

IRAN'S EXPERIENCE IN DEVELOPING HIGH-TECH MEDICAL INNOVATIONS AND THE PATH AHEAD

Kiarash Fartash, Shahid Beheshti University

Mahdi Elyasi, Allameh Tabataba'i University

Over the last two decades, the Islamic Republic of Iran has made significant progress in the health and medical sector, expanding both in market size and coverage. The ever-growing medical innovation ecosystem is supported by ongoing policy framework developments, incentives, and regulatory bodies. In addition, the emergence and development of the biopharma sector in Iran, which is a complex, high-tech sector, hosts several successful local export firms.

The focus of this chapter is the evolving pro-innovation ecosystem of the health sector in Iran. This ecosystem has achieved effective policy and regulatory synergies and has supported the supply- and demand-side of medical innovation. Demand-side innovation has paved the way for advanced endogenous medical innovations in Iran while, historically, conventional medical solutions were not easily accessible due to sanctions or affordability.

The chapter provides policy- and firm-level recommendations to highlight common success factors of medical innovation, based on the mentioned case studies and field interviews conducted with firms and policymakers. In addition, we discuss ways to mitigate impediments to further innovation.

Advancing health coverage, research, and innovation

Iran's improvement in health-related indicators has been consistent and promising. According to the Human Development Index (HDI), the mean years of life expectancy in Iran has increased dramatically from 51.1 in 1980 to 76.2 in 2018, an approximate 25-year increase over the past three decades.¹

From a science, technology, and innovation (STI) perspective, Iran has boosted scientific production in areas such as nano-tech, biotechnology (biotech), biomedical engineering, bioengineering, biomaterials, and biophysics. For instance, rankings have improved from either non-existent or around 60th position in the late 20th century to 4th in nano-tech, 12th in biomedical engineering, 9th in bioengineering, and 8th in biomaterials, in 2017.²

STI efforts to transform the medical and health sector resulted in synergies between human capital supply, technological regime, and the innovation ecosystem. In addition, state-of-the-art medical innovation continues to advance through expanding medical education, support for university- and firm-level research and development (R&D), and the creation of an evolving pro-innovation, medical policy framework. The medical innovation ecosystem—supported by over 19,300 faculty members from medical universities and research institutes, and responsible for roughly 37,450 scientific papers and 1,589 patent applications in 2018—has the capacity to host various research activities.³

In 2018, the National Medical Device Directorate (NMDD) reported that the Iranian medical equipment market was worth US\$2.5 billion, of which 30% belonged to over 1,000 domestic firms.⁴ On a global scale, 56% of 500,000 medical equipment items available in the world market have Iranian-made versions.⁵ In pharmaceuticals, around 70% of Iran's US\$4.5 billion market is domestic products and, in 2018, 97% of pharmaceuticals consumed in the country were manufactured locally.⁶ Furthermore, in 2018, 67% of the active pharmaceutical ingredients (APIs) used to produce drugs in Iran were made locally.⁷

Boosting the medical innovation ecosystem through policy framework

Medical innovation policy framework

Iran has integrated its healthcare system with medical education to improve health conditions. Sixty-five medical universities, responsible for both health services and medical higher education, constitute a decentralized network of provincial healthcare bodies that are managed centrally by the Ministry of Health (MOH). This network has contributed to the creation of a strong healthcare system characterized by extensive and convenient access to medical services, both in rural and urban areas. In each province, public medical universities provide medical services, administer vaccinations, and assist in fighting local diseases. Because of countrywide distribution, the network has the ability to undertake endogenous research and innovation and train medical cadres based on local demands and epidemic situations.

Since the early 1990s, the MOH has followed a five-year national development plan (FYDP), revised in five-year intervals, as the principal policy framework for enhancing Iran's health sector.⁸ In 2014, during the 5th FYDP, the MOH initiated and funded the Health Transformation Plan (HTP), which has resulted in a sharp decrease in the share of medical expenses paid by patients—from an initial out-of-pocket expense of 37% of overall patient health costs to 5% for rural citizens and 10% for urban citizens. The key health policy for the 6th FYDP (2016 to 2021), is dedicated to providing universal health coverage using coordinated public insurance schemes governed by the MOH. According to the MOH, 100% of urban and 98% of rural areas in Iran now have access to at least primary medical services.⁹

Policies supporting the supply side of medical innovations:

In the 1980s, lack of access to foreign drugs and medical equipment became a threat to national health and well-being in Iran. For this reason, Iran adopted import substitution policies and promoted local production. In 2011, the Food and Drug Administration of Iran, under the MOH, introduced a set of regulations to support the supply of local medical equipment and pharmaceutical products. These regulations ban or limit the import of foreign drugs and medical equipment to 10% of market share when a similar local product becomes available. When local products are available, public health insurances do not cover the costs of foreign drugs for patients, but they do cover from 90 to 100 percent of the total cost of the domestic equivalent.¹⁰

Imposing high tariffs on foreign drugs and/or medical equipment, when an equivalent is locally produced and developed to meet domestic demand, is also a tool to support medical innovation. In cases where the domestic equivalent is not available, low tariffs of 4% are set on foreign products. However, when the domestic equivalent is available and verified by the MOH, these tariffs increase from 4 percent to between 32 to 45 percent, and public health insurances will no longer cover patient medical

expenses for these products.¹¹ Supporting the local production of drugs has successfully promoted domestic product share in the national pharmaceutical market, from 63.4% in 2009 to 78.6% in 2018.¹²

But, this approach will not guarantee the success of medical innovations in the long run. Policymakers and firms are aware of the possible harmful consequences of import substitution on future medical innovation.¹³ Hence, exporting medical innovations is strongly encouraged by recent policies, such as the law for supporting knowledge-based firms (KBFs). This law, approved by Parliament in 2010, was introduced as a mechanism to encourage the supply side of technology and innovation in high-tech firms, benefitting the health sector.¹⁴ The Vice-Presidency for Science and Technology (VPST) administers this law and the Innovation and Prosperity Fund (IPF) channels funds to the innovative and technological activities of eligible KBFs. Eligible firms include private entities that produce high-tech products, require in-house R&D and skilled employees, are high value-added, and are difficult to imitate. In early 2019, US\$85 million had been allocated in the form of low-interest rate loans to fund 474 medical innovation projects by the IPF. Additionally, the VSPT supports 4,300 KBFs, of which approximately 1,100 KBFs are private health and medical sector firms.¹⁵

Policies supporting the demand side of medical innovations:

Policy efforts are also in play to push medical innovation on the demand side (Figure 16.1). One example is the Iran Lab Expo (ILE), initiated by the VPST in 2012 to promote technology & innovation (T&I) development by private firms.¹⁶ Depending on the depth of domestic capabilities to design and manufacture independently as well as the technological complexities of the lab equipment and/or device, public buyers, such as universities and hospitals, are entitled to a VPST subsidy of between 10 and 40 percent of total cost. To encourage and stimulate demand from private buyers, the ILE grants low-rate, medium-term loans of up to US\$120,000.¹⁷ In addition, the Heyat Omana Arzi (HOA) plays a critical role, on behalf of the MOH, to procure and supply medical disposables, devices, and equipment to public hospitals and medical centers. The HOA also provides patients with prerequisites for domestic treatment, minimizing dependency on foreign treatment and medical expenditure.¹⁸

Medical innovation ecosystem and its key actors

A community of vibrant young entrepreneurs in Iran has pioneered state-of-the-art medical innovations. Their efforts are reinforced by evolving government support in the form of tariff barriers, tax exemption, and guaranteed purchase. The law for supporting KBFs has played a key role in empowering the medical innovation ecosystem. There are 4 dedicated S&T parks, 78 incubators, and 739 research centers in a variety of medical fields affiliated with the MOH.¹⁹ Furthermore, 68 incubators and 27 S&T parks, under the supervision of the Ministry of Science Research and Technology (MSRT), specialize in supporting medical and pharmaceutical sectors.²⁰ As of February 2019, medical related KBFs—approximately 1,100

FIGURE 16.1

Key policies and actors supporting medical innovation in Iran

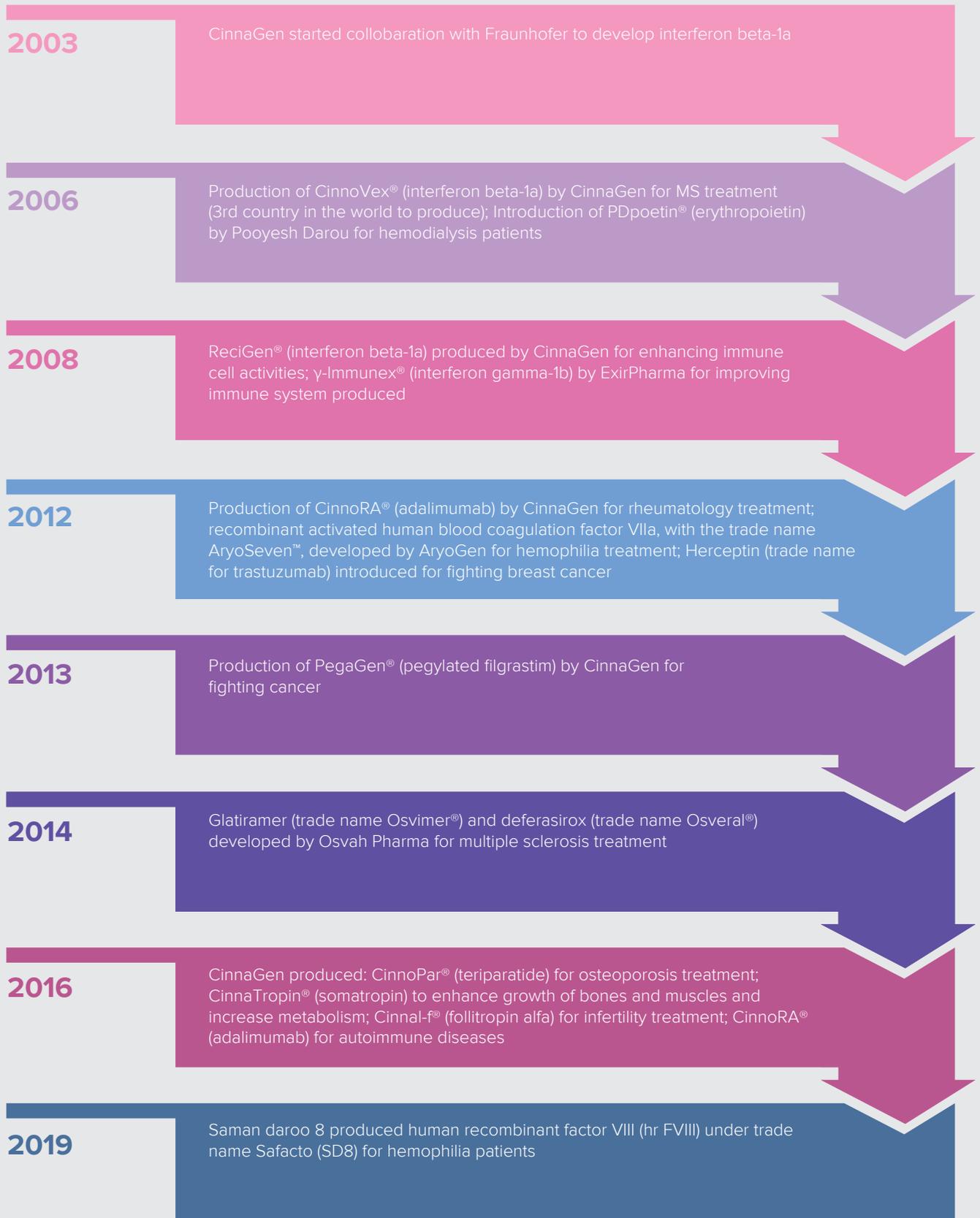


■ Regulators ■ Supply side ■ Intermediaries ■ Demand side

Sources: Ministry of Health and Medical Education, 2019; Institute for Trade Studies and Research, 2017a,b; UNCTAD, 2016.
 Note: Data extracted from information provided by actors on their websites and available periodical reports.

FIGURE 16.2

Iran's biopharma evolution and key products



Source: Institute for Trade Studies and Research, 2017a.

Note: Data in this figure have been partially extracted from the information provided on websites and periodical reports of Iranian biopharma firms.

firms—are engaged in T&I development, including 200 biotech firms, 255 advanced pharmaceutical firms, and 175 medical equipment firms.

Accelerators and innovation centers are the most recent mechanisms used by the government and, in particular, the VPST to expand and increase the efficiency of KBFs. To date, 29 accelerators and 79 innovation centers are operational and open to medical innovators and entrepreneurs. PersisGen, established in 2016 by CinnaGen, is an example of a medical accelerator—perhaps the most successful and prominent in Iran—which provides corporate venture capital (CVC).²¹ As of February 2019, PersisGen had hosted 15 teams to work on 20 advanced biopharma innovations, of which 4 teams had reached the final product.

The major funding institution, IPF, supports medical innovation mainly by granting loans—US\$85 million to date—to facilitate KBF efforts in developing medical equipment, biotech, and advanced drugs. Another active funding body, the Iran Biotech Fund (IBT), was founded in 2015 by the Biotech Development Council, an affiliate to VPST, and is supported by joint investment from the private sector.²² At the end of 2017, IBT had invested US\$4 million in venture capital (VC) in 24 innovative ideas and, from its inception, has granted 350 loans—total of US\$11.7 million—to a wide range of innovative biotech ideas and projects.

Biopharma in Iran: a unique and advanced sector

Over the last two decades, Iran's STI efforts, accompanied by policy support, in biotechnology and pharmaceuticals has resulted in a rapid increase in biotechnology scientific publications—ranking 9th in bioengineering, 9th in applied microbiology and biotechnology, and 13th in biotechnology in 2017.²³

Iran's history in biopharma dates back to the 1920s when the Pasteur and Razi Institutes, initially specializing in producing vaccines and then biotechnology, gradually diversified into biopharma. In the 1980s, the National Institute of Genetic Engineering and Biotechnology and the Iranian Red Crescent boosted biopharma development. The turning point, in the 1990s, came when the government supported and collaborated with foreign countries, including Cuba, to train Iranian scientists and researchers. Shortly after, trainees, along with other ambitious scientists and researchers, formed an inner circle of Iranian biotechnology and biopharma pioneers that revolutionized biopharma in Iran by founding firms such as CinnaGen, ExirPharma,²⁴ Ronak Daru,²⁵ Pooyesh Darou,²⁶ Osvah Pharmaceutical,²⁷ Saman daroo 8,²⁸ Zist Daru Danesh,²⁹ and AryoGen.³⁰ International collaboration and STI linkages in biopharma have been instrumental to the success of medical innovation in this sector, but global collaboration barriers, such as sanctions, remain a challenge. Key events in the course of biopharma development in Iran are shown in Figure 16.2.

Currently, there are 20 Iranian biopharma firms, 7 of which are KBFs supported by the VPST. Of the 22 drugs that these firms produce, at least 10 are considered state of the art. The

local development of biopharma products has resulted in savings of US\$980 million annually, created over 4000 quality jobs for Iranian scientist and researchers, and is accountable for roughly US\$60 million of Iran's pharmaceutical exports—of which a sizeable share is exported to Europe.³¹

Although the quantity of biopharma products sold in the local market is not comparable to conventional drugs, three of the top five pharmaceutical manufacturers—in terms of total sales in 2017—are CinnaGen, ExirPharma, and AryoGen. These three manufacturers hold 11.2% of the pharmaceutical market share. In the same vein, AryoTrust™ (Trastuzumab for breast cancer treatment), Cinnovex® (interferon beta-1a for multiple sclerosis treatment),³² and Zytux™ (Rituximab for fighting cancer and autoimmune diseases developed by AryoGen) are among the top 10 drugs sold in 2017.³³

Cases of advanced medical innovations in Iran

The increasing and developing market for pharmaceuticals and medical equipment—fueled by local technological and innovative efforts, continued public support, and an influx of interested young medical entrepreneurs—reflects the dynamics of medical innovation in Iran. Three noteworthy cases of advanced medical innovations are explored below, whilst looking at the main drivers of success and challenges as well as the barriers to further innovation.

Medical devices and equipment incubator (MDEI)³⁴: The MDEI, based at the Imam Khomeini hospital in Iran, hosts several promising firms that are equipped to design and manufacture advanced medical equipment and develop cutting-edge technologies.³⁵ One of these firms, Sina Robotics and Medical Innovators Co, a KBF, develops Sina—a robotic telesurgery system which assists surgeons in sophisticated surgeries.³⁶ A guaranteed purchase order by the government in 2009 drove Sina's development, which had commenced in the early 2000s, and by 2013, the first generation of Sina became available.³⁷ The improved Sina, equipped with added force feedback capability and more, has advantages over similar products on the market and has gained significant international interest.

With over 30 patents registered on Sina, the drivers of its success include: the government order, which overcame sanctions that had made the system locally inaccessible; internal R&D capabilities; the availability and dedication of qualified and talented human resources; and the proximity to clinical practice. Sina creators have faced lack of interest from private investors and delays in allocating public support funds.³⁸

Tanin Pardaz Pasargad (TPP)³⁹: TPP, a KBF, specializes in designing and manufacturing the external unit of the cochlear implant system (CDS) called TAPPS+.⁴⁰ Established as a company in 2013, the founders began research efforts almost two decades earlier. After several generations of prototypes, TAPPS+ was introduced in 2016 with the expectation of release to the public in 2019. TPP is one of five firms in the world offering a similar product and interest from leading firms to collaborate on TAPPS+ is growing.

One complementary asset to TAPPS+ is executing the transtympanic promontory stimulation test (TPST) using the ETT device.⁴¹ TPST is a tool used to evaluate the effectiveness of cochlear implant surgeries, especially in patients with weak auditory nerves and those who have been deaf for a prolonged period. Another significant innovative product by TPP uses *deafness recognition by baby crying*, which offers free and efficient evaluation of infant cry signals to detect deafness in babies.⁴²

Although TPP provides a number of innovative products, a few challenges inhibit TPP's ability to realize its efforts. For example, complying with local standards is a complicated and lengthy process. Moreover, there is a need to implement a proactive marketing strategy and to increase stakeholder involvement—in particular, sales representatives of foreign CDSs.⁴³

Behyaar Sanaat Sepahan (Behyaar)⁴⁴: Behyaar, founded in 2003, is a KBF specializing in radiotherapy and radiography solutions.⁴⁵ In 2010, the founder—a young engineer active in linear accelerator (LINAC) maintenance in Isfahan hospitals—decided to build a locally made LINAC. Given Iran's need to produce 240 LINACs by 2025—almost three times the available amount—it was a wise decision. In 2017, relying on in-house R&D, Behyaar built the OMID 6MV, a medical linear accelerator which puts Iran among roughly 10 countries involved in building medical LINACs. Furthermore, LINAC design and development led Behyaar to develop the first Iranian-made cargo inspection system, called Sayyad, designed to inspect loaded trucks, containers, and vehicles at ports, airports, and borders. It uses a dual energy LINAC that penetrates up to 320 millimeters in steel.

Despite numerous failed attempts owing to product complexity and lack of available expertise, Behyaar transformed from a company that used to build simple hospital beds to one designing optical lenses, 3D water phantoms, X-ray systems, image viewing systems, and U-arm ceiling radiology systems. Overcoming these challenges required persistence, risk-taking and in-house R&D. Yet, Behyaar faces a barrier to further innovation and commercialization—the prolonged process to acquire approvals for equipment using radiation. This process can be longer than the product development period itself.⁴⁶

Conclusions and policy recommendation to strengthen medical innovations

Over the past two decades, several domestic firms have pursued medical innovations, some of which are more advanced and user-friendly than world-leading products—particularly in the biopharma and medical equipment sectors. These innovations were driven by the necessity to fulfill local demand for drugs and medical equipment when international solutions were neither accessible nor affordable. Providing all citizens with affordable universal healthcare and medical services that are recognized by government and firms encourages the realization of medical innovations.

National necessity, foreign currency saving, self-reliance, ambition, public incentives, and public policies have afforded Iranian medical researchers and entrepreneurs the opportunity to design and develop medical equipment and advanced drugs. Despite the sizeable share of local medical products in the Iranian market, further domestic innovation requires economies of scale that cannot be attained solely by tariff barriers and market protection. To achieve economies of scale, local firms must export their products. It is imperative that the government systematically continues to facilitate and monitor the export of medical products.⁴⁷

Even with many successes, Iranian firms face barriers to continued innovation, such as lack of customized public support, branding, international acceptance, and standards. Overcoming these barriers would require establishing a coordinated policy framework and creating synergies between current policies. Several policy recommendations to strengthen medical innovation and increase economic impact include:

- The scale of the domestic health market is not large enough to justify the development of costly and long-lasting medical innovations. To deter exclusive reliance on the domestic market, strong policy measures should be established to encourage local firms to export their products. The export process can be lengthy, which suggests that enhancing accreditation infrastructure and standardization facilities would encourage exports more than, for example, access to low-rate loans.
- Government support of local firms has proved to be beneficial; therefore, government should increasingly trust and encourage local firms to engage in high-end medical innovations.
- As leading firms play an important role in the economy, the government should adequately support them in the development of medical innovations and the creation of a dynamic knowledge regime. This would entail enforcing fewer formalities on leading firms, facilitating medical exports, and assisting with the import of raw materials and production equipment. To this end, the Vice-Presidency for Science and Technology has devised *Pioneer KBFs*, a direct communication line to gather information about the needs and challenges of leading firms and to address these in the shortest time possible. The Ministry of Health is encouraged to adopt a similar approach to facilitate and support leading firms.
- According to local firms, some foreign firms that import medical equipment do not face the same difficulties experienced by locals, specifically in obtaining permissions and certifications needed to launch their product in the market. Giving procurement and tender priority to domestic products and firms over the foreign equivalent should be reinforced by the Ministry of Health. In other words, government should take measures to limit foreign medical imports, especially products of lower quality, as a means to encourage local firms to engage in medical research and innovation, as is the case with many other countries.
- Current funding systems that support medical innovation are largely risk-averse. Although institutional mechanisms—

such as the Iran Biotech Fund and the Innovation and Prosperity Fund—have helped to mitigate innovation risks, there is a need to enhance efficiency and availability of funding, particularly venture capital. Formulating a comprehensive technology and innovation funding system in the health sector by socializing some of the inherent risks—for example, through guaranteed public procurements and grants in the medical innovation process—could be the starting point to attract more private funding.⁴⁸

Notes:

- 1 United Nations Development Programme, 2018.
- 2 StatNano, 2019; Scimago, 2017.
- 3 Ministry of Health and Medical Education, 2019.
- 4 Masaeli, 2018a.
- 5 Masaeli, 2019.
- 6 Food and Drug Organization, 2017; Food and Drug Organization, 2018; Pirsalehi, 2019.
- 7 Pirsalehi, 2019.
- 8 The five-year development plan (FYDP), revised in five-year intervals, is the main national policy to steer Iran's economic development, involving all national sectors, including the health sector.
- 9 Ministry of Health and Medical Education, 2019.
- 10 Institute for Trade Studies and Research, 2017a; Institute for Trade Studies and Research, 2017b.
- 11 Institute for Trade Studies and Research, 2017a; Institute for Trade Studies and Research, 2017b.
- 12 Jahanpoor, 2019.
- 13 Negotiation for ascension to the WTO is in progress; Iran may eventually have to let go its support for import substitution by wall of tariffs according to page 49 of UNCTAD, 2016.
- 14 UNCTAD, 2016.
- 15 Information on KBFs and their fields of activity can be found at <https://pub.daneshbonyan.ir/> (Accessed in March 2019; In Persian)
- 16 More information about ILE procedures and statistics can be found at <http://iranlabexpo.ir/index.php?lang=2>
- 17 Iran Vice-Presidency for Science and Technology, 2019.
- 18 More information can be found at <http://hoa-ir.com/en/Page/2677/About-Us.html>
- 19 Vatanpour, 2017.
- 20 Ministry of Science, Research and Technology, 2018. By February 2019, 195 incubators and 44 S&T parks are under the supervision of the Ministry of Science, Research and Technology.
- 21 More information about CinnaGen and PersisGen can be found at <http://persisgen.com/en> and <https://www.cinnagen.com/>
- 22 More information on IBT approach and initiatives can be found at <http://en.biotechfund.ir/>
- 23 Scimago, 2017.
- 24 More information can be found at <http://www.exir.co.ir/index.php/en/>
- 25 More information can be found at <http://ronakpharm.com/>
- 26 More information can be found at <https://pooyeshdarou.com/>
- 27 More information can be found at <http://www.osvahpharma.com/en>
- 28 More information can be found at <http://samandaroo.com/english/>
- 29 More information can be found at <http://zistdaru.ir/?lang=en>
- 30 More information can be found at <http://www.aryogen.com/EN/index.html>
- 31 Institute for Trade Studies and Research, 2017a.
- 32 Multiple sclerosis, or MS, is a long-lasting disease that can affect brain, spinal cord, and the optic nerves in eyes. It can cause problems with vision, balance, muscle control, and other basic body functions. MS insulates covers of nerve cells in the brain and spinal cord are damaged.
- 33 Food and Drug Organization, 2017; Food and Drug Organization, 2018.
- 34 More information on the incubator activities can be found at <http://ic-med.tums.ac.ir/>
- 35 Imam Khomeini hospital is a medical institution affiliated to Tehran University of Medical Sciences
- 36 More information about Sina Robotics and Medical Innovators can be found at <http://sinamed.ir/>
- 37 PARSISS Integrated Company, established in 2006, is another competent firm located at the MDEI. PARSISS has successfully developed the Parseh surgical navigation system (SNG) that was introduced in 2011. Thanks to Parseh, Iran is among only seven countries in the world manufacturing SNG. Parseh market share in Iran is about 80 percent and its market price is between 30 and 50 percent of foreign SNGs. The main success factors of Parseh are building trust between PARSISS team and surgeons, mastering SNG core technologies by in-house R&D, and proximity to clinical practice; based on Interview with PARSISS business development manager, Mr. Javad Hasani, conducted by authors in 30 January 2019.
- 38 Interview with the CEO of Sina Robotics and Medical Innovators, Mr. Alireza Mirbagheri, conducted by authors in 27 January 2019.
- 39 More information about TPP can be found at <http://taninpardazco.com/en-us/>
- 40 More details on TAPPS+ can be found at <http://taninpardazco.com/en-us/Products/Tapps>
- 41 More details on ETT can be found at <http://taninpardazco.com/en-us/Products/ETT>
- 42 More information on baby crying test can be found at <http://taninpardazco.com/en-us/Activities/Hearing-Detection/BabyCrying>
- 43 Interview with Tanin Pardaz Pasargad CEO, Ms. Samira Kooshkestani, conducted by authors in 28 January 2019; Interview with Tanin Pardaz Pasargad founder, Mr. Hamed Sajedi, conducted by authors in 28 January 2019.
- 44 More information about Behyaar is available at <http://www.behyaar.com/en/>
- 45 More details on Behyaar products is available at http://www.behyaar.com/?page_id=3299
- 46 Interview with Behyaar's CEO, Mr. Navid Nejatbakhs, conducted by authors in 23 January 2019.
- 47 Masaeli, 2018b.
- 48 Mazzucato, 2015.

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