's market orientation

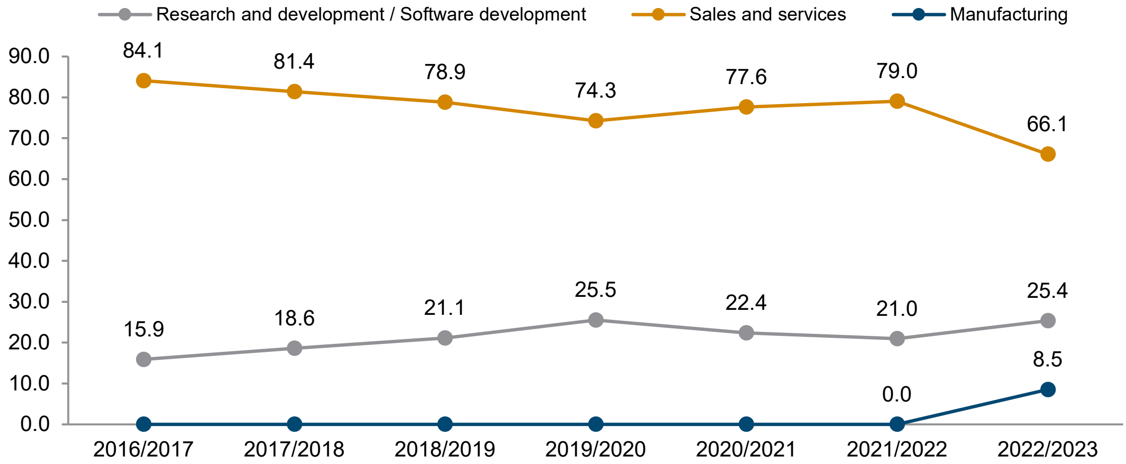


Source: Author's calculations based on annual financial statements

In fact, the distribution of revenue based on operational segments revealed that the share of sales and services (associated with goods), which dominated in FY 2016/2017 with an 84.1% revenue share, had declined by more than 10% by FY 2019/2020 and declined further, to 66%, in FY 2022/2023 (Figure 20). On the other hand, it is significant that the share of R&D/software development increased from 15.9% in FY 2016/2017 to 25.5% in FY 2019/2020 and stood at 25.4% again in FY 2022/2023 (despite some decline during the pandemic years).

Thus, it is clear that the increase in services exports by the Indian subsidiary after FY 2018/2019 entirely came from increased software exports. On the other hand, during FY 2022/2023, manufacturing, which was negligible until then, also saw its share in total revenue increase to 8.5%. Production facilities for diagnostics and those for medical imaging products (e.g. CTs, MRIs and C-arms) had both seen an expansion in production.

Figure 20 / Indian subsidiary B's revenue streams by segment of operation (% share)



Source: Author's calculations based on annual financial statements

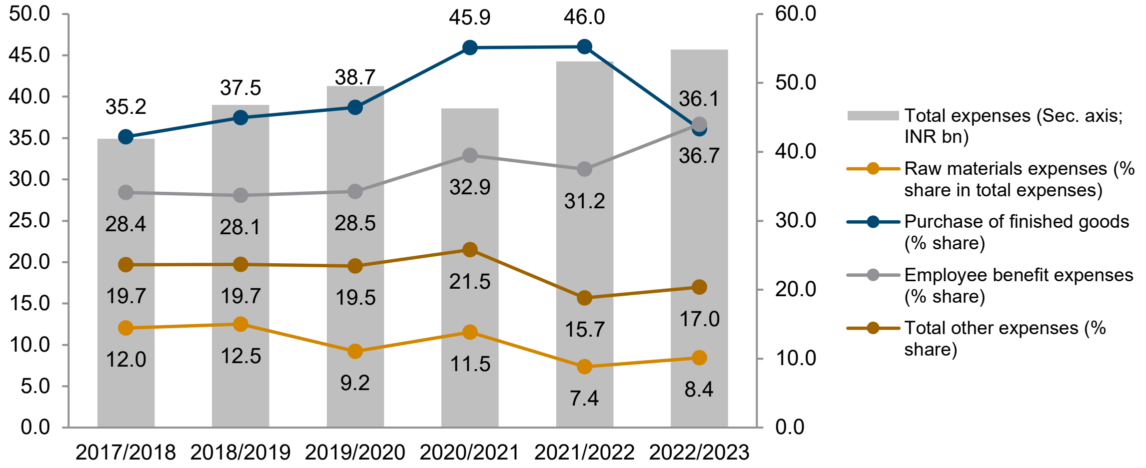
The diagnostics manufacturing unit used to comprise two product lines: urine analysis strips and AUTOPAK biochemistry reagents. However, during the pandemic period, local manufacturing of molecular testing kits, including COVID-19 testing kits and others, was ramped up in August 2021 in what was considered a breakthrough in the up-scaling of testing during the crisis. These kits were designed and developed by the Indian subsidiary in collaboration with eminent researchers from Indian universities and research centres to enhance the company's efforts in expanding precision medicine.

The second facility produced CT scanners under the Production-Linked Incentive (PLI) scheme (see Section 3.2 above) and was also expected to start the manufacturing of MRIs. Although this points to some shift away from the earlier strategy of wholesale imports for serving the domestic market, the production was largely limited to import-based assembly in medical equipment and reagents with heavy dependence on China (see below for more details).

The distribution of total expenses of the company (Figure 21) captures both the increased imports (purchase of finished goods/goods purchased for resale) during the scaling up of local production in diagnostics products during the pandemic-era FYs 2020/2021 and 2021/2022 as well as the subsequent drop in FY 2022/2023 following the slight expansion in local production in both diagnostics and imaging products. Even though the cost of raw materials went up at the same time, from INR 3.905 billion to INR 4.630 billion, its share in total expenses did not significantly increase owing to the much sharper increase in employee benefit expenses with new hiring during FY 2022/2023.

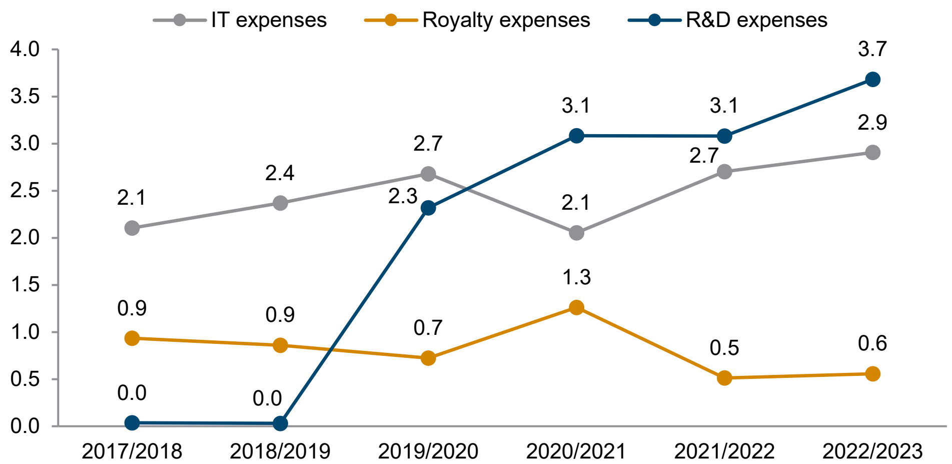
Figures 21 and 22 together also capture the sharp increase in shares of R&D expenses, followed by expenses on IT and employee benefits. Given that a significant portion of the employees belong to the software segment, the increase in the cumulative expense on R&D, IT and employee benefit expenses – from 30.5% in FY 2017/2018 to 33.5% in FY 2019/2020 (i.e. pre-COVID-19) and then to 43.3% in 2022/2023 –clearly captures the increasing role of the R&D and software development division of the Indian subsidiary within the lead firm's digitalisation strategy.

Figure 21 / Indian subsidiary B's major expense components



Source: Author's calculations based on Annual Financial Statements

Figure 22 / Share of IT, royalty & R&D expenses in Indian subsidiary B's total expenses (%)



Source: Author's calculations based on Annual Financial Statements

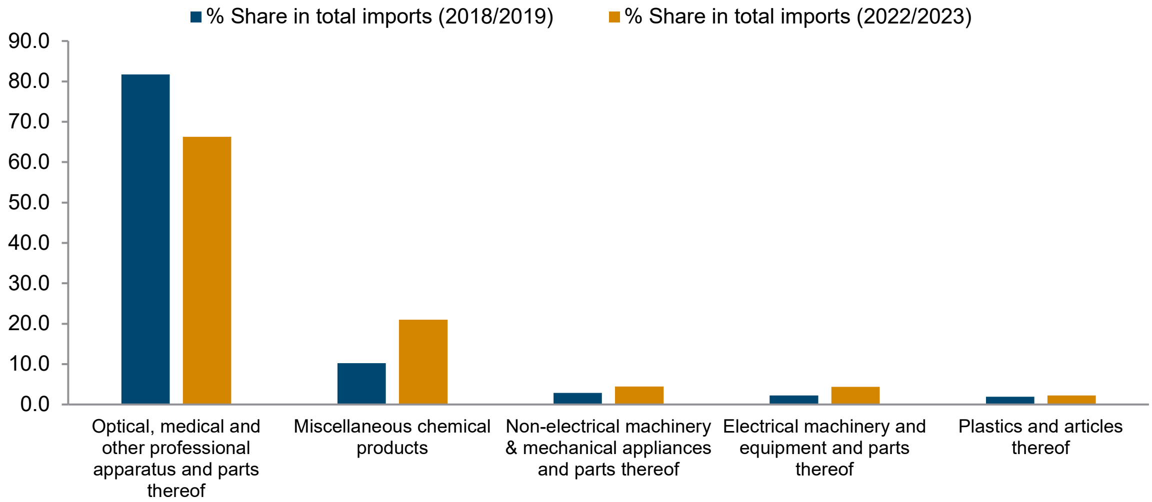
India's pivotal role in the lead firm's GVC on the R&D and software development side is also reflected in the fact that India, which also hosts the lead firm's global software development centre, is home to about 54% of the company's global software/digital technologies teams. Nearly half of the company's Indian employees in 2023 were software and digital experts.

Continuous technological improvements had been made at the Indian centre to develop new products, improve product features and boost productivity in several areas, including cloud computing, data analytics and software testing automation. In FY 2022/2023, it continued to make technological improvements driven by software engineering. While all of the reported improvements appear to fall under the category of (digital) process optimisation, they use technologies (e.g. DevOps, AI, automation and countless software platforms) with integrated data analytics. Given that high-quality data is a key ingredient for continuously improving the output provided by its products, the Indian subsidiary has invested in building a database over the last few years, which can potentially access billions of curated images, reports, and clinical and operational data. This data will then be fed into algorithms and used to train them.

One would expect that the restructuring of the India operations – with an increase in local production of imaging equipment and diagnostics and an expanded role for the Indian subsidiary in R&D/software development in the lead firm's digitalised health device portfolio – could have led to some changes in the Indian subsidiary's procurement patterns during this period. This was examined using the customs trade data.

Overall changes in Indian subsidiary B's import composition between FYs 2018/2019, 2021/2022 and 2022/2023 (Figure 23) reveal that imports of medical imaging equipment along with their parts remained significant even in FY 2022/2023; however, there was a drop in the share of CT scans, reflecting the increase in its domestic production (Table 12). At the aggregate level, this was captured in a decline in the share of HS Chapter 90 products as a whole and a significant increase in miscellaneous chemical products, followed by electrical and non-electrical machinery products and parts thereof.

Figure 23 / Changing trends in Indian subsidiary B's imports



Source: Author's calculations based on customs trade data

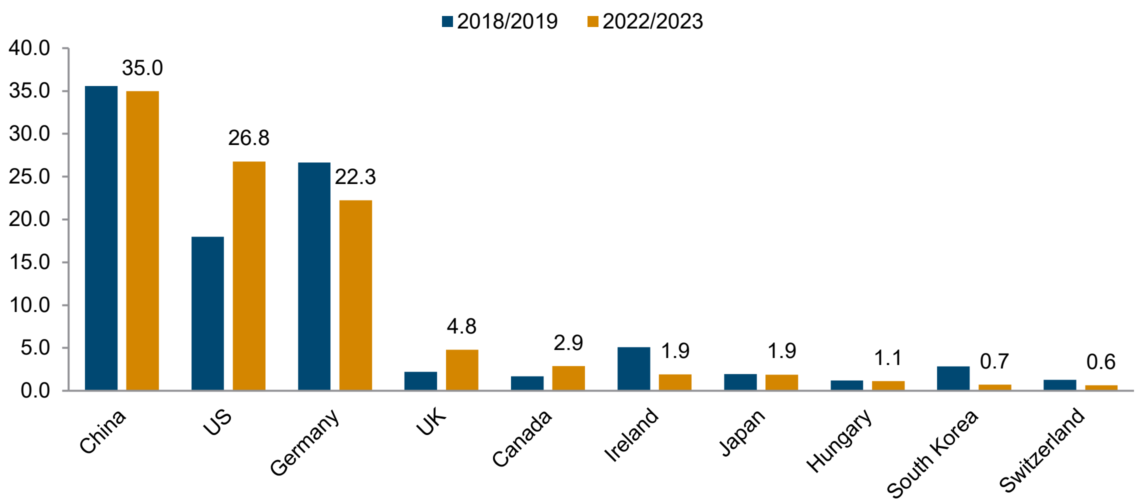
The increased imports of miscellaneous chemical products (other diagnostic reagents under HS Chapter 38), which were imported mainly from South Korea, reflected the expansion of production in the diagnostics production facility. On the other hand, there was increased imports of digital processing units during FYs 2021/2022 and 2022/2023 (Table 12), which comes under HS Chapter 84 and led to the increase in the non-electrical machinery sector's share (Figure 24).

Table 12 / Major imports by Indian subsidiary B (% share in total)

S. no.	Product description	2018/2019	2021/2022	2022/2023
1	Other diagnostic or laboratory reagents	10.1	21.0	20.6
2	MRI apparatus	17.5	13.8	16.4
3	CT apparatus	15.8	18.3	11.4
4	Other parts for radiation generation or beam delivery units	12.1	4.8	9.8
5	Other diagnostics instruments	12.8	6.2	8.0
6	X-ray tubes	2.6	5.8	7.8
7	Other instruments for checking, measuring or controlling/testing	0.0	1.3	5.1
8	Other X-ray machines for medical uses	3.8	5.8	4.9
9	Other articles of plastic nes	0.7	1.8	2.1
10	Digital processing units	0.0	2.1	1.9
11	Other parts and accessors of heading 9027	3.4	1.6	1.9
12	Others	0.2	0.2	0.6
13	Total imports (USD m)	230.9	338.5	289

Source: Author's calculations based on customs trade data

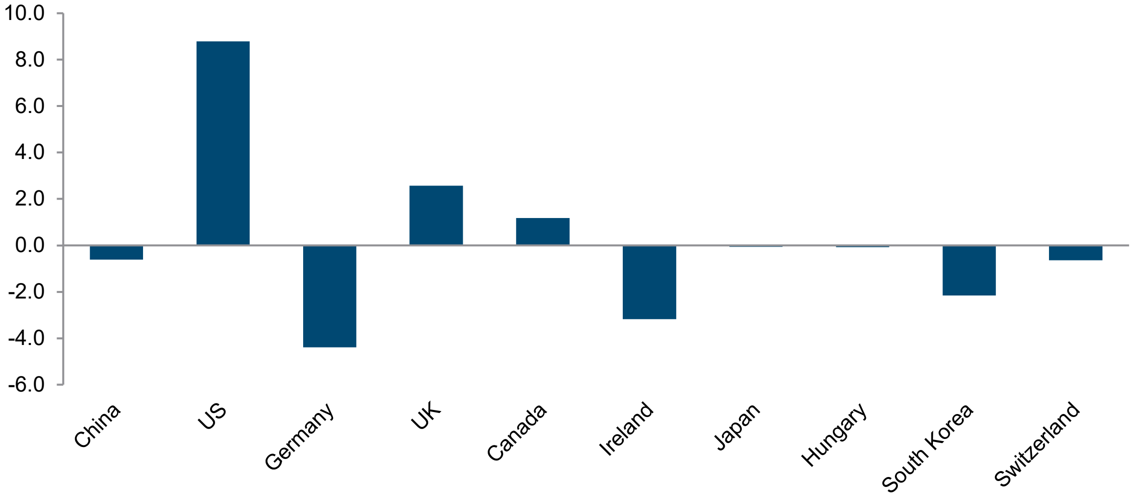
Figure 24 / Indian subsidiary B's major import sources (% share)



Source: Author's calculations based on customs trade data

Despite the expansion in local production, the Indian subsidiary's dependence on China did not show a significant decline when compared to the pre-pandemic FY 2018/2019, with more than one-third of total imports still coming from China in FY 2022/2023 (Figure 24). On the other hand, the share of imports from the US increased significantly in FY 2022/2023 (followed by those from the UK and Canada), which came at the expense of those from Germany, along with Ireland, South Korea and Switzerland (Figure 25).

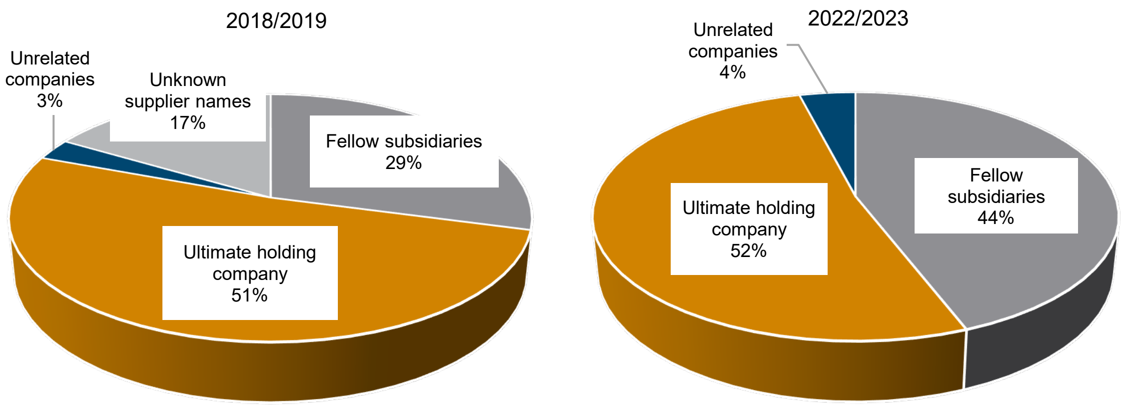
Figure 25 / Changes in Indian subsidiary B's import sourcing based on foreign country (% points)



Source: Author's calculations based on customs trade data

The distribution of its imports according to related party status clearly reveals that the procurement of imports was dominated by the lead firm and its subsidiaries in China, Germany and the US, followed by those in the UK, Canada, Japan, Ireland and South Korea. The combined share of the UHC and its subsidiaries across various countries stood at as high as 96% of the Indian subsidiary's total imports in FY 2022/2023 (Figure 26).

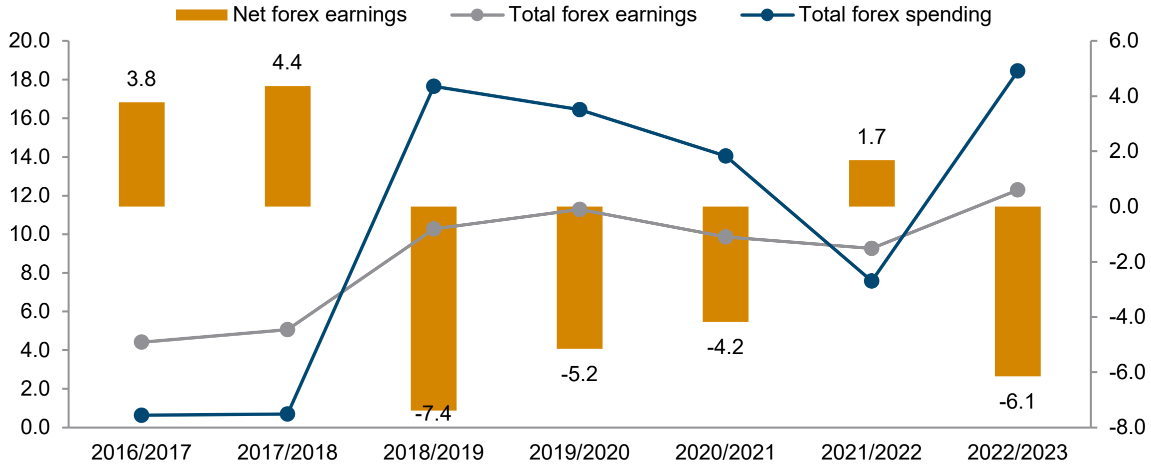
Figure 26 / Indian subsidiary B's import distribution by type of related party



Source: Author's calculations based on customs trade data

When the total forex transactions of the company were analysed, the Indian subsidiary registered net forex earnings during the first two years after its incorporation when it started exporting services. Subsequently, there were significant net forex outflows from the Indian subsidiary starting in FY 2018/2019 (Figure 27). This was true except for in FY 2021/2022, but the trend subsequently reversed, as the Indian subsidiary registered a net forex outflow of INR 6.1 billion in FY 2022/2023.

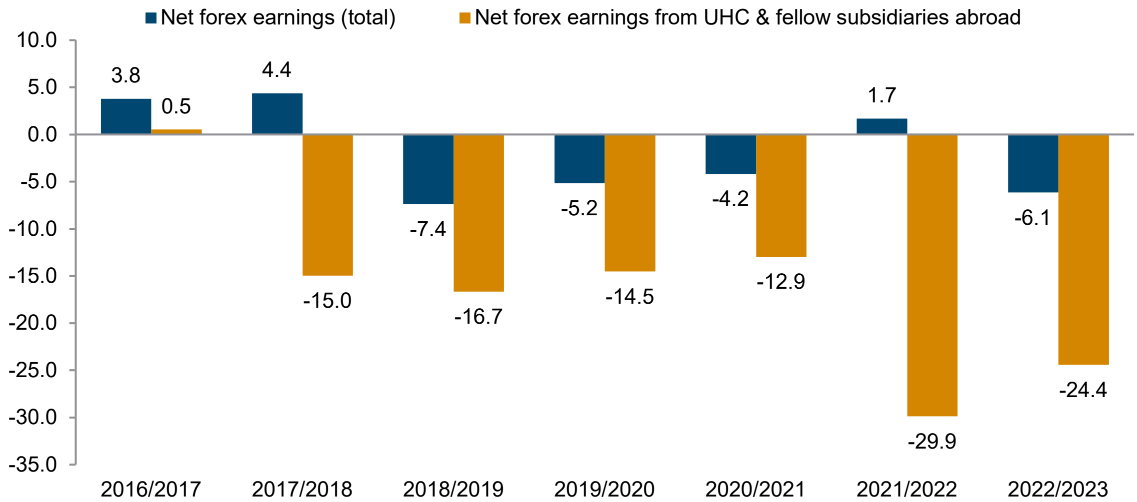
Figure 27 / Trends in Indian subsidiary B's net forex earnings (INR bn)



Source: Author's calculations based on annual financial statements

However, when we only consider the UHC and fellow subsidiaries abroad (without considering fellow subsidiaries in India), net outflows began from FY 2017/2018 onwards, with a dramatic increase in outflows to related parties abroad in FY 2021/2022 (Figure 28). There was also some decline observed in net forex outflows to this group in FY 2022/2023 when compared to FY 2021/2022. This was due to a slight increase in income from related parties abroad along with a decline in the expenses registered (Figure 28). Despite a slight increase in services imports from a Chinese fellow subsidiary in FYs 2021/2022 and 2022/2023, total payments for services imports from the lead firm and fellow subsidiaries abroad registered a decline during FY 2022/2023.

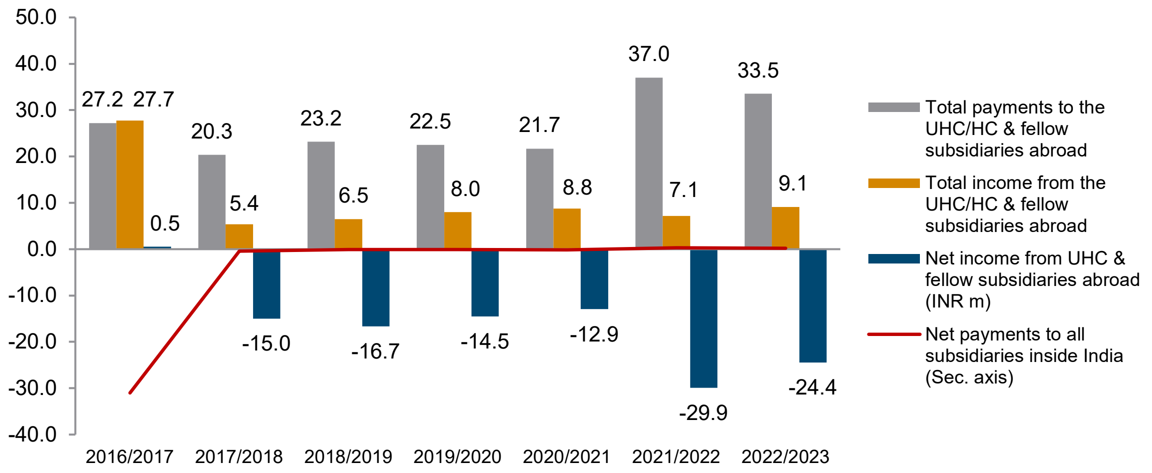
Figure 28 / Indian subsidiary B's net forex transactions with related parties (INR bn)



Note: The payments to, and income from, fellow subsidiaries in India are not considered in the estimation of net forex earnings from related parties abroad.
Source: Author's calculations based on annual financial statements

However, when compared to the pre-pandemic years, payments to related parties abroad were significantly higher (Figure 29). Consequently, net forex payments abroad to the lead firm group were still significantly higher in FY 2022/2023 when compared to the pre-pandemic years.

Figure 29 / Indian subsidiary B's related party transactions in India and abroad (INR bn)



Source: Author's calculations based on annual financial statements

This is explained by the fact that even as the Indian subsidiary predominantly received income from the export of services to a fellow subsidiary in Germany, followed by exports to a fellow subsidiary in the US and other related parties, its payments for the import of services from these related parties were higher (see Table 13).

Table 13 / Major services transactions between Indian subsidiary B and related parties (INR m)

Exports/imports	2016/2017	2017/2018	2018/2019	2019/2020	2020/2021	2021/2022	2022/2023
Ultimate holding company							
Import of services	98.2	405.3	266.0	386.9	506.8	543.5	333.1
German lead firm							
Export of services	2784.6	3099.0	3994.5	5482.0	5491.0	6447.8	8224.9
Import of services	7388.0	6733.1	8589.9	7682.0	7884.2	13168.9	9802.6
US fellow subsidiary X							
Export of services	1288.8	1491.9	1938.7	1654.7	1529.5	0.0	0.0
Import of services						1592.1	1768.9
US fellow subsidiary Y							
Import of services	1419.1	1554.5	2342.0	2790.1	1560.6	1842.5	2398.7
Chinese fellow subsidiary							
Import of services						54.7	27.5
Unspecified other related parties							
Export of services						123.5	295.6
Import of services						4495.8	4625.3

Note: This table does not include all transactions between these related parties, as it only captures major trade in services reported in the annual financial statements. The blanks indicate that no data were reported for those years.
Source: Author's calculations based on annual financial statements

The higher payment for the import of services from foreign fellow subsidiaries can again be explained as follows. Since India is one of the global software development centres for the parent company, the software development for product design, process optimisation and so on carried out at the Indian subsidiary is embedded into patented software platforms, operating systems and applications for value-added services by the main foreign fellow subsidiaries in Germany and the US. These platforms, systems and applications are then exported back to India as proprietary platforms and healthcare solutions or as healthcare equipment and manufacturing/automation equipment with embedded software. The premium attached to proprietary products is captured in the higher payments for the import of services and goods by the Indian subsidiary. Following the expansion in local production, there was also the expense category ‘purchase of manufacturing technology’ from a German fellow subsidiary.

There were also services transactions between the company and its local fellow subsidiaries. A separate limited liability partnership (LLP) was incorporated in December 2020 as part of the parent firm’s India strategy. Set up as a centre of competence to drive digital solutions through AI, data analytics, immersive experience, IoT, diagnostic automation and the like, the LLP helps the lead firm to boost organisational flexibility.

The local fellow subsidiary started operations in 2020, and all of its turnover came from the sale of services. Even though the annual financial statements for this LLP were only available for FYs 2019/2020 and 2020/2021, subsidiary B’s financial statements showed that it purchased services from this LLP in India in all the years since the latter’s incorporation (i.e. during FYs 2020/2021, 2021/2022 and 2022/2023). Given that its income from the LLP (only reported as ‘amounts receivable’) was not lower, the company was making net payments to this local LLP. These transactions are explained by the fact that the local fellow subsidiary has been set up as a captive service provider tasked with carrying out research and experimental development services in inter-disciplinary fields, such as bio-medical engineering/science. At the same time, the LLP is also providing complementary IT services, such as software design as well as application and software development services. The analysis of forex earnings and forex expenses for the two years for which data were available showed that this LLP had also registered net forex outflows in FY 2020/2021, even though there was only forex income from services exports in the first quarter of its operation (January-March 2020).

In addition to this LLP, the parent firm reported four other fellow subsidiaries in India.[24] Out of these, the company received income from one of them beginning in FY 2017/2018 (except in FY 2020/2021); however, this income was recorded as sale of services per se only beginning in FY 2021/2022, as they were only reported as ‘amounts receivable’ in the earlier years. In the case of the second one, apart from the purchase of property and other assets (i.e. imports of medical equipment) during FYs 2016/2017 and 2017/2018, no other transactions were reported. Transactions with the third one involved payments for leasing and the settlement of liabilities for FYs 2021/2022 and 2022/2023. On the other hand, the transaction recorded with the fourth fellow subsidiary was for a single financial year (2022/2023), which was also for the settlement of liabilities by the case study company.

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24 It also had an Indian subsidiary that it purchased services from and sold services to during FYs 2018/2019 and 2019/2020. But no transactions with this subsidiary were subsequently reported.

Subsequently, we investigated the imports of three of these local fellow subsidiaries for which customs trade data were available. It was found that one of them had imported programmable logic controller and automation systems from the parent firm in FYs 2021/2022 and 2022/2023. These imports involved a series of programmable logic controller and automation systems developed by the lead firm for industrial automation and production, which run in software environments created by it.

This finding (also) supports our argument that even as India's role in software and product design and innovation in the EU-based lead firm's digitalising value chains is increasing, the lead firm will retain a high value share through the higher value-added exports of its patented software-embedded medical devices, systems and automation equipment back to its Indian subsidiary/ies.

Meanwhile, the Indian subsidiary has announced strategic partnerships and research collaborations with several Indian academic and scientific institutes, healthcare organisations and hospitals aimed at making India an innovation centre for its parent firm globally.

7. Discussion of the results

Analysis of global trade trends and the movements in the global shares of the major exporters and importers of medical device product segments until 2023 showed that in both the radiation-based and non-radiation imaging equipment segments, which together comprise the largest category within global medical devices industry, Germany and the Netherlands have been the most dominant EU exporters while facing direct competition from both China and the US. Germany and the Netherlands have also been the largest EU importers in these two segments. Significantly, Mexico overtook Germany as the second-largest global exporter of non-radiation-based imaging equipment. Further, Mexico and Costa Rica – along with Poland, the Czech Republic, the Dominican Republic and Gambia –registered an increase in their shares in the global two-way trade in medical devices, which indicates that there is some GVC realignment underway, although further investigation is needed. Notably, China's role as an importer saw a decline in both imaging equipment segments, reflecting its growing domestic capabilities. Until 2023, no significant change was observed in China's share in exports of global medical devices.

In the case of India, the purchasing and production patterns of medical device companies, including of the selected EU-based subsidiaries, appeared to have become entrenched over the last several years due to:

(i) the cumulative effect of non-strategic liberalisation of India's trade and FDI regimes;

(ii) the lack of a coherent national policy focused on building up technological capabilities and skills; and

(iii) the extent of OEMs' dependence on China due to the scale of production and accumulated capabilities built up in that country through strategic industrial policies.

Any significant change in procurement away from China is therefore likely to take time.

Significantly, the Indian subsidiaries' import procurements were fully dominated by supplies from the lead firm and fellow subsidiaries abroad (including those in China), reflecting the high levels of intra-firm trade within their digitalising GVCs.

Meanwhile, advanced digitalisation strategies in the medical device industry driven by the EU-based (and US-based) lead firms have been impacting GVC dynamics through the increased role of software. The latter arises from the fact that software/algorithms and other embedded technologies are required for datafication (e.g. data gathering, transfer and analytics) and intelligentisation across value chain segments – including innovation/R&D, product development and manufacturing, post-production stages of end-user interfaces for sales, marketing and after-sale services. This is found to increase the share of software design and development as well as software services in medical device GVCs.

The analysis of intra-firm transactions in goods and services between the Indian subsidiaries of leading EU-based MedTech MNCs and their related parties confirmed the expansion in the software development and software services happening in the Indian subsidiaries. It must be remembered that

MNCs from developed countries have been establishing their captive R&D centres or software design and development centres in developing countries – particularly in India (and China) – since the late 1980s[25] owing to the cost advantages and skill levels of Indian software labour (UNCTAD 2005; Krishna et al. 2012). However, despite the available evidence on global innovation networks (GINs; see Ernst 2016b and Nathan 2023), software development for product design has been neglected as part of the discussion on value distribution within GVCs.

In both the standardised in-depth case studies, the leading EU-based medical device lead firms were found to be leveraging India’s strengths in software design, electronics system design and data-analytics capabilities for co-developing their software-embedded ‘health systems’ and medical solutions, which are patented and marketed by the EU-based lead firms or their foreign subsidiaries abroad back to India. Thus, even when services exports – primarily contributed by increased R&D/software development exports – from Indian subsidiaries went up with increasing digitalisation and intelligentisation, significant and increasing shares of the revenue generated by them were found to return to the lead firm group in the form of net forex outflows to the holding company, ultimate holding company and fellow subsidiaries abroad. This was found to occur through the imports of proprietary software-embedded medical devices and equipment (as captured in import supplies dominated by the lead firm group) apart from the higher-valued proprietary software platforms, operating systems and the like (as services imports) from related parties abroad.

Such outcomes in value distribution within digitalising GVCs materialise because patent systems prohibit the patentability of ‘computer programme per se or algorithms’ (SFLC 2022; Joseph and Dhar 2019).[26] The Indian Patent Office and the European Patent Convention (EPC) also exclude computer programs ‘as such’ from patent protection. However, in both jurisdictions, inventions involving software are not excluded from patentability as long as they have a technical character. In the case of India, while algorithms as such are not patentable, they can be patented if the claims in a patent application establish a technical process or achieve a technical effect caused by the interaction between the novel software and the hardware.[27] Similarly, claims for ‘system’ patentability are also allowed in India, provided that different components of the system interact with each other to produce a technical or real-world effect (EPO n.d.). In the EU, inventions involving AI are considered ‘computer-implemented inventions’ (CIIs), with the Guidelines for Examination in the EPO (Section F-IV, 3.9) defining CIIs as inventions that ‘involve computers, computer networks or other programmable apparatus, whereby at least one feature is realised by means of a program’.

In other words, while computer programs and algorithms (and, similarly, AI) are excluded from patentability, the manner of the exemptions allowed under the existing patent laws imply that they are patentable when they are embedded in systems, medical devices, equipment and the like or in production automation machinery or programmable apparatus. Such proprietary ownership over their software-embedded devices and equipment enables lead firms to retain high value shares within their own networks while digitalising their value chains. These findings are supported by Benjamins et al. (2023), who showed

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[25] For instance, global electronic majors (e.g. Texas Instruments, Cadence, Motorola, Microsoft, GE, Philips, HP, Accenture, DELL, CISCO, Oracle, Adobe, SAP and Google) began setting up technology development centres in India beginning in the late 1980s (Warerkar 2020). See also Basant and Mani (2012), Patra and Krishna (2015) and Joseph et al. (2019).

[26] See also Medical devices and diagnostic inventions in India: patentability requirements – Lexology, and IP protection for medical devices in India increases | IP STARS.

[27] Opcit.

that two of the leading EU medical imaging equipment firms ranked among the top five international companies, which accounted for the greatest shares in the increase of AI- and ML-based patents in health care during the period between January 2012 and July 2022.

8. Implications and policy suggestions

Post-pandemic supply chain realignments in the global medical electronics industry resulting from geopolitical factors and the industrial policies adopted by major countries to improve supply chain resilience proceeded gradually until 2023.[28] Even as MNCs accelerate their search for greater supply chain diversification amidst growing geopolitical uncertainties, two other factors are likely to lead to increased interest by medical device MNCs to gradually expand operations in India:

(i) increasing digitalisation of medical device value chains; and

(ii) foreign investment-friendly policies in India to support local production.

The extensive and in-depth standardised firm-level case studies in this paper have showed an expansion in software development and software services happening in the Indian subsidiaries of EU-based MedTech corporations. This arises from the increased role of software development services for the optimisation of processes across digitalising GVC segments as well as for product design and development. The leading EU medical device subsidiaries are leveraging India's strengths in software design, electronics system design and data-analytics capabilities for the co-development of their expanding range of innovative 'intelligent' health 'systems', medical devices and value-added service offerings. It is the software that provides the ability to turn digital data into intelligence and creates the analytical and predictive power for new generic and customised products.

While data-centric software development and innovation in the medical devices industry involves the joint creation of innovations by subsidiaries in India and related parties abroad, due to the nature of the patenting regime, lead firms with advanced algorithms for data mining and analytics own the IP for the new digitalised products (i.e. devices/equipment and services) developed using Indian and other data. This means that increasing digitalisation has a significant impact on the distribution of gains within GVCs, which will continue to be in favour of lead firms. Even when the smart products are domestically produced in subsidiaries across the lead firm's network nodes, subsidiaries in countries like India may witness an increase in net outward payments to related parties abroad for both goods and services in the form of:

(i) proprietary software-embedded equipment and devices; and (ii) proprietary embedded technologies, software solutions, platforms and the like (Francis 2023).[29]

India's recent industrial policy changes are therefore unlikely to have a significant impact on the value shares of EU-based lead firms in their medical electronics GVCs unless there is a paradigmatic shift that builds up hardware-software synergies nationally.[30] As many EU and other countries have successfully practised for decades, government procurement of indigenously developed software-embedded devices and equipment has a critical role to play in this strategy. This, in turn, requires that the EU must not include government procurement-related policy constraints in its trade and investment agreements with India.

[28] The findings are based on global data until 2023 and Indian data until FY 2023/2024.

[29] Such outward payments will be in addition to payments related to foreign-owned digital infrastructural layers, such as telecom networks, cloud infrastructure and platforms (Francis 2023, 2025).

[30] This argument was originally made in Francis (2023, 2025).

India's potential role as a large market and the intrinsic nature of data-centric innovations means that its role in GVCs for R&D and software development is likely to increase further. India's attractiveness also derives from the large volumes of data that networked intelligent devices in the world's second most populous country provide access to, given the latter's critical role in training algorithms and generating digital intelligence.

However, non-personal data continues to be treated by the EU – implicitly and automatically – as the private property of data processors, and first movers are allowed to make exclusive claims over all possible future uses of the data collected (Gurumurty and Chami 2022).[31] This is the prevailing business model that GVC lead firms have utilised to garner the large value share within digitalising value chains.

While the de facto 'ownership' of data and the ensuing monopolisation of the intelligence advantage by lead platform corporations[32] have been acknowledged by regulatory authorities in the EU, the fact that lead firms in manufacturing industries are adopting similar anticompetitive business strategies needs to be incorporated into public policy. This calls for acknowledging that major manufacturing sector lead firms are also developing software platforms as part of an important strategy to take on the data lead of Big Tech firms in the cloud, internet search and e-commerce domains.

In the medical device industry, such software platforms and the software/algorithms embedded in them are continuously gathering and analysing data not only on the usage and operations of the associated equipment (i.e. machine-to-machine data), but also that of patients, care providers, healthcare organisations and, in fact, the entire health sector. These lead firms are also involved in various kinds of collaborations with public universities, research institutes, private firms, government agencies, suppliers and clients. Leveraging vast amounts of data through different strategies gives them a huge advantage by enabling these firms to keep refining the training of their data-analytics algorithms. This, in turn, helps them to design better and more 'intelligent' healthcare products.

The powerful economies of scale and scope enjoyed by first movers implies that the dominant market positions occupied by such EU-based lead firms in the medical device industry may become even more entrenched. This is likely to be the case – especially in the diagnostic imaging equipment segment – given the already existing patent concentration within the two major EU-based lead firms. The competitive dynamics of data-centric innovations may give them first-mover advantages in other segments of the industry as well.

The resulting high market concentration is likely to pose tough challenges to new entrants (and especially SMEs) both in India and the EU. Investing in data management (e.g. networking, data storage and computing) and access is particularly important in the age of generative AI.[33] Without access to similar and expanding sets of data to train algorithms/AI models, the SMEs and other small socioeconomic actors (including the public sector) will not be able to create better insights and more

[31] In most countries, non-personal data falls outside the jurisdiction of current data regulation. 'Personal data that is anonymised and machine-observed data that does not have personal identifiers at the point of collection are treated [by the EU] as alienable 'non-personal data', whose free and unrestricted flows as an economic object must be maximised for the development of the data market. In this approach, except in the case of wilful/inadvertent deanonymisation that reveals personal identifiers, there are no claims that citizens can make on data processors with respect to non-personal data processing' (Gurumurty and Chami 2022: 7).

[32] See Rikalp (2022) and Gurumurty and Chami (2022).

[33] Greenlight Guru (2024)

intelligent products that could potentially compete with those of these market leaders and generate greater public value. Even though advances in open-source technologies provide web-based information systems for the collection, storage and analysis of public health data, the costs of data acquisition, cleansing and anonymisation are enormous (Sridhar at al. 2022).

This means that both India and the EU (and other regions and countries) are likely to confront issues surrounding healthcare-sector monopolisation by market-leading firms. Even as digitalisation of health care accelerates on the promise of improved patient care and reduced risks, the current models of digitalisation may lead to adverse implications for equitable access to health care,[34] which is an especially chronic rights issue in India.

India has been supporting foreign medical device companies to expand their revenue by being 'co-creators in innovation' as well as through different modes of fiscal support from the government. However, there is very little sharing of the benefits generated through this business model. As the role of generative AI expands, it is not evident whether even the domestic value addition through the relatively large employment of skilled software labour will be sustainable.

India must therefore design and implement revenue-sharing mechanisms that will enable the country to benefit from the value being created by the data lakes generated in India, which GVC lead firms use to innovate and generate premiums. The discussions on the taxation of globally operating firms on the basis of their revenues generated in respective geographical territories is very relevant in this context.[35] However, the problems in terms of corporate governance and taxation[36] in the context of transfer-pricing issues are well known.

Therefore, more fundamentally, both the EU and India must enable a rights-based resource ownership regime for data under the 'data semi-commons' framework, as proposed by Gurumurty and Chami (2022). This framework starts with 'the legal recognition of data as inappropriable social commons with commensurate freedom of open use for all, balanced by limited privileges for data producers' (ibid.: 14). Only this kind of data-governance framework will ensure the fair and equitable distribution of the gains from the advancing intelligentisation of value chains for India and other countries integrated into rapidly digitalising medical device GVCs.

[34] The rapid expansion of networked and interoperable electronic health records and digitised personal health records also raise significant issues related to the privacy rights of individuals and the potential for harm against communities and groups. See Sridhar et al. (2022) for a discussion on the challenges associated with the use of non-personal health information. See also Malhotra et al (2021) and Pandey (2024) for a discussion of the challenges faced under India's Health Data Management Policy. It has been pointed out that India's privacy framework around health data is weak in design as well in accountability mechanisms vis-à-vis the secondary use of digital health data for research and policy planning, particularly by private firms.

[35] The discussions in Chowdhary and Diasso (2023) on the significant revenues that can be generated by developing countries if the United Nations can provide clear international tax guidelines that allow withholding taxes (WHTs) on computer software payments are also relevant.

[36] Verma (2023)

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