Journal of Pharmaceutical Enterprise

J Pharm Enterp. 2026;1:e2026001
https://pharmenterprise.org/articles/turkiye-entry-protocol/

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RESEARCH PAPER

Entering Türkiye: a staged protocol for Iranian pharmaceutical companies, with the case of CinnaGen

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Received	Accepted	Published	Article
27 November 2026	27 November 2026	27 November 2026	Volume 1, e2026001

ABSTRACT

Iranian pharmaceutical manufacturers looking to Türkiye meet a regulated market and a sanctions environment at once. The state sets prices, one public insurer pays for most medicine spending, and payments connected with Iran fall under United States and European Union sanctions law. Theories of entry mode and staged internationalization offer no procedure with decision gates for such an entrant.

This single-case study read, from public documents only, the Turkish trade-registry record of CinnaGen İlaç from 2014 to 2026, a company founded by the chief executive of an Iranian biopharmaceutical group. It was set against Türkiye's rules on licensing, inspection of foreign sites for good manufacturing practice, pricing, reimbursement and company law, and against other foreign manufacturers' entries.

A Singapore company held 90% of CinnaGen İlaç from 2018, a Turkish individual all its shares from 2024, and a private equity fund 55% by January 2026. In the notices read, set-off of shareholders' receivables paid 148,490,800 of the 179,950,000 Turkish lira by which capital grew from 2014 to 2020. The company was renamed three times and continues, with its plant. The article derives a protocol of ten stages, each closed by a gate that passes, holds or stops: purpose and fit; compliance and banking feasibility; market, price and reimbursement case; regulatory route; entry mode; legal vehicle, ownership and control; financing; build, license, price, list; export base; and review of scale, hold or exit. The lessons are to fix Türkiye's role first, obtain legal and bank clearance in writing before any other commitment, document ownership up to natural persons, fund through channels banks will process, and plan exit from the start.

The evidence is one case in public documents. The protocol was derived and has not yet been tested on an entry, and it reflects the rules in force in November 2026.

Keywords: Türkiye; Iran; pharmaceutical industry; foreign market entry; sanctions; case study

1. Introduction

Iranian pharmaceutical manufacturers work under sanctions that bind on banking, payments and imported inputs. Medicines are formally exempt, yet restrictions on money transfers and insurance have forced Iranian companies to pay cash in advance for imported medicines and raw materials, and credit for such imports has been extremely difficult to obtain [1]. The industry is exposed at exactly that point. Domestic manufacturers produced 96% of the country's generic medicines but relied on imported raw materials and active pharmaceutical ingredients, as Setayesh and Mackey report from earlier sources [2]. The same authors cite a currency that lost two-thirds of its value against the US dollar from 2010, inflation of 40–50% in 2013 and medicine price rises of 30–40% [2]. Supply was affected. In a sample of 26 medicines and medicine groups for non-communicable diseases, market availability fell significantly for 13 after the banking sanctions of 2011 and the sanctions on the Central Bank of Iran in 2012 [3]. Imported drugs, and drugs made from imported raw materials, were the more likely to be affected [3]. The industry has nonetheless built real capability. By 2012, newly established, science-based Iranian companies were manufacturing biopharmaceuticals, and about six non-originator biopharmaceuticals had been registered in Iran since 2003 through a national, case-by-case route [4]. In the same author's view, biosimilars developed outside the EU and the US had a very low chance of approval as biosimilars by the EMA or the FDA [4].

Firms from such home economies have reasons to go abroad beyond selling more. Luo and Tung describe an international springboard, a strategy by which a firm from an emerging economy catches up with established rivals relatively quickly by seeking strategic assets and opportunities abroad and by benefiting from favourable institutions in foreign countries [5]. In their account, such firms expand abroad to acquire resources that compensate for gaps in their capabilities and to ease institutional and market constraints at home [5]. Witt and Lewin, writing about advanced economies, treat outward investment as one form of escape, a partial or complete departure from a home business system whose institutions no longer fit a firm's needs [6]. Mathews argues that latecomer multinationals from the Asia-Pacific region internationalised to gain resources through links with external firms, and that partnerships and joint ventures were their usual way of reducing the risk of entry [7]. A constrained home market can also leave a capability that a firm can use abroad. Every foreign entrant bears a liability of foreignness, the extra cost of operating in a country as an outsider to it [8]. Multinationals from developing countries were more prevalent among the largest foreign affiliates in least developed countries with weaker regulatory quality [8]. They still favoured host countries with a stronger rule of law [8].

Sanctions shape how such firms can go abroad. Meyer and colleagues define sanctions as nonmilitary coercive measures imposed by a country or a group of countries against another country, organisation or individuals [9]. Secondary sanctions are penalties imposed on third parties for failing to comply with a sanctions regime, and firms in third countries weigh that risk when deciding whether to deal with a sanctioned economy [9]. The effect on trading partners can be measured. After new EU measures against Iran in January 2012, the monthly number of French firms exporting to Iran fell from 457 to 276, and firms that relied more heavily on trade finance were hit harder [10]. Iranian exporters, for their part, changed where they sold. After the export sanctions of March 2008, they redirected an estimated two-thirds of the export value lost in sanctioning countries to countries that imposed no sanctions [9,11]. Larger and more experienced exporters redirected more, and exporters already present in an alternative destination did so more easily [11]. The move had a price, since unit prices in the first shipment after redirection were 7.4% lower on average [11]. Sanctions also change the decisions of firms already established abroad. Of 22 Western multinationals with subsidiaries in

Russia after February 2022, ten divested, four froze operations and eight stayed [12]. The pharmaceutical firm in that sample froze new clinical trials and new investment while keeping its operations [12].

Türkiye, Iran's neighbour, is a large and regulated destination for an Iranian manufacturer. It was the world's 19th-largest pharmaceutical market in 2024, at USD 11.5 billion, according to a sector report prepared by IQVIA for AIFD, the association of research-based pharmaceutical companies in Türkiye [13]. Medicines produced in Türkiye held 55.4% of the market by value and 92.8% by volume in 2025, in the figures of İEİS, the employers' association of Turkish pharmaceutical manufacturers [14]. The inspectorate of TİTCK, the Turkish Medicines and Medical Devices Agency, has been a participating authority of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), the scheme through which national inspectorates of good manufacturing practice (GMP) co-operate, since January 2018 [15]. Iran's Food and Drug Administration has been listed with the same accession date [15]. Türkiye also favours local manufacture. İEİS dates the country's localisation policy, which favours medicines produced in Türkiye, to 2016 [14], and the European Union challenged that policy at the World Trade Organisation (WTO) in 2019 [16]. Pharmaceutical trade between the two countries already flows mainly one way. Türkiye reported pharmaceutical exports to Iran of USD 92.0 million in 2024 and imports from Iran of USD 1.4 million, in UN Comtrade data [17], and Iran was among the ten largest destinations of Turkish pharmaceutical exports that year [13].

Entry-mode theory explains how a firm chooses its route into such a market. An entry mode is the arrangement through which a firm serves a foreign market, from exporting and licensing to contract manufacturing (producing under contract for another company), joint ventures, acquisition and building its own plant [18,19]. Anderson and Gatignon framed the choice as a trade-off between control and the cost of committing resources, often under considerable risk and uncertainty [18]. A review of the empirical work found that no single mode performs best, while firms whose choices matched theoretical predictions performed better [19]. Hennart argues that the mode depends on how easily the local assets an entrant needs, such as distribution, permits and licences, can be traded, as well as on its own knowledge [20]. Where a permit cannot be bought on its own, acquiring or forming a joint venture with the firm that holds it may be the only access route [20]. Staged-internationalization theory explains entry as a sequence of growing commitments. In the Uppsala model, firms move from exporting through an agent to a sales subsidiary and then to production, because the market knowledge each step needs is gained mainly by operating in the market [21]. The Swedish pharmaceutical firm Pharmacia had sold through an agent or a licensee before setting up its own organisation in eight of the nine countries where it had one by 1972 [21]. The model's authors later stressed that commitment may also decline or stop when performance and prospects are not promising enough [22].

Pharmaceutical firms from emerging economies have entered foreign markets in stages and by acquisition. Indian manufacturers invested abroad mainly through joint ventures before 1990, through joint ventures and wholly owned subsidiaries in equal numbers in the 1990s, and mainly through acquisitions after 2000 [23]. Ranbaxy and Dr Reddy's favoured the acquisition of generic companies in Europe, which gave them product portfolios, sales networks and regulatory capacity [24]. Indian biosimilar makers combined alliances with multinationals, imported technology and plants abroad, and one of them sold biosimilars in emerging markets before seeking approval in the US and Europe [25]. Across 206 Indian pharmaceutical firms, access to foreign technology and foreign finance went with a higher share of foreign sales between 1995 and 2004 [26]. These literatures explain why a firm chooses a mode and in what order it commits [18,19,20,21,22]. They do not offer a staged

procedure with decision gates for a manufacturer from a sanctioned home market entering a tightly regulated pharmaceutical market. The sanctions literature describes its own evidence on firm-level responses as rather thin and its managerial guidance as limited [9].

The case examined here is one such entry. In January 2017 CinnaGen, an Iran-based biopharmaceutical group, announced that it would build a plant in Türkiye through a Turkish company, CinnaGen İlaç [27,28]. In June 2019 the Turkish daily Daily Sabah reported, quoting the company's chief executive, that CinnaGen İlaç had opened a biopharmaceutical manufacturing plant with a research and development facility at Çerkezköy, in Tekirdağ province in north-western Türkiye [29]. The company presented the plant as serving both local and international markets [29]. In 2025 the company then named Yerlika Biopharma described itself as a Turkish contract manufacturer and developer of biological medicines, working from the Çerkezköy Organized Industrial Zone [30]. Section 3.3 traces the company's ownership and names from official Turkish company records.

This article reads the public record of that case, from 2014 to 2026, against Türkiye's rules on medicines regulation, pricing, reimbursement and company law, and against the routes by which other foreign manufacturers entered Türkiye. From that reading it derives a staged protocol for an Iranian pharmaceutical company that is considering Türkiye as a market, a production site or an export base. Each stage ends in a gate, a short set of pass/fail conditions that the company meets before it commits further resources. The protocol is built from public documents only.

2. Methods

2.1 Design

This study follows a single case through public documents. It reads the case against the rules a foreign manufacturer meets in Türkiye and against the routes by which other foreign manufacturers entered the same market, and it uses that reading to build a practical protocol. A case study, in Eisenhardt's definition, is a research strategy that focuses on understanding the dynamics present within single settings, and it can combine qualitative and quantitative evidence [31]. One case can carry such a purpose when it is selected for the information it holds, which Flyvbjerg calls information-oriented selection [32]. He argues that one can often generalise from a single case, depending on the case and how it is chosen, and that an atypical case often reveals more than an average one [32].

CinnaGen İlaç was selected on that ground. It is a Turkish manufacturing company set up by an Iranian biopharmaceutical group, with a public record continuous enough to follow from 2014 to 2026, in official company records, in Turkish law and in the company's own statements [27,30,33]. Such a case suits the building of practical knowledge and propositions. Eisenhardt names concepts, a conceptual framework and propositions as the outputs of building theory from cases, and she finds the approach most appropriate where little is known about a topic [31]. The claims of this study concern what must be in place, and in what order, for one kind of entry. Flyvbjerg leaves to large samples the question of how often a phenomenon occurs in a group and how it varies across cases [32].

2.2 Sources

The core source is the company's record in the trade registry, the public register in which Turkish companies record acts such as their founding, transfers of shares, changes of capital, appointments to the board and changes of name. Each registered act is published as a notice in the Türkiye Ticaret Sicili Gazetesi, the official gazette of the trade registry [33]. The company's record is held under

İstanbul registry number 927931, which stays with the company through changes of name. It comprises 35 notices, from the founding notice of June 2014 to a notice of May 2026 [33]. Of these notices, 17 were read from the gazette's page images and transcribed, including every notice indexed as a share transfer, a capital increase or a change of name; the other 18 are known only by their date, issue and type in the gazette's index. The notices read do not show the capital step of 2017 to 2018, or how the shares passed to the sole shareholders recorded in 2020 and 2024. A registered act appears with its date, and the reasons for it lie outside the record. The notices name private individuals as shareholders and directors, and this article describes such persons by role and nationality [33].

Turkish law and regulation were read in the texts in force when they were collected. The regulation on the licensing of human medicinal products dates from 2021 and was read in its consolidated text, with amendments to December 2025 [34]. TİTCK's guideline on applications for the GMP inspection of manufacturing sites abroad was read in its tenth revision, of September 2025 [35]. Prices are governed by the presidential decision on the pricing of human medicinal products of March 2026 [36]. Reimbursement is governed by the drug reimbursement regulation of SGK, the Social Security Institution, which decides which medicines it pays for; that regulation was read in its text as published in August 2022 [37]. The foreign direct investment law of 2003 was read in its consolidated text [38], and the presidential decision on state aid for investment in the text dated May 2025 [39].

The compliance frame comes from US and EU sanctions law. The US Treasury's Office of Foreign Assets Control (OFAC) grants a general licence for the sale of medicine to Iran in its Iranian Transactions and Sanctions Regulations, read in the current text as last amended in July 2026 [40]. A general licence is a standing authorisation, published by the sanctioning authority, that permits a defined class of transactions without an individual licence [40]. The European Union's Council Regulation 267/2012 on restrictive measures against Iran was read in its consolidated text of 1 August 2026 [41]. Both texts were read for what they permit and require of the companies, banks and suppliers they bind [40,41].

Market and policy reports supply the facts of the host market. The 2025 sector report prepared by IQVIA for AIFD covers mainly the year 2024 [13], and İEİS's 2025 industry report covers 2015 to 2025 [14]. The Turkish Competition Authority (Rekabet Kurumu) published in August 2026 the preliminary report of its pharmaceutical sector inquiry, an investigation of competition across a whole industry [42]. The award of the arbitrators in the WTO dispute over the localisation policy (DS583), issued in July 2022, records their findings on that policy [43]. Pharmaceutical trade between Türkiye and Iran was taken from UN Comtrade data for 2024, as reported by Türkiye [17].

The comparator entries come from the companies' own statements. Amgen announced in April 2012 an agreement to acquire Mustafa Nevzat, a privately held Turkish pharmaceutical company [44]. ADQ, an Abu Dhabi investment and holding company, announced in June 2022 an agreement to acquire the Turkish Birgi Mefar Group [45]. In January 2023 Eczacıbaşı İlaç, a listed Turkish company, reported in a public disclosure that it had integrated Gensenta, a Turkish manufacturer it had bought from Amgen's Turkish company [46]. That disclosure records one foreign owner's exit from a Turkish company, by sale of its shares to a Turkish group [46]. In September 2026 Fareva announced its acquisition of a manufacturing site at Lüleburgaz, in Türkiye [47].

CinnaGen İlaç's own account of its plans comes from news reports of 2017 to 2019. The company's press release of January 2017 was relayed by the news service Matriks [27]. Interviews followed, one with the company's and the group's chief executives in the Turkish daily Dünya in November 2017 [48] and one with the company's chief executive in the trade publication PharmaBoardroom in December

2018 [49]. Daily Sabah reported the plant's opening in June 2019 [29]. Yerlika's present account of itself comes from its corporate web page [50] and from a 2025 interview with its chief executive in GaBI Journal [30].

The peer-reviewed literature supplies the theory of entry mode and staged internationalization [18,19,20,21,22] and the work on firms under sanctions [9]. All documents were collected in November 2026, and each is kept as captured, with its date of capture.

2.3 How the record was read

Each source was read at the strength of what it can show. The registry shows what was registered and on what date [33], and a legal text shows what the rule was on a given date [34,36]. Official reports state an authority's findings. The WTO award states the arbitrators' findings [43], and the Competition Authority's report states the preliminary assessments of the Authority's staff, ahead of any decision of its Board [42]. AIFD and İEİS speak for the companies whose market they describe, so their reports are read as statements of interested parties [13,14].

Company statements relayed by the press are reported as the company's claims and plans, in its name [27,29,48,49]. The 2025 interview with Yerlika's chief executive was funded by Yerlika, as the journal states, and is read in the same way [30]. The Amgen and ADQ releases announced agreements whose completion was subject to closing conditions, including regulatory approvals, and they are reported as agreements [44,45]. Where sources disagree, the article gives each figure with its source and does not choose between them. The press items of 2017 to 2019 state the investment and the export targets in different amounts, currencies and bases [29,48,49], and the article reports the range.

The registry chronology was built first. Each registered act was entered with its date, and every other source was then placed against that timeline [33]. Laws and sanctions texts were dated by their publication and amendments, so that each act of the company stands beside the rules in force at the time [34,40,41]. Eisenhardt notes that when a pattern from one data source is corroborated by evidence from another, the finding is stronger and better grounded [31].

The study used public documents only. The companies were not approached, no one was interviewed, and no confidential document was used. No other private individual is named; the two executives named in Section 3.3 appear in their public roles. Motives were not inferred from dates. The article reports when an act was registered and sets beside it the rules then in force. Meyer and colleagues observe that, under sanctions, people in firms and governments are unlikely to discuss their actions and motivations openly and may have strong incentives to disguise critical aspects of them [9].

2.4 How the protocol was built

The protocol was derived from theory, from Turkish rules and from the record, read together. The theory is the staged logic of internationalization and the choice of entry mode. In the Uppsala model, commitment to a foreign market grows in steps as the firm gains knowledge by operating there [21], and it may also decline or stop when performance and prospects are not promising enough [22]. Entry-mode theory frames each route into a market as a trade-off between control and the cost of committing resources [18], and Brouthers and Hennart group the modes into contracts and equity, with joint ventures and wholly owned subsidiaries both on the equity side [19].

Turkish rules impose an order of their own on a foreign manufacturer. A licence application must come from a person or trading company resident in Türkiye, and GMP evidence for every finished-product manufacturing step must be filed with it [34]. A manufacturing site abroad applies for TİTCK's

GMP inspection through an importer resident in Türkiye [35]. Only a firm holding a manufacturing or import authorisation can apply for SGK to reimburse a medicine [37]. The foreign direct investment law, the pricing decision and the investment-incentive decision set the conditions for establishing the company, for its prices and for state support of a plant [36,38,39].

The CinnaGen record and the comparator entries show what happened at each of these points [33,44,45,46,47]. Eisenhardt treats the comparison of a framework built from cases with both similar and conflicting literature as a step that strengthens its internal validity and widens its generalizability [31].

The result is a sequence of stages, set out in Section 4. Each stage is written with its objective, the questions the company must answer, the evidence it should gather, what CinnaGen İlaç did at that point, and a gate. The gates are simple pass/fail conditions by design, with no weighting or scoring. A gate can also end in a decision to hold or to stop, in line with the Uppsala view that commitment may decline or stop [22].

3. Results

3.1 Türkiye as a destination: regulation, pricing, reimbursement, company law

Türkiye offers a foreign manufacturer a large market in which prices are set by the state and most spending is paid for by one public insurer [36,42]. İEİS put the pharmaceutical market at TL 430.8 billion and 2.65 billion boxes in 2025, across hospital and pharmacy channels, with reimbursed medicines at 93.2% of its value [14,51]. TL denotes the Turkish lira. The Competition Authority's preliminary report states that SGK pays for more than 85% of medicine spending by value and 95% by quantity [42]. Growth has come from prices more than from volume. In the AIFD/IQVIA report, price increases accounted for 90.6% of the growth in 2024 of the audited market, the pharmacy and hospital sales that IQVIA measures, while the number of boxes sold fell by 3.5% [13].

Local plants supply most boxes and somewhat more than half the value. Medicines produced in Türkiye made up 57% of the market by value and 90% by boxes in 2024 in the AIFD/IQVIA figures, which count as local whatever is produced in Türkiye without splitting it by the owner of the plant [13]. For 2025 the Competition Authority's report gives 59.59% by value and 89.98% by boxes, in data it takes from a domestic manufacturers' association [42]; the İEİS shares for the same year were given in Section 1. Imports are concentrated in originator and biotechnological products. In 2025, 68.8% of the value of originator medicines was imported, while 99.4% of generic boxes were produced in Türkiye, and biotechnological medicines made up 45.8% of the value of imports [14]. Biotechnological medicines held about 21.1% of the market by value, and 42 biosimilar products of 11 brands were manufactured in the country [14,51]. More than 80% of active ingredients are imported, in the AIFD/IQVIA account [13]. İEİS counted 111 manufacturing facilities and 15 active-ingredient facilities in December 2025, and about 850 companies [14]. Sales are concentrated. The 50 largest companies held 86% of value and 81% of volume in 2025 [14], and the 50 largest global companies held 48% of the Turkish market in 2024, against 88% of the US market [13].

Türkiye is also an export base. İEİS reports pharmaceutical exports of USD 2.51 billion and imports of USD 7.3 billion in 2025 [14]. In UN Comtrade, Türkiye reported exports of USD 2.27 billion in chapter 30 of the Harmonized System, the pharmaceutical chapter of the international goods classification, for 2024, and imports of USD 5.43 billion valued with freight and insurance [52]. Europe took 51.1% of exports in 2025 and Asia 38.8%, and the 20 largest destinations took 72% [14]. Iran was the fifth-largest destination in the İEİS table, at USD 97 million in 2024 and USD 82 million in 2025, or 3% of exports [14,51]. These figures come from the Turkish statistical office through İEİS and differ from the UN

Comtrade value for 2024 given in Section 1 [14,17]. Iran does not appear among the 20 largest sources of Turkish pharmaceutical imports in 2025 [14]. In the association's view, export markets use Turkish prices as reference prices, so Turkish firms enter them at lower prices than they otherwise could [14]. The rules that follow are summarised, in the order a foreign manufacturer meets them, in Table 1.

Table 1 Requirements a foreign pharmaceutical manufacturer meets in Türkiye, in the order of entry, from company formation to sanctions compliance; rules in force as read in November 2026. The euro values are those fixed by the decisions named. TL denotes the Turkish lira.

Step	Authority / instrument (with date)	Rule	Time limits or thresholds	Source
Company formation	Trade registry; Turkish Commercial Code, Law 6102 (2011)	Joint-stock company (A.Ş.) with one or more founders, so a foreign parent may found it alone; legal personality on registration in the trade registry.	Minimum capital TL 250,000 (TL 500,000 initial, registered-capital system), raised 24 Nov 2023; 25% of cash paid before registration; gazette announcement within 30 days.	[53]
Shareholding notification	Turkish Commercial Code, Law 6102 (2011), Article 198	A holder whose direct or indirect stake crosses a threshold notifies the company and authorities; share rights stay frozen until registration and announcement.	Thresholds of 5, 10, 20, 25, 33, 50, 67 and 100% of capital; notification within 10 days.	[53]
Foreign investment	Foreign Direct Investment Law 4875 (2003)	Freedom to invest and national treatment unless agreements or special laws provide otherwise; free transfer abroad of profits, dividends and proceeds through banks.	Notification of statistical information, no permission or approval; no distinction by the investor's nationality.	[38]
Licensing (applicant and filing)	TİTCK; Regulation on the licensing of human medicinal products (2021, amended to Dec 2025)	Applicant is a person or trading company resident in Türkiye, with a qualified authorised person, for an imported product, named by the foreign licensor as sole representative; GMP evidence per step.	Filing all year; process starts only in February, May, August, November; completeness checks up to 30 days, 30 to complete, second check 30.	[13,34]
Licensing (clock and validity)	TİTCK; Regulation on the licensing of human medicinal products (2021, amended to Dec 2025)	Licence renewed once after five years, then valid indefinitely unless TİTCK orders one further five-year review; sales permit before first marketing.	210 days from TİTCK's start notice (90 days with reliance), clock stopped for requests; renewal file 9 months before; suspension if no batch within 30 months.	[34]
GMP inspection of the foreign site	TİTCK; guideline on GMP inspection of sites abroad (in force 22 Sep 2025, for applications from 24 Sep 2025)	An importer established in Türkiye applies; a new site is inspected on site; file-based route only once a reference product of the same site has been found compliant on site; risk-based reviews extend certificates.	Required since 1 Mar 2010; certificate 3 years, up to 12 years (PIC/S country, 3 reviews) or 9 years (2 reviews); refusal bars reapplication for 6 months.	[35,54]
Pricing (reference price)	Ministry of Health, TİTCK; Presidential decision on pricing (11 Mar 2026, published 12 Mar 2026); communiqué of 29 Aug 2026	Maximum price from the lowest ex-factory price, discounts excluded, in 5 to 10 EU reference countries (France, Spain, Italy, Portugal, Greece); repealed the 2017 decision.	First price applications concluded within 90 days (decision), ordinary ones within 45 days (communiqué); euro-value rises apply after 5 days, falls after 45.	[36,55]
Pricing (euro value)	Price Evaluation Commission; pricing decisions of February 2017, 23 Oct 2024, 18 Dec 2025 and 11 Mar 2026	Euro value is the previous year's average euro selling rate of the Central Bank of the Republic of Türkiye times an adaptation coefficient, 70% under the 2017 decision and 65% under the 2026 decision.	TL 21.6721 (Oct 2024, kept for 2025); TL 25.3346 (Dec 2025); TL 26.8767 at 60% until 1 Apr 2026; TL 29.1164 at 65% from 1 Apr 2026.	[36,55,56,57,58]
Reimbursement (listing)	SGK; Drug Reimbursement Regulation (25 Aug 2022); Health Implementation Communiqué	Only listed trade names and barcodes are paid; applicant holds a manufacturing or import authorisation; evaluation commission reviews, Drug Reimbursement Commission decides, SGK President approves.	Last application days in March and August; decisions sent within 15 working days, evaluated within 10; re-application within two months without a new dossier.	[37,59]

Step	Authority / instrument (with date)	Rule	Time limits or thresholds	Source
Reimbursement (payment limits)	SGK; Health Implementation Communiqué (text valid from 1 Apr 2026)	SGK pays up to the cheapest equivalent's discounted unit price plus 6%, the cheapest counting only with 1% group share in one of the last five months.	No discount at or below TL 52.43; reference without generic 10/31/41%, reference with generics and generics 10/18/28%, bands to TL 100.37, to TL 151.24, from TL 151.25.	[42,59]
Localisation	TİTCK, SGK and Ministry of Health announcement (4 Mar 2016); WTO DS583 arbitration award (21 Jul 2022)	Products whose local-production commitments were not given, accepted or fulfilled lost SGK reimbursement; the award left it inconsistent with GATT Article III:4, unjustified under XX(b) or XX(d).	Aim of 60% of demand by value from domestic production; commitments within 18 months; compliance period expired 25 Apr 2023.	[16,43,60]
Investment incentives	Presidential decision on state aid for investments (29 May 2025)	Pharmaceutical manufacturing (NACE 21) is a high-technology product with no sector condition; each project needs an incentive certificate after assessment.	Minimum fixed investment TL 12 million (regions 1 and 2) or TL 6 million; TL 100 million Strategic Move; TL 500 million priority; applications until 31 Dec 2030.	[39]
Sanctions compliance (US licence)	OFAC; Iranian Transactions and Sanctions Regulations, section 560.530 (amended July 2026)	General licence for EAR99 medicine to Iran by covered persons, including non-US persons for items subject to the Export Administration Regulations; excludes listed drug classes, military, intelligence and law-enforcement buyers, blocked persons.	Shipment within 12 months of the contract; excluded items need a one-year specific licence; OFAC decides each year whether to revoke.	[40,61]
Sanctions compliance (EU transfers)	Council Regulation (EU) 267/2012 (consolidated text of 1 Aug 2026)	Transfers with banks domiciled in Iran prohibited except listed categories, including healthcare; no new accounts or correspondent relationships with them.	Healthcare transfers notified in advance from EUR 10,000; prior authorisation from EUR 100,000; bank records kept five years.	[41]
Sanctions compliance (banks' exposure)	US Treasury, OFAC; Golden Global Bank designation (4 Sep 2026); alert to foreign financial institutions (5 Oct 2026)	Foreign banks doing business with Iran's financial sector risk sanctions, including restricted US correspondent accounts; a Türkiye-based bank was designated.	Targeting at any time without advance notice; civil penalties on a strict-liability basis.	[62,63,64]

A manufacturer that wants its own company in Türkiye meets the joint-stock company first, the anonim şirket (A.Ş.) of the Turkish Commercial Code of 2011 [53]. Such a company needs one or more founders who hold shares, and the natural and legal persons who subscribe shares and sign the articles of association are its founders [53]. A foreign parent company can therefore found one alone, as a single-shareholder A.Ş. [53]. Where the company is founded with one shareholder, or all its shares come to be held by one person, the sole shareholder's name, place of residence and citizenship are registered and announced. A fall to one shareholder is notified to the board within seven days, and the board has it registered within seven more [53]. The articles are written, with the founders' signatures notarised or given before the registry director, and they state among other things the trade name and seat, the business, the capital and the number of board members [53]. The company acquires legal personality on registration in the trade registry. Its articles are registered at the registry of its seat and announced in the Türkiye Ticaret Sicili Gazetesi within thirty days of formation [53]. A registered fact takes effect against third parties from the working day after its announcement in that gazette [53].

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The Code prints a minimum capital of TL 50,000, and TL 100,000 of initial capital for a non-public company in the registered-capital system, under which the articles authorise the board to raise capital up to a ceiling [53]. A footnote to the consolidated text records that a presidential decision of 24 November 2023 raised these minima to TL 250,000 and TL 500,000, and that a correction to that decision was published on 26 November 2023 [53]. At least 25% of the nominal value of shares subscribed in cash is paid before registration, into a special bank account in the name of the company being formed, and the rest within 24 months [53]. Capital is increased by the general assembly or, in the registered-capital system, by the board, and an increase lapses if it is not registered within three months of the decision [53]. New capital can be subscribed in cash, contributed in kind or created from the company's own reserves [53]. The Code has no separate article on raising capital by setting off a shareholder's receivable against the company. It requires instead that the board's declaration on an increase state that any debt to be set off exists, is valid and can be set off [53]. Receivables contributed as capital are valued by experts appointed by the commercial court, and receivables not yet due cannot be capital [53]. Shareholders have a pre-emption right to new shares in proportion to their holdings, which the general assembly can restrict or remove only for justified reasons and with 60% of the capital voting in favour [53].

The board consists of one or more persons [53]. A legal person can sit on it, in which case one natural person designated by it is registered and announced alongside, and only that person attends and votes [53]. Article 359 of the Code sets no residency or nationality condition for board members and requires full legal capacity, while the residence and citizenship of board members are recorded in the registry [53]. Holdings are disclosed as well. Article 198 sets thresholds of 5, 10, 20, 25, 33, 50, 67 and 100% of a company's capital. An undertaking whose direct or indirect holding reaches one of them, or falls below it, notifies the company and the competent authorities within ten days, and the notification is registered and announced [53]. Until that is done, the voting and other rights attached to the shares concerned are frozen [53].

The foreign direct investment law of 2003 sets the investor's rights. Unless international agreements or special laws provide otherwise, foreign investors are free to invest in Türkiye and receive national treatment, that is, treatment equal to that of domestic investors [38]. Founding a new company or branch and acquiring shares both count as direct foreign investment [38]. Such investments cannot be expropriated or nationalised except in the public interest and against compensation [38]. Net profit, dividends, the proceeds of a sale or liquidation, payments under licence and management agreements, and loan principal and interest may be freely transferred abroad through banks or private finance institutions [38]. Disputes under investment contracts may go to national or international arbitration where the relevant legislation allows it and the parties agree [38]. Foreign staff receive work permits from the labour ministry [38]. The law replaced a system of permission and approval with one of notification, under which foreign investors report statistical information on their investments [38]. It draws no distinction by the investor's nationality [38].

The licence comes next. The regulation of 2021 on the licensing of human medicinal products, read with its amendments to December 2025, allows only natural persons or trading companies resident in Türkiye to apply to TİTCK for a licence, the marketing authorisation [34]. A company applicant must employ, as its authorised person, a graduate in pharmacy, medicine or chemistry entitled to practise in Türkiye [34]. For an imported product the applicant files the foreign licensor's document naming it the sole authorised representative for import, licensing and sale in Türkiye, and a product to be made under contract in Türkiye needs a contract-manufacturing agreement with a qualifying plant [34]. The dossier names the sites of every manufacturing step and carries GMP evidence for each step of the finished product [34]. That evidence can be a TİTCK document, a document of another competent

authority that TİTCK accepts, or a GMP document from a country with which Türkiye has a mutual recognition agreement [34]. Official documents from abroad need an apostille or consular certification and are submitted in Turkish, with English accepted for the parts TİTCK allows [34]. In the AIFD/IQVIA account, the licensing process cannot be completed before a GMP certificate is issued [13].

Applications can be filed all year, but TİTCK starts the licensing process only in February, May, August and November [13,34]. A preliminary check of completeness takes up to 30 days, the applicant has 30 days to complete missing items, and a second check takes up to 30 days more [34]. The licensing process is then concluded within 210 days of TİTCK's separate notice that it has started, and the clock stops while TİTCK waits for information it has requested [34]. The period is 90 days for applications that rely on earlier assessments by authorities of comparable standards [34]. Elapsed times are longer than these legal periods. The Competition Authority states that licences take longer to complete than the law provides, without giving a figure [42]. A 2025 review, drawing on consultancy and industry reports, puts the average time from a licence application to listing for reimbursement at about three years [65]. A licence is renewed once after five years, on a file submitted nine months before, and is then valid indefinitely unless TİTCK orders one further five-year review [34]. It can be suspended if no commercial batch reaches the market within 30 months of licensing [34]. A sales permit is required before a product is first placed on the market, and again when its manufacturing site moves from abroad to Türkiye [34]. A reference product first licensed in the customs union of the European Union and Türkiye after 1 January 2005 has six years of data exclusivity from that first licence, limited by any patent term in Türkiye [34]. TİTCK granted 507 licences in 2025 [14,42].

A plant outside Türkiye must also pass TİTCK's GMP inspection, a requirement that has applied to imported products since 1 March 2010 [54]. The procedure is set by TİTCK's guideline on applications for the GMP inspection of manufacturing sites abroad, in force from 22 September 2025 and applied to applications made from 24 September 2025 [35,54]. The application is made by an importer established in Türkiye. The foreign manufacturer may send documents directly only after the importer has applied electronically, quoting the importer's file number, and responsibility for the file lies with the importer [35]. A site TİTCK has not inspected before goes to an on-site inspection, planned in an order of priority decided by TİTCK's priority assessment board [35]. A file-based inspection is open only where a reference product at the same site has already been inspected on site and found compliant, and a risk-based review serves to extend a certificate already issued [35]. The product must be seen in production during the inspection, and the site's documents must also be available in English [35]. Application fees must be paid in full for each dose and volume of each product, and the guideline states neither the amounts nor a time within which TİTCK decides [35].

An on-site certificate is valid for three years from the inspection [35]. Risk-based reviews can extend it to a total of 12 years, through three reviews, for a site in a country whose authority is a PIC/S member, and to 9 years, through two, for other sites [35]. When these are used up, the certificate can be extended once, by up to 12 months, on a current GMP certificate issued by a PIC/S member authority [35]. A file-based application also rests on PIC/S, since it requires the report of an inspection by a PIC/S member authority other than TİTCK within the last three years [35]. The guideline names no country; Section 1 gave the PIC/S listing of the Turkish and Iranian regulators [15,35]. One or more critical deficiencies found on site lead to refusal, and no new on-site application is accepted for six months [35]. A critical deficiency found at an inspection decided during a risk-based review leads to cancellation of the product certificates and a stop to imports [35]. For products licensed before 2010 whose foreign sites had never been inspected, TİTCK opened a one-off file-based route for

applications made by 31 December 2025, on the latest inspection report of a PIC/S member authority [54]. The Competition Authority calls TİTCK's admission to PIC/S from 1 January 2018 important for proving the quality of medicines made in Türkiye [42].

Every medicine needs a state price before it can be sold. A product with no retail price cannot be sold in pharmacies, and one with no wholesale price cannot be sold by wholesalers or pharmacies [55]. The rules are now those of the presidential decision on the pricing of human medicinal products of 11 March 2026, published on 12 March 2026 and in force from the following day, which repealed the decision of 2017 [36]. The Ministry of Health sets maximum prices, and it names 5 to 10 member states of the European Union as reference countries, the countries whose prices are the basis of the Turkish price [36]. Its communiqué of 29 August 2026 names France, Spain, Italy, Portugal and Greece [55]. The real reference price is the lowest ex-factory price, discounts excluded, of the reference product licensed and marketed in those countries, and a lower price in a country where the batch is released or imported is used instead [36,55]. Where no such price exists, a price from another EU country, and failing that from any country, may be declared [36]. The euro price is converted into lira at the euro value, a fixed rate announced each year by the Price Evaluation Commission, on which the Ministry of Health, the Ministry of Treasury and Finance, the Presidency of Strategy and Budget and SGK sit [36]. The euro value is the previous year's average euro selling rate of the Central Bank of the Republic of Türkiye multiplied by an adaptation coefficient, now 65% [36]. An increase takes effect five days after it is announced and a decrease 45 days after [36,55].

The coefficient and the value have both changed often. The 2017 decision set the coefficient at 70% [56]. İEİS reports that it was cut to 60% in 2019 [14], and the AIFD/IQVIA report dates the 70% to the period until 2018 [13]. A presidential decision of 23 October 2024 raised the euro value by 23.5% to TL 21.6721 and kept it for 2025 without a new valuation [57]. A decision of 18 December 2025 raised it by 16.9% to TL 25.3346, to apply until it was set again in February 2026 [58]. The 2026 decision set it at TL 26.8767, with the coefficient applied at 60% until 1 April 2026, and at TL 29.1164, at 65%, from that date [36]. The industry associations measure the gap from the market rate. AIFD/IQVIA put the euro value at 58.7% of the current rate on 24 October 2024 [13], and İEİS at 50.6% after the December 2025 rise and 54.5% in May 2026 [14]. AIFD/IQVIA state that a value below the market rate creates problems of supply and raises costs for domestic producers as well as importers [13]. Before 2015 the value was frozen at TL 1.9595 from 2009, according to İEİS and to a 2016 review [14,66]. A 2026 review reads the gap between the official value and the market rate as the point where the mechanism fails to offset cost pressure when exchange rates are volatile [67].

Generics and older products are priced at fixed shares of the reference. Until a generic reaches the market, the original product may be priced up to its real reference price; from the first generic, the original and all generics are capped at 60% of the benchmark reference price held in the Ministry's database [36]. First generics marketed after the 2026 decision took effect, with a 60% price of at least TL 139.62 (TL 151.25 from 1 April 2026), may take 80% in their first year, 75% in the second and 70% in the third [36]. The second and third steps rise to 80% and 75% if generics manufactured in Türkiye reach 5% and then 10% of consumption [36,55]. Products of which any form first reached a market anywhere before 1 January 2000 are price-protected, and those priced above TL 92.65 are capped at 80% of the real reference price [36]. Biosimilars, blood products, orphan products, vaccines and several other classes are priced under separate Ministry rules [36]. A product made in Türkiye with no reference product can be priced on a cost card, a statement of its costs approved by a sworn financial adviser [36,55]. Applications go to TİTCK electronically. The decision requires first price applications to be concluded within 90 days, and the communiqué sets 45 days for ordinary price applications [36,55]. For an imported product, and for a locally made reference product whose licensor is abroad,

the applicant files a price declaration document from the source countries, apostilled or certified by a Turkish consulate [55]. Reference prices are searched again every year, in fixed application periods [55].

Reference pricing dates from 2004, when it replaced a cost-plus model [68,69,70]. Before then, prices were regulated through profit margins based on declared production costs [70]. Studies covering 2007 to 2013 found that prices fell on generic entry because of these rules more than because of competition. Across 15 first generics listed in 2012, prices fell by 39% on average, with little further erosion as more generics entered [71]. In five groups of hypertension medicines, the fall in original prices after generic entry was attributed to direct price controls [72]. The authors of a 2023 review state that the fixed shares and the euro value lower companies' margins and lead to fewer or more hesitant requests to enter the market [70].

A price allows a sale, while payment by SGK requires a place on its reimbursement list. The Health Implementation Communiqué, SGK's rulebook for what general health insurance pays, states that medicines whose trade names and barcodes are not on the list are not paid for under any condition [59]. The procedure for entering the list is set by SGK's drug reimbursement regulation, read here in its text as published on 25 August 2022; it was amended in November 2024 [13,37]. Only a firm holding an authorisation to manufacture or to import the medicine may apply [37]. A Medical and Economic Evaluation Commission reviews the dossier, including pharmacoeconomic studies by cost-minimisation or cost-effectiveness. Its 13 voting members come from SGK, the Ministry of Health, the Ministry of Treasury and Finance, the Presidency of Strategy and Budget and two universities, and four industry associations sit as observers without a vote [37]. The Drug Reimbursement Commission, chaired by SGK, then decides, and the President of SGK approves [37]. The Commission works in two periods a year, with last application dates on the last working day of March and of August [37]. It sends its decisions within 15 working days of completing its work, the President of SGK evaluates them within 10 working days, and applicants not accepted are told the reasons within 10 working days of approval [37]. The regulation sets no total time from filing to decision, and a rejected firm may re-apply within two months without a new dossier [37]. Decisions are published as additions to and changes of the list, as in SGK's notice of 20 March 2026 on its 2025/2 period, which took effect five working days after publication [73].

Price-competitive products have faster routes. Each week the SGK secretariat lists a product whose unit price is at least 5% below the cheapest in its group, and the list takes effect on the second day after its Wednesday publication [37,42]. The first biosimilar of a reference product is given priority if its unit price is at least 30% below that of the listed reference product [37]. A newly listed medicine must show within five months that it is distributed on the market, or it is made passive, and it is removed from the list at the end of the tenth month [37]. Listed medicines carry a mandatory public institution discount on the wholesale price. In the communiqué as valid from 1 April 2026, no discount applies at or below TL 52.43, and a base discount of 10% or 11% applies above it [59]. A reference product with no generic carries 10%, 31% or 41% in the price bands up to TL 100.37, up to TL 151.24 and from TL 151.25, while reference products with generics, and generics, carry 10%, 18% or 28% [59]. Price-protected products carry 0%, 10% or 28%, and 40% in the top band if they have no reference [59]. A new molecule is exempt from the additional discounts for its first year on the list [59].

Internal reference pricing then caps what SGK pays within a group of equivalent products, those with the same active substance at the same dose in a similar form. SGK pays up to the cheapest product's discounted unit price plus 6%, and the cheapest product counts only if it held 1% of the group's market in at least one of the last five months; SGK does not pay the excess [42,59]. The Competition

Authority states that, in a market where at least one medicine is reimbursed, not being reimbursed can be an entry barrier [42]. The payer may also favour local production. The communiqué allows SGK to create alternative payment models to encourage the production of products that are imported or not made in Türkiye, and the move of imported products to local production [59]. Alternative reimbursement agreements for high-cost innovative medicines have been made since 2016, with confidential terms [13].

The localisation policy tied reimbursement to local production. As the WTO panel and arbitrators described it, Türkiye required foreign producers to commit to producing certain medicines in Türkiye, and products whose commitments were not given, not accepted or not fulfilled were no longer reimbursed by SGK [43,60]. The stated aim, taken from the Tenth Development Plan for 2014 to 2018, was to meet 60% of domestic demand by value from domestic production [43,60]. The panel noted that about 40% was met in this way in 2018 and 2019 [60]. TİTCK, SGK and the Ministry of Health issued a public announcement on the localisation process on 4 March 2016 [43]. The requirement ran in five phases, set by the domestic share of each group of equivalent products. In January 2018 SGK announced that 45 products in the first phase would no longer be reimbursed from 8 February 2018 [60]. Commitments were typically to be implemented within 18 months, and once a commitment was accepted the company had a year to apply to change its marketing authorisation from import to local [60]. Türkiye told the panel that only the first two phases had been implemented [60]. The panel also examined a prioritisation measure, under which domestic products' applications for the reimbursement list, GMP inspection and marketing authorisation were reviewed before those of like imported products [16,43]. A study of İEİS data found that domestic sales grew faster than imported sales in 2014 to 2019, which its authors relate to a possible effect of the programme and to increased production capacity rather than a move to higher-value production [74].

The European Union requested consultations in the dispute, DS583, on 2 April 2019 [16]. The panel issued its report to the parties on 11 November 2021 [43]. Türkiye appealed on 25 April 2022 to arbitration under Article 25 of the WTO's dispute settlement rules, which the parties had agreed to use because the Appellate Body was not able to hear an appeal [16,43]. The award, issued on 21 July 2022, left standing the panel's finding that the localisation requirement was inconsistent with Article III:4 of the General Agreement on Tariffs and Trade 1994 (GATT), the national treatment obligation for imported products [16,43]. The arbitrators held that the requirement was not government procurement, since SGK does not acquire the medicines it pays for [43]. They upheld the finding that Türkiye had not justified it under Article XX(b) or XX(d), the general exceptions Türkiye invoked, the panel having found that Türkiye had not shown it to be a measure taken to protect human life or health [43,60]. The panel's finding that the prioritisation measure was also inconsistent with Article III:4 was not appealed and forms part of the award [16,43]. The arbitrators recommended that Türkiye bring its measures into conformity, and the parties agreed that the period for doing so would expire on 25 April 2023 [16,43]. Türkiye then informed the WTO of steps it had taken. These included a new drug reimbursement regulation in force from 25 August 2022, a recommendation that firms apply to re-activate their products in the reimbursement system, and a new alternative reimbursement regulation published on 12 May 2023 [16]. İEİS describes the localisation process as halted before it was complete. It also reports that the Medium-Term Programme for 2025 to 2027 states that the domestic production strategy will be reassessed with international obligations taken into account [14,51].

State aid for a plant is set by the presidential decision on state aid for investments of 29 May 2025. Applications under it are assessed until 31 December 2030, and its TL amounts are revalued each year [39]. The decision classes the manufacture of basic pharmaceutical products and preparations, code

21 of the NACE classification of economic activities, as a high-technology product, and its sector table sets no specific condition for that code [39]. The general minimum fixed investment is TL 12 million in the first and second of its six regions, graded by socio-economic development, and TL 6 million in the others [39]. A high-technology investment of at least TL 100 million can be considered under the Strategic Move Programme. That programme screens projects on five criteria, among them import dependence, value added of at least 30% and own funds of 20% of the investment, and sends those meeting three of them for a feasibility report [39]. High-technology investments of at least TL 500 million, or in products on a published priority list, are priority investments [39]. The instruments include exemption from customs duty and value-added tax on machinery, a reduction of income or corporate tax, interest support on investment loans, machinery support, land allocation and support for employers' social-security contributions, with rates and caps that differ by programme and region [39]. The tax reduction, for instance, has contribution rates of 50%, 40%, 30% and 20% across the programmes [39]. Each project needs an incentive certificate, issued after a sectoral, financial and technical assessment [39]. İEİS reports incentive certificates for fixed investment of TL 140.5 billion in pharmaceuticals between 2015 and 2023 [14], and the AIFD/IQVIA report notes that pharmaceutical manufacturing was made a priority investment area in 2015 [13].

Payments connected with Iran are governed by US and EU sanctions law, which binds the parties within its reach and exposes foreign banks to US measures [40,41,63]. The US general licence for medicine is section 560.530 of the Iranian Transactions and Sanctions Regulations, as amended in July 2026. It authorises a covered person to export or re-export medicine and medical devices to Iran, or to buyers in third countries purchasing for resale to Iran [40]. For items subject to the US Export Administration Regulations, a covered person includes a non-US person [40]. The licence extends to the related shipping, insurance, financing and payment, provided the goods are shipped within 12 months of the contract and payment terms stay within those the regulations authorise [40]. The items must be designated EAR99 under those export regulations, and the US Bureau of Industry and Security lists medicines that are not [40]. Analgesics other than non-steroidal anti-inflammatory drugs, cholinergics, anticholinergics, opioids, narcotics, benzodiazepines and bioactive peptides are excluded and need a one-year specific licence [40]. No sale to military, intelligence or law-enforcement buyers and no dealing with blocked persons is authorised [40]. The licence does not cover US technology or software used to manufacture medicine, such as technology to design or produce biotechnological items [40]. OFAC determines each year whether to revoke it [40]. In December 2016 OFAC published an answer to one of its frequently asked questions. It stated that a non-US person may export or re-export medicine to Iran under the general licences if the items are subject to the Export Administration Regulations and every condition of the licence is met [61].

Council Regulation 267/2012 binds the territory of the European Union, its nationals and companies wherever they are, and any business done wholly or partly in the Union [41]. In its consolidated text of 1 August 2026 it prohibits transfers of funds between banks within its scope and banks domiciled in Iran, except in listed categories that include healthcare and medical equipment [41]. Such transfers below EUR 100,000 need no prior authorisation but are notified in advance from EUR 10,000, and transfers from EUR 100,000 need prior authorisation; transfers below EUR 10,000 need neither [41]. Transfers for healthcare to or from other Iranian persons need no prior authorisation and are notified from EUR 10,000 [41]. Linked transfers count as one for these thresholds [41]. Banks within scope must keep continuous watch over such accounts, refuse payment instructions with incomplete information on the originator or beneficiary, keep records for five years and report suspicions [41]. They may not open new accounts or new correspondent relationships with banks domiciled in Iran [41]. The Central Bank of Iran, Bank Mellat and Bank Melli are among the entities whose funds are frozen [41]. National

authorities may authorise sales of listed goods for medical or humanitarian purposes, and claims by Iranian parties under contracts affected by the measures cannot be satisfied [41]. Knowing and intentional participation in activities whose object or effect is to circumvent the measures is itself prohibited [41].

US action has reached a bank based in Türkiye. On 4 September 2026 OFAC designated Golden Global Bank and two İstanbul subsidiaries, adding them to its list of persons whose property under US jurisdiction is blocked [62,75]. Treasury stated that the bank had facilitated transactions for the Qods Force of Iran's Revolutionary Guard Corps and given Iran correspondent banking access, the accounts banks hold with one another to make payments abroad [62,63]. OFAC issued a general licence the same day authorising the wind-down of transactions with the persons blocked [75]. Treasury also stated that OFAC can prohibit, or impose strict conditions on, the US correspondent accounts of a foreign bank that knowingly conducts or facilitates a significant transaction for a designated person, and that its civil penalties apply on a strict-liability basis [62]. On 5 October 2026 OFAC alerted foreign financial institutions that continue to do business with Iran or its financial sector to the risk of sanctions under Operation Economic Outcast, announced by Treasury on 24 August 2026 [63,64]. It stated that those transacting with sanctioned Iranian banks could be targeted at any time without advance notice [63]. Such restrictions are published in the Federal Register or on an OFAC list of foreign financial institutions whose US correspondent accounts are restricted [64]. Türkiye's stated position differs. Answering a question about sanctions on Russia on 14 February 2024, the spokesperson of the Ministry of Foreign Affairs said that Türkiye implements only sanctions decided by the UN Security Council, and that unilateral sanctions concern the states and bodies that impose them [76]. In the same answer the spokesperson said that Turkish banks and companies borrow and lend abroad and that the Ministry informs them regularly about unilateral sanctions [76].

3.2 How foreign manufacturers entered Türkiye

Foreign manufacturers have entered the Turkish pharmaceutical industry mostly by buying companies and plants that were already operating there. Kahraman and Uğurluoğlu compiled 38 acquisitions in and around the sector between 2006 and 2014 from consultancy reports, a list that also includes some cosmetics, chemicals and distribution companies [77]. Foreign acquirers, mostly European, made 71% of these acquisitions, and 55% were for the whole of the company bought [77]. The authors found no merger in the period, since every transaction took the form of an acquisition [77]. Citing the 2015 report of İEİS, they add that 33 multinational companies had entered the Turkish market in the previous five years, and that 106 foreign-linked companies held 67% of the domestic market [77]. The entries are listed in Table 2.

Table 2 Foreign entries into, and one exit from, Türkiye's pharmaceutical manufacturing recorded in Section 3.2, 2007–2026, grouped by mode and in date order within each mode, with stake, value as printed and status; sources are the company releases, annual and stock-exchange disclosures, press reports and the Kahraman and Uğurluoğlu list of acquisitions.

Year	Entrant	Target or site	Mode	Stake	Value as printed	Status	Source
2007	Zentiva	Eczacıbaşı Health Products and Eczacıbaşı Fine Chemical Products (75% of the Eczacıbaşı generics business)	Acquisition of a local manufacturer	75%; seller kept 25%	Not stated in the seller's report; USD 610 million as listed by Kahraman and Uğurluoğlu	Completion (signed March 2007, concluded July 2007)	[77,78]
2009	Zentiva	Eczacıbaşı-Zentiva Health Products (further stake)	Acquisition of a local manufacturer	25%	Not stated (no value disclosed in Kahraman and Uğurluoğlu)	Completion (as recorded by Kahraman and Uğurluoğlu)	[77]
2012	Amgen	Mustafa Nevzat, a privately held Turkish company	Acquisition of a local manufacturer	95.6% agreed; more than 99% completed	USD 700 million valuation of the company (Amgen); USD 669 million for 95.6% as listed by Kahraman and Uğurluoğlu	Agreement 25 April 2012; completion 12 June 2012	[44,77,79]
2022	ADQ (Abu Dhabi)	Birgi Mefar Group, sterile injectables	Acquisition of a local manufacturer	Not stated	Not stated	Agreement (13 June 2022); closing subject to regulatory approvals	[45]
2007	Sandoz	Roche's Gebze plants	Purchase of an existing plant	100% of the plant, as listed by Kahraman and Uğurluoğlu	Not stated	Completion (reported April 2007 as bought; no purchase date given)	[77,80]
2026	Fareva	Company operating Sanofi's Lüleburgaz plant	Purchase of an existing plant	70%; Sanofi keeps 30% (Linklaters); the Fareva release states no stake	Not stated	Agreement (January 2026); acquisition announced 15 September 2026, closing date not stated	[47,81]
2025–2026	SK Plasma (Korea)	Proturk plasma fractionation plant, Çubuk, Ankara, with the Turkish Red Crescent	Joint venture, new plant	15% of the joint venture	EUR 500 million, as quoted from the Turkish President	Agreement (November 2025); groundbreaking reported 15 June 2026; plan: completion second half of 2028	[82]
2022	Amgen (seller); Eczacıbaşı Group (buyer)	Gensenta, formerly Mustafa Nevzat	Exit by sale	99.96%	USD 135 million (Daily Sabah); lira price equal to USD 135 million (KAP disclosure)	Exit: agreement reported 29 June 2022; completion announced 2 November 2022	[46,83]

The acquisition of a local manufacturer is the route most often on record. In 2007 Zentiva, which the seller's annual report describes as a leading branded generic company in Central and Eastern Europe, took 75% of the generics business of the Eczacıbaşı Group, a Turkish industrial group [78]. The agreement was signed in March 2007 and concluded in July 2007 [78]. It covered Eczacıbaşı Health Products, the company formed in 2003 from the group's manufacturing complex at Lüleburgaz, and Eczacıbaşı Fine Chemical Products, its active-ingredient company, and the seller kept 25% of each [78]. In June 2007 the group's marketing company transferred to the new company its marketing and distribution rights for all its generic products and several original medicines [78]. The report gives the complex an area of 60,000 square metres and a capacity of 400 million dosage-form units a year, and

states that an FDA audit in April 2007 led to FDA approval of acyclovir capsule production there [78]. It prints no price. Kahraman and Uğurluoğlu list the 75% at USD 610 million, and record a further 25% of Eczacıbaşı-Zentiva Health Products bought by Zentiva in 2009, with no value disclosed [77]. In the seller's account, the new company would join a strong position in the Turkish market to Zentiva's international presence [78]. The transfer, the report adds, reduced the group's exposure to generics, freed resources for new areas of rapid growth and intensive research and development, and ended its manufacturing arm's direct involvement in pharmaceutical production [78].

Amgen, a US biotechnology company, came to its acquisition with a commercial presence already in place. It had set up an affiliate in Türkiye in 2010 and was marketing two products there [44]. On 25 April 2012 it announced an agreement to acquire 95.6% of Mustafa Nevzat, a privately held Turkish company, in an all-cash transaction that valued the company at USD 700 million [44]. Amgen described the target as the leading supplier of medicines to the Turkish hospital sector and a major supplier of injectables, with an export business and revenues of about USD 200 million in 2011 [44]. It stated that the transaction would significantly expand its presence in Türkiye and the surrounding region, which it called large, fast-growing priority markets [44]. Completion was subject to customary closing conditions, including regulatory approvals [44]. On 12 June 2012 Amgen announced that it had completed the acquisition of more than 99% of the shares, and presented the deal as a platform for growth in Türkiye and the surrounding region [79]. Kahraman and Uğurluoğlu list the transaction at USD 669 million for 95.6% [77].

An investment holding company from Abu Dhabi took the same route in 2022. On 13 June 2022 ADQ announced a definitive agreement to acquire the Birgi Mefar Group, which it described as one of Türkiye's leading producers of sterile injectables and a full-service contract developer and manufacturer [45]. In ADQ's description, the group makes vials and pre-filled syringes used for vaccines, specialises in lyophilisation and exports to more than 30 countries [45]. The release states neither the stake nor the price, and makes the transaction subject to customary closing conditions, including regulatory approvals [45]. ADQ placed the deal within its effort to build an integrated healthcare and life-sciences platform in the United Arab Emirates [45]. An ADQ executive quoted in the release called Türkiye an important market for ADQ's investments, and the release named access to a customer network that ranges from large multinationals to local and regional companies [45].

The most recent entry joins a contract manufacturer to a multinational's plant. In January 2026 the law firm Linklaters announced that it had advised Fareva, which it described as a world leader in industrial subcontracting for the pharmaceutical, cosmetics and household sectors, on a share purchase agreement with Sanofi [81]. Under that agreement Fareva would acquire 70% of the company operating Sanofi's manufacturing facility at Lüleburgaz, and Sanofi would keep a minority stake of 30% [81]. Completion was subject to customary regulatory approvals, among them clearance by the Competition Authority [81]. On 15 September 2026 Fareva announced the acquisition of the Lüleburgaz site, without naming the seller or stating a stake, a price or a closing date [47]. Fareva states that the site covers 338,000 square metres, of which 72,000 are industrial buildings, that it can produce up to 445 million packs a year on three shifts, and that nearly 750 employees are joining the group [47]. In the company's description, the site makes solid, liquid, semi-solid and sterile forms, penicillins and cephalosporins, for an international customer portfolio with markets in Europe, Asia, South America, Africa and Oceania [47]. Fareva gave greater capacity, flexibility and geographic reach, and efficient access to several international markets, as its reasons [47].

An earlier purchase of an existing plant from another multinational is on record in 2007. In April 2007 the Turkish daily Hürriyet reported that Sandoz, the generics company of Novartis, had bought the Gebze plants of the Swiss company Roche [80]. Kahraman and Uğurluoğlu list the purchase in 2007, as 100% of Roche's Gebze production facility, with no value disclosed [77]. The newspaper gives no price and no date of purchase [80]. Sandoz was already in the market, sixth in Türkiye by its chief executive's account [80]. He said that the company saw Türkiye as a production centre, that the Gebze plant would raise its production capacity in the country to 8 billion tablets, and that its exports from Türkiye would rise [80]. He also said that Sandoz was not looking for a local partner, but might consider buying a local company if a good opportunity arose [80].

The record also holds one exit by a foreign owner. On 29 June 2022 Daily Sabah reported that the Eczacıbaşı Group had agreed to buy 99.96% of Gensenta from Amgen for USD 135 million, subject to approval by the Competition Authority [83]. According to the same report, Gensenta was the former Mustafa Nevzat, bought by Amgen in 2012 and renamed in 2020 [83]. Eczacıbaşı İlaç published a disclosure on 6 January 2023 on the Public Disclosure Platform (Kamuyu Aydınlatma Platformu, KAP), where Turkish listed companies report material events [46]. It recorded there its purchase of the shares representing 99.96% of Gensenta's capital from Amgen İlaç Ticaret Limited Şirketi, Amgen's Turkish company, for a price in Turkish lira equal to USD 135 million [46]. The disclosure states that completion of the purchase had been announced on 2 November 2022 [46]. After the purchase, the buyer's marketing subsidiary took over domestic distribution, promotion, marketing and sale of the 88 finished products for which Gensenta holds the licence [46]. The consolidated workforce of the buyer and its subsidiaries went from 352 at 30 September 2022 to 1,099 on 6 January 2023 [46]. The Eczacıbaşı Group said that the acquisition added local production capabilities in pharmaceuticals, biosimilars and active ingredients, and export competency, to its portfolio [83]. Amgen called the transaction a strategic sale and stated that it would continue its activities in Türkiye [83]. The disclosures give no other reason for the sale [46,83].

One entry is a greenfield plant, one built new rather than bought, set up through a joint venture. SK Plasma, a Korean maker of plasma-derived medicines, signed a shareholders' agreement with the Turkish Red Crescent (Kızılay) to build a plasma fractionation plant and to set up a joint venture, Proturk [82]. Plasma fractionation separates blood plasma into medicines, here albumin, immunoglobulin and factor VIII [82]. The Korean daily Edaily reported on 15 June 2026 that ground had been broken at Çubuk, in Ankara, and dated the agreement to November of the previous year [82]. The plant is to have about 36,000 square metres of floor area and to process 600,000 litres of plasma a year, with completion targeted for the second half of 2028 and commercial production for 2030 [82]. SK Plasma holds 15% of the joint venture. It is to transfer its fractionation technology, support construction, quality control and the training of local staff, receive technology fees and take part in management on the basis of its stake [82]. Until commercial production begins, the company plans to fractionate plasma collected in Türkiye at its Andong plant in South Korea and to supply the finished products under a contract-manufacturing arrangement [82]. The Turkish President, as quoted in the report, put the investment at EUR 500 million [82]. In the report's account, the plant is expected to stabilise the supply of plasma-derived products, which had relied entirely on imports [82].

Acquisitions in the sector pass through merger control. The Competition Authority's preliminary report observes that the mergers and acquisitions brought before its Board in human medicines generally transfer brands, licence rights, control and business lines [42]. Board decisions on mergers and acquisitions in the pharmaceutical, health and medical-supply sector rose strongly from 2021 and peaked at 24 in 2023 [42]. The Authority's staff consider that a 2020 amendment to the communiqué on notifiable mergers played an important part in that rise. The amendment exempted

technology undertakings, a class that includes firms in biotechnology, pharmacology and health technologies, from the Turkish turnover thresholds [42]. Three pharmaceutical transactions in 2022, four in 2023 and four in 2024 were examined under that exemption [42]. An amendment published on 11 February 2026 raised the thresholds that make a transaction notifiable, the individual-turnover threshold from TL 250 million to TL 1 billion, the Turkish-turnover threshold from TL 750 million to TL 3 billion and the worldwide-turnover threshold from TL 3 billion to TL 9 billion [42]. It also limited the exemption to technology undertakings established in Türkiye, and transactions involving biotechnology, pharmacology and health-technology firms are now subject to an individual-turnover threshold of TL 250 million, below the new general threshold [42]. The Gensenta and Lüleburgaz transactions were both announced as subject to the Authority's clearance [81,83].

Read against entry-mode theory, the entries spread across the trade-off between control and the cost of committing resources that Anderson and Gatignon describe [18]. Amgen ended with more than 99% of Mustafa Nevzat, Zentiva took 75% with the seller keeping 25%, Fareva agreed to take 70% with Sanofi keeping 30%, and SK Plasma holds 15% of Proturk [78,79,81,82]. In Anderson and Gatignon's framing, low-control modes minimise the resources committed, and with them the risk, often at the expense of returns [18]. Brouthers and Hennart treat how much of a venture to own and whether to buy or build it as separate decisions [19], and the entries differ on both. Hennart argued in 1989 that contracts protect the parties poorly when one of them has better information or when the environment changes in unpredictable ways, whereas equity aligns their incentives [84]. The Proturk arrangement joins the two forms, with technology fees beside a 15% stake and a part in management [82]. Amgen's own sequence, an affiliate selling two products from 2010 and a manufacturer acquired in 2012, follows the order of growing commitment that the authors of the Uppsala model observed, from a sales organisation to production [21,44].

The entries also show what was bought. Hennart argues that the mode of entry depends on how easily the entrant's knowledge and the local assets it needs can each be traded, and that acquisition is the efficient route when those assets are embedded in firms and the market for firms works [20]. Where a permit or licence cannot be traded on its own, acquiring or forming a joint venture with its holder may be the only way to obtain it [20]. The Turkish acquisitions bought bundles of this kind. Zentiva's purchase brought a plant, an active-ingredient company and the marketing and distribution rights for the seller's generics [78]. The Gensenta purchase brought 88 products for which the company held the licence [46], and Fareva describes the Lüleburgaz site as coming with its customer portfolio and nearly 750 staff [47]. The Competition Authority describes the sector's acquisitions in the same terms, as transfers of brands, licence rights, control and business lines [42]. Ranbaxy and Dr Reddy's acquired European companies on the same logic, for their portfolios, sales networks and regulatory capacity [24].

Commitments made in this way can also be reversed. The authors of the Uppsala model allow commitment to decline or cease, and they add that an acquisition is not necessarily a quick way to build a position in a foreign market [22]. Hennart illustrates with Borden's exit from Japan that a foreign footprint can contract as well as grow [20]. Brouthers and Hennart note that entry modes, once established, are difficult to change [19]. The Amgen record shows such a change made through a sale of shares. Ten years after it acquired Mustafa Nevzat, Amgen agreed to sell the company, by then named Gensenta, to a Turkish group, and stated that it would continue its activities in Türkiye [46,79,83].

3.3 The CinnaGen case, 2014–2026

The trade registry records CinnaGen İlaç as one company, under İstanbul registry number 927931, from its founding in June 2014 to a change of name in May 2026 [33]. The CinnaGen group's chief executive founded it alone. A company in Singapore came to hold 90% of it in November 2018, and the Turkish company's own chief executive held all of its shares in 2020 [33]. A Turkish individual was its sole shareholder from 2024, and from December 2025 that individual and a private equity investment fund held it together [33]. Its capital rose from TL 50,000 to TL 393,325,800, and it was renamed three times, as Asena Biopharma, Yerlika Biopharma and Yerlika İlaç [33]. The plant at Çerkezköy whose opening the press reported in June 2019 is described today by Yerlika as its own research and production facility, established in 2019 [29,50]. The record is drawn as a timeline in Figure 1, and capital and ownership by registration date are set out in Table 3.

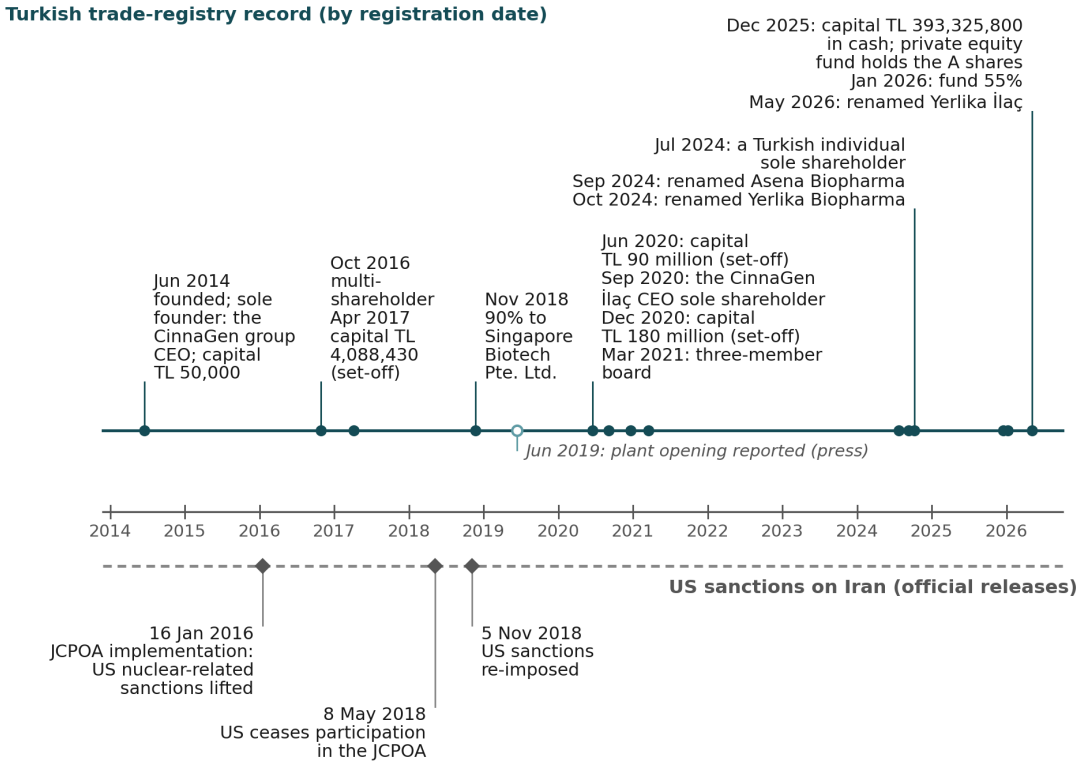


Fig. 1 CinnaGen İlaç, later Yerlika İlaç, in the İstanbul trade registry (registry number 927931), 2014 to 2026, and three dated US releases on sanctions on Iran. Upper track, registry events at their registration dates; events close in time share one label, with a marker for each date. The open marker is a press report of the plant opening in June 2019, not a registry event. Lower track, US Treasury and OFAC releases on the implementation of the JCPOA (16 January 2016), the end of US participation in it (8 May 2018) and the re-imposition of US sanctions (5 November 2018). The two tracks share only the time axis and are not linked, and the registry states no reason for any event. Private persons are described by role. Sources are the trade-registry notices [33], Daily Sabah [29] and the US releases [85,86,87].

Table 3 Registered capital and ownership of CinnaGen İlaç, renamed Asena Biopharma, Yerlika Biopharma and Yerlika İlaç, İstanbul trade registry, registry number 927931, by registration date, June 2014 to May 2026; source is the 17 gazette notices, of the record's 35, read for this study, and the CinnaGen İlaç CEO and the CinnaGen group CEO are named by role.

Registered	Capital after (TL)	Increase and how paid	Shareholders after	Source
17 June 2014 (founding)	TL 50,000	Founding: 50 shares of TL 1,000; one quarter on registration, the rest within 24 months	The CinnaGen group CEO (founder), 100%	[33,53]
28 October 2016	TL 50,000 (no change)	None	Multi-shareholder from 20 October 2016; no shareholder or share transfer named	[33]
5 April 2017	TL 4,088,430	TL 4,038,430, set off against the two shareholders' receivables	The CinnaGen group CEO (founder) and the CinnaGen İlaç CEO; split not shown	[33,53]
22 November 2018	TL 35,547,630	Increase from TL 4,088,430 not shown in the notices read for this study; no price stated for the transfer	Singapore Biotech Pte. Ltd. 90% (31,992,867 shares, taken over 2 November 2018); the CinnaGen İlaç CEO 10% (3,554,763 shares)	[33,53]
16 June 2020	TL 90,000,000	TL 54,452,370, set off against the receivables of Singapore Biotech Pte. Ltd. and the CinnaGen İlaç CEO	Singapore Biotech Pte. Ltd. and the CinnaGen İlaç CEO; percentages not shown	[33]
3 September 2020	TL 90,000,000 (no change; printed in notice of 15 September 2020)	None	The CinnaGen İlaç CEO, sole shareholder; transfer of Singapore Biotech's 90% not shown in the notices read for this study	[33]
21 December 2020	TL 180,000,000	TL 90,000,000, set off against the CinnaGen İlaç CEO's receivable	The CinnaGen İlaç CEO (sole shareholder in the preceding notices)	[33]
16 March 2021	TL 180,000,000 (no change)	None	Single-shareholder status ended; no shareholder or share numbers named	[33]
24 July 2024	TL 180,000,000 (no change)	None	A Turkish individual, sole shareholder; transfer to this person not shown in the notices read for this study	[33]
9 September 2024	TL 180,000,000 (no change)	None (name changed to Asena Biopharma)	Not restated in the notice	[33]
8 October 2024	TL 180,000,000 (no change)	None (name changed to Yerlika Biopharma)	Not restated in the notice	[33]
17 December 2025	TL 393,325,800	TL 213,325,800, paid in cash: 95,996,610 shares by the individual, 117,329,190 by the fund	A Ziraat Portföy private equity fund 216,329,190 shares (group A); a Turkish individual 176,996,610 shares (group B)	[33]
6 January 2026	TL 393,325,800 (no change)	None (notification of the change in ownership shares)	A Ziraat Portföy private equity fund 55% (from 0%); a Turkish individual 45% (from 100%)	[33,53]
6 May 2026	TL 393,325,800 (no change)	None (name changed to Yerlika İlaç)	Not restated in the notice	[33]

Seventeen of the record's 35 notices were read in full from their page images [33]. The other 18, published between March 2015 and December 2023, are known only by their date, issue, page and type in the registry's index. They are listed there as amendments of the articles of association, notices on the board and on representation, and internal directives, the company's own rules on how its general assembly works and who may sign for it [33]. Nothing is drawn here from their content. Amounts below are as printed in the notices. From 2017 every share has a nominal value of TL 1, and no notice read for this study states a price paid for any share [33].

The company was registered on 17 June 2014 and announced in the gazette of 23 June 2014 as Cinnagen İlaç Sanayi ve Ticaret Anonim Şirketi (so spelled in the gazette), with its seat in Ataşehir, İstanbul [33]. Its one founder was Haleh Hamedifar, the chief executive of the CinnaGen group, shown

in the notice as an Iranian national resident in Tehran [33]. The founder subscribed all 50 shares of TL 1,000 each, a capital of TL 50,000, with a quarter payable on registration and the rest within 24 months [33]. That was the minimum capital printed in the Turkish Commercial Code [53]. The founder alone formed the first board, for three years, as chair with sole signing authority [33]. The articles covered the manufacture, import, export and wholesale of medicines and active substances, and allowed the company to set up factories, to manufacture under contract and to obtain medicine licences [33].

On 20 October 2016 the board resolved that the company, until then a single-shareholder joint-stock company, would continue with more than one shareholder from that day [33]. The resolution was registered on 28 October 2016 and names no new shareholder [33]. The company's own later accounts date its founding to 2016. Ferhat Farşi, the chief executive of CinnaGen İlaç, told PharmaBoardroom in December 2018 that he had co-founded the Turkish affiliate in 2016 [49]. Daily Sabah reported the same in 2019, and Yerlika's web page gives November 2016 as its date of founding [29,50].

The first capital increase read for this study was decided by the general assembly on 3 April 2017 and registered on 5 April 2017 [33]. It raised the capital from TL 50,000, stated as fully paid, to TL 4,088,430 [33]. The increase of TL 4,038,430 was paid by set-off against the receivables that the two shareholders, the founder and Ferhat Farşi, held against the company, so that the company's debts to them became shares [33,53]. A certified accountant's report of 25 February 2017 established the receivables, and Ferhat Farşi chaired the meeting as deputy chair of the board [33].

The company's public plans date from the same months. In January 2017 a press release relayed by Matriks announced that CinnaGen had chosen Türkiye as its new production and research base for local and regional markets, with a plant to be founded that year in the Çerkezköy Organized Industrial Zone [27]. The release described the project as a greenfield investment with a Turkish partner, without naming the partner or giving any shares, and put Europe first among the export markets [27]. At the end of January 2017 Ekonomist, a Turkish business magazine, reported an investment of USD 30 million, operation from the third quarter of 2018 and a first product in 2019 [28]. It quoted Ferhat Farşi, described as a founding partner of CinnaGen İlaç, as saying that the company had obtained from the group the right to export to 20 countries [28]. The magazine added that the group's seven companies were all in Iran and that CinnaGen İlaç was the first of its companies in another country [28].

In November 2017 the two chief executives gave the project a larger total. In Dünya and in a column in Sabah, a Turkish daily, both of 27 November 2017, the plant was described as under construction, with test production planned for September 2018 [48,88]. The investment was put at USD 30 million of physical investment and USD 100 million in all once the transfer of technology and know-how was counted [48,88]. The chief executive of CinnaGen İlaç set an export target of USD 100 million for 2023 [48,88]. He told Sabah that the company had itself undertaken to the Ministry of Health to produce everything in Türkiye, the protein included [88]. He told Dünya that, for the time being, exports would be made from Iran on a re-export model, and that the project had been given priority-investment status [48]. The group's chief executive gave cultural closeness, the size of the population, and an investment climate and incentives that inspired confidence as the reasons why Türkiye was the group's first choice for investment abroad [48].

Ownership changed in November 2018. On 16 November 2018 the company notified the registry, under Article 198 of the Code, that the founder's whole holding of 31,992,867 shares, 90% of a capital of TL 35,547,630, had been taken over on 2 November 2018 by Singapore Biotech Pte. Ltd., a company based in Singapore [33,53]. Singapore Biotech had held none of the shares until then, and Ferhat Farşi kept his 3,554,763 shares, or 10% [33]. He signed the notification for the company. It was registered on

22 November 2018 and announced in the gazette of 28 November 2018, and it states no price [33]. No notice read for this study records the increase of the capital from TL 4,088,430 to the TL 35,547,630 stated in the notification, and none shows who owns or controls Singapore Biotech [33].

US sanctions on Iran are dated in 2018 by two official releases. On 8 May 2018 the US President ceased US participation in the Joint Comprehensive Plan of Action (JCPOA), and OFAC published a statement on that decision the same day [86]. The JCPOA is the agreement on Iran's nuclear programme under which the United States had lifted its nuclear-related sanctions on 16 January 2016 [85]. On 5 November 2018 the US Treasury stated that all US sanctions lifted or waived in connection with the JCPOA were re-imposed and in full effect from that day [87]. It stated on the same day that OFAC continued to maintain humanitarian authorisations and exceptions for the sale of food, medicine and medical devices to Iran [87].

In December 2018 the chief executive of CinnaGen İlaç told PharmaBoardroom that the plant at Çerkezköy would become operational in the first half of 2019 [49]. He said that two bioreactors of 2,000 litres each in the plant would be able to meet Türkiye's demand for monoclonal antibodies, and that the company would spend EUR 70 million to transfer the group's technology to Türkiye [49]. He also said that, while production had not yet started, the company had made an export agreement of USD 50 million covering, in his account, five countries [49]. In his account the Turkish company opened the door to exports to Europe, with three projects in preparation for submission to the EMA [49].

The opening of the plant was reported in June 2019. TGRT Haber, a Turkish news channel, reported on 11 June 2019 that the factory had opened that day, and Hürriyet and Daily Sabah reported the opening on 12 and 13 June [29,89,90]. In these reports the investment was USD 100 million, of which about USD 30 million was physical and USD 70 million technology transfer or know-how [29,89,90]. A 2019 profile published by Global Business Reports, written in the company's voice, put the same two parts at EUR 30 million in physical assets and EUR 70 million in research, development and technology transfer, and the company's staff in Türkiye at 54 [91]. The plant was described as including a research and development facility, and as the first in Türkiye to make medicines based on monoclonal antibodies, with rare and orphan drugs as its focus [29,90,91].

The export figures differ between sources and within them. The target was USD 100 million of exports in 2023 in the interviews of November 2017, in TGRT Haber, in Sabah in July 2019 and in the Global Business Reports profile [48,88,89,91,92]. It was USD 100 million a year to 20 countries in Daily Sabah and in the body of the Hürriyet report, and USD 150 million in the Hürriyet subheading [29,90]. The countries with signed agreements numbered twelve in Hürriyet and Daily Sabah, eleven in TGRT Haber and seven in Sabah [29,89,90,92]. A sale to Algeria was put at EUR 38 million in Dünya in 2017, and an Algerian agreement at USD 45 million over three years in TGRT Haber in 2019 [48,89]. In July 2019 the chief executive told Sabah that a second facility would be built, for filling vials, and that new molecules would be brought from the group's headquarters in Iran and produced in Türkiye [92]. In Sabah and in TGRT Haber he said that three or four more factories would follow if the company kept its momentum [89,92].

The capital was raised again in 2020, by set-off. The increase registered on 16 June 2020 took it from TL 35,547,630 to TL 90,000,000 [33]. The TL 54,452,370 was paid by set-off against the receivables of the two shareholders, Singapore Biotech Pte. Ltd. and Ferhat Farşi, as established in an accountant's report of 3 March 2020 [33]. The same notice registered Singapore Biotech (Holdings) Pte. Ltd., with the same registered address in Singapore, as chair of the board for one year, acting through a natural person

resident in Singapore [33]. Ferhat Farşi, resident in İstanbul, became deputy chair, and each of the two was given sole signing authority [33]. The notices read for this study do not say how the two Singapore names relate to each other [33].

By the notice registered on 3 September 2020 the company was a single-shareholder joint-stock company, and its sole shareholder was Ferhat Farşi [33]. The roles of Singapore Biotech (Holdings) Pte. Ltd. as board member and chair ended, and he was elected chair [33]. A notice registered on 15 September 2020 printed the articles with the whole capital of TL 90,000,000 belonging to him [33]. On 21 December 2020 an increase to TL 180,000,000 was registered. Its TL 90,000,000 was paid by set-off against his receivable from the company, as established in an accountant's report of 7 December 2020 [33]. The notices read for this study do not show how the 90% held by Singapore Biotech Pte. Ltd. passed to him, or at what price [33]. The notice of 25 September 2020, which falls between these dates, is among those not read for this study [33].

Single-shareholder status ended by a notice registered on 16 March 2021 [33]. The same notice registered a board of three, each elected until 21 January 2024, made up of an Iranian national resident in Tehran, a Turkish national resident in İstanbul and Ferhat Farşi [33]. He is printed there as a Turkish national resident in İstanbul and was elected chair with sole signing authority [33]. The notice names no shareholders and no numbers of shares [33]. Between 2014 and 2020 the capital grew by TL 179,950,000. The notices read for this study record TL 148,490,800 of that as paid by set-off against shareholders' receivables, in 2017 and twice in 2020, and the remaining TL 31,459,200 is the step from TL 4,088,430 to TL 35,547,630 that no notice read for this study records [33].

A notice registered on 26 December 2023 appointed a Turkish national resident in İstanbul as a signatory with limited authority, under an internal directive published on 22 December 2023 that was not read for this study [33]. By the notice registered on 24 July 2024 the company again had a single shareholder, a Turkish national resident in İstanbul [33]. The notice gives this shareholder the same name as the Turkish board member elected in 2021, and no notice read for this study shows how the shares came to that person [33]. The general assembly of 5 September 2024 changed the name to Asena Biopharma İlaç Sanayi ve Ticaret Anonim Şirketi, registered on 9 September 2024 [33]. The general assembly of 3 October 2024 changed it to Yerlika Biopharma İlaç Sanayi ve Ticaret Anonim Şirketi, registered on 8 October 2024 [33].

The capital was raised in cash in December 2025. The notice registered on 17 December 2025 took it from TL 180,000,000 to TL 393,325,800 [33]. Of the increase of TL 213,325,800, 95,996,610 shares were subscribed and paid in cash by the individual shareholder [33]. The other 117,329,190 were subscribed and paid in cash by Ziraat Portföy Yönetimi A.Ş. Element Özel Girişim Sermayesi Yatırım Fonu, a private equity investment fund managed by the portfolio management company Ziraat Portföy Yönetimi A.Ş. [33]. The notice calls both of them existing shareholders. Its share table gives the fund 216,329,190 shares of group A and the individual 176,996,610 shares of group B [33]. The fund is thus shown with more shares than it subscribed in the increase, and no notice read for this study records how it came to hold the others [33]. In a notification under Article 198 registered on 6 January 2026, the board stated that the fund's share of the capital had risen from 0% to 55% and the individual's had fallen from 100% to 45% [33,53].

The articles registered in December 2025 divide control between the two groups of shares. The board has five members, three nominated by group A and two by group B, and a group that falls below 25% of the capital loses its right to nominate [33]. Important board decisions need at least one A member and one B member present and voting in favour, and the general assembly meets and decides with 75% of the total capital [33]. An internal directive requires the joint signatures of an A and a B

signatory for listed transactions, among them any single transaction above USD 100,000 [33]. All five board members, elected until 10 December 2028, are printed as Turkish nationals, and the chair is the individual shareholder [33]. The general assembly of 1 May 2026 changed the name to Yerlika İlaç Sanayi ve Ticaret Anonim Şirketi, registered on 6 May 2026 [33]. The registered office stayed at the same address in Ataşehir, İstanbul, from 2017 to 2026 [33].

Yerlika's own pages describe the plant today, and what follows is the company's account. It states that it was founded in November 2016 to manufacture biotechnological medicines in Türkiye and to take part in international markets [50]. It offers its own products and contract manufacturing and contract development and manufacturing (CDMO) services for other firms, from its facility in the Çerkezköy Organized Industrial Zone [50]. It gives the facility an area of 4,215 square metres, single-use bioreactors of 10, 50 and 500 litres, and a filling capacity of 2.5 million units a year in vials, cartridges and syringes, for liquid and freeze-dried products [93]. In December 2018 the chief executive of CinnaGen İlaç had spoken of two bioreactors of 2,000 litres each [49]. Yerlika states that the facility holds a GMP certificate and that national and international authorities, which it does not name, audit its quality control regularly [93,94].

The company's timeline lists the establishment of the research and production facility in 2019, and TİTCK GMP certificates for two molecules in 2021 and for seven in 2023 [50]. It lists the licensing and launch of a recombinant factor VIIa biosimilar in 2022 [50]. For 2024 it lists its first contract production of cartridges, the start of a phase I study of an adalimumab biosimilar and licence applications for three further biosimilars [50]. In a 2025 interview in GaBI Journal, which Yerlika funded, its chief executive described the company as a contract manufacturer and developer that aims to reduce Türkiye's reliance on imported biologicals [30]. The interview's product table lists eptacog alfa, for haemophilia, as approved in Türkiye in 2021 and marketed since 2022, with technology transfer for local manufacturing under way [30]. The two sources date the product's approval differently, 2022 in the company's timeline and 2021 in the interview. It lists five further products with marketing authorisations expected between 2026 and 2029 [30]. The journal's editor added that follow-on biologicals approved in Türkiye might not have been authorised under the European Union's process for biosimilars [30].

The chief executive's message on the company's website states that the company was founded to bring to Türkiye the raw-material production technology of the largest biotechnological pharmaceutical company in the Middle East, which the message does not name [95]. The member directory of the Çerkezköy Chamber of Commerce and Industry lists a Çerkezköy branch of Yerlika İlaç Sanayi ve Ticaret A.Ş., with an address in Kapaklı, Tekirdağ, and medicine as its business [96]. The CinnaGen group's website, as captured on 25 November 2026, lists a head office in Tehran and a manufacturing site in Karaj, both in Iran, and names five companies of the group and no Turkish affiliate [97,98]. The group's history page does not mention Türkiye [99]. It states that CinnaGen received EU GMP certification in 2016, and in its latest entries that the EMA issued a positive opinion recommending approval of CinnaGen's teriparatide biosimilar [99].

The record shows a Turkish joint-stock company founded in 2014 by the chief executive of an Iranian biopharmaceutical group, with the chief executive of the Turkish company a shareholder by 2017 [33]. Its shareholders financed it from 2017 to 2020 mainly by converting their receivables into capital [33]. Singapore Biotech Pte. Ltd. held 90% of it from November 2018, Singapore Biotech (Holdings) Pte. Ltd. chaired its board in 2020, and the Turkish company's chief executive held all its shares from September 2020 until the notice of March 2021 [33]. A plant at Çerkezköy was announced in 2017 and reported opened in June 2019, with investment and export figures that the company gave differently

from one source to the next [27,29,48,90]. A Turkish individual owned the company from 2024, and from December 2025 it was owned jointly by that individual and a private equity investment fund, the fund holding 55% [33]. In those years the company raised capital in cash, adopted shared control between two groups of shares and took the names Asena Biopharma, Yerlika Biopharma and Yerlika İlaç [33]. The company and its plant continue, and the company describes itself today as a Turkish contract manufacturer and developer of biological medicines [30,33,50].

4. A protocol for Iranian pharmaceutical companies entering Türkiye

The protocol set out here is for an Iranian pharmaceutical company that is considering Türkiye as a market, a production site or an export base, or as each of these in turn. It orders the decisions such a company takes before it commits resources, and names the evidence each decision needs [18,21]. It was built, as Section 2.4 describes, from the staged logic of internationalization and entry-mode choice, from the order that Turkish rules impose on a foreign manufacturer, and from the CinnaGen İlaç record read beside the comparator entries [22,33,34]. Every rule and figure it relies on was given, with its source, in Sections 1 to 3, and each is cited again where a stage uses it.

The stages run from 0 to 9. Each states its objective, the questions the company must answer, the evidence it should gather and what CinnaGen İlaç did at that point in its own entry. That last part reports dated acts and attributed statements only, and says so where the record is silent [33]. Each stage closes with a gate, a short list of conditions written so that a board can mark each one as met or not met. A gate passes when every condition is met. It holds when a condition is not yet met but can be, and the company then waits without committing further resources. It stops when a condition cannot be met, and the entry, or the part of it that depends on that condition, ends there. The three outcomes follow the Uppsala view that commitment grows in steps and may also decline or stop when performance and prospects are not promising enough [21,22]. The stages and their gates are drawn in Figure 2 and summarised in Table 4.

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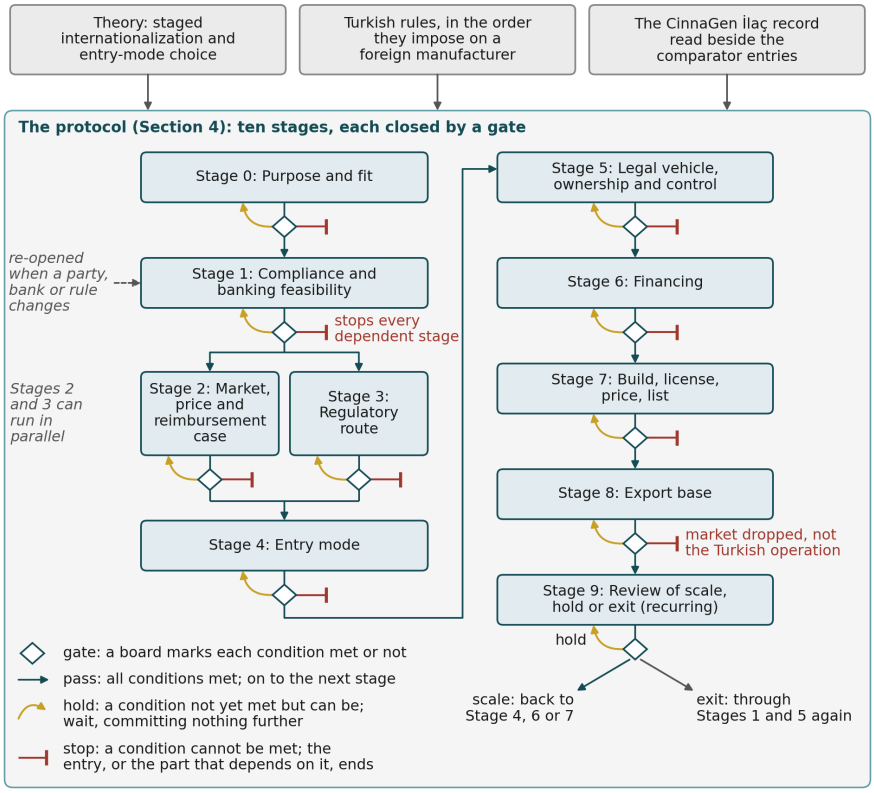


Fig. 2 The protocol for an Iranian pharmaceutical company entering Türkiye. Stages 0 to 9 are each closed by a gate that passes when every condition is met, holds when a condition is not yet met but can be, so that the company waits without committing further resources, and stops when a condition cannot be met, so that the entry, or the part that depends on that condition, ends. A stop at Stage 1 stops every dependent stage, and Stage 1 is re-opened whenever a party, a bank or a rule changes. Stages 2 and 3 can run in parallel. A market that fails at Stage 8 is dropped without stopping the Turkish operation. Stage 9 recurs and leads to scaling, by a return to Stage 4, 6 or 7, to holding, or to exit through Stages 1 and 5 again. The protocol was built from the three inputs set out in Section 2.4. Source is Section 4 of this article.

Table 4 The protocol at a glance: for each of the ten stages, numbered 0 to 9, its objective, the conditions under which its gate passes, when it holds or stops, and what CinnaGen İlaç did at that point, with company statements attributed. The table summarises Section 4, where the full gate conditions and their sources are given.

Stage	Objective	Gate: passes when	Hold or stop	What CinnaGen İlaç did
0. Purpose and fit	A written statement of Türkiye's role: market, production site, export base, or these in sequence.	Role and order of steps stated in writing; each product placed in its Turkish product class; capability brought and sought named; board has approved role and product list.	Holds while the role is agreed and the product list is not; stops if no product fits the role.	Registered June 2014; January 2017 release announced Türkiye as production and research base for local and regional markets, Europe first among export markets [27,33]
1. Compliance and banking feasibility	Every flow of goods, technology and money lawful under each binding sanctions regime, and processed by banks with full knowledge.	Legal opinion (US, EU, Turkish law) finds every flow permitted or licensed, none circumventing a measure; products classified against the general licence; US technology authorised; all counterparties screened; banks fully informed, confirming in writing.	Holds while an opinion, licence or bank answer is pending; stops, with dependent stages, if any condition fails.	Sanctions assessment and banking not shown in the record; founded 2014, multi-shareholder 2016, plant opening reported June 2019 [29,33]
2. Market, price and reimbursement case	A product-by-product case that holds at the price Türkiye allows and the amount SGK pays.	Per product: maximum price computed from the five reference countries, euro value dated; SGK payment computed; case holds without a euro-value rise; reimbursement timing follows SGK dates; local-production instrument named, existence stated.	Holds pending cost-card price or payment-model decision; stops a product failing at the reimbursed amount, the entry if none passes.	No price or reimbursement decision recorded; November 2017, its CEO said it had undertaken to the Ministry of Health to produce everything in Türkiye [88]
3. Regulatory route	A licensing and inspection route for each product, with a dated plan the rules allow.	Resident licence holder with qualified authorised person named; for foreign-made products, a Turkish importer agrees to seek TİTCK GMP inspection; GMP evidence for every step; plan treats legal periods as minimums; exclusivity and patents checked.	Holds while GMP inspection is pending, and for six months after refusal; stops without resident holder or inspectable site.	June 2014 articles allowed licences, factories and contract manufacturing; pre-opening licence applications not shown in the record; Yerlika lists three further biosimilar applications in 2024 [33,50]
4. Entry mode	An entry mode that fits the Stage 0 role and survives Stages 1 to 3.	Modes compared on control, resources, local assets and reversal cost; local assets listed with tradability; chosen mode serves the role and uses only cleared flows; competition clearance checked; partner contracts cover know-how and changed conditions.	Holds while a partner or target is sought; a failing mode is dropped; stops only if no mode passes.	Own plant: January 2017 release described a greenfield investment with an unnamed Turkish partner; plant reported under construction November 2017, opened June 2019 [27,29,48]
5. Legal vehicle, ownership and control	A Turkish company whose ownership and control are documented, disclosable and able to change in an orderly way.	Ownership chain to ultimate natural persons documented for the banks; Article 198 notifications planned for every threshold; board, chair and signatories named, with group rights where shared; change-of-control rules agreed; owners and directors screened.	Holds until the documents exist; stops if an owner or controller cannot be disclosed to the company's banks.	Founded 17 June 2014 by the CinnaGen group CEO alone; 2 November 2018 Singapore Biotech Pte. Ltd. took the founder's 90%; its owner not shown [33]

Stage	Objective	Gate: passes when	Hold or stop	What CinnaGen İlaç did
6. Financing	A financing plan naming the source, form and channel of each amount, from founding capital to the plant.	Each tranche's source, amount, form and date named; cross-border amounts use cleared, informed bank channels; set-off receivables documented, origin showable; state aid certified, or plan holds without it; response to delayed or refused transfers stated.	Holds while certificate or bank answer is pending; stops if a needed transfer has no channel cleared at Stage 1.	Increases of TL 4,038,430 (April 2017), TL 54,452,370 (June 2020) and TL 90,000,000 (December 2020) paid by set-off; TL 213,325,800 in cash, December 2025 [33]
7. Build, license, price, list	A product on the market: made at a certified site, licensed, priced and, where needed, listed for reimbursement.	Per product: site holds accepted GMP evidence per step; licence, sales permit, approved price before launch; first commercial batch within 30 months; SGK application filed where needed, distribution shown within five months; local-production commitments documented.	Holds a product until every condition is met; commitment beyond the first products waits for the Stage 9 review.	Opening reported 11–13 June 2019; Yerlika lists TİTCK GMP certificates for two molecules in 2021, seven in 2023; factor VIIa biosimilar licensed and launched 2022 [29,50,89,90]
8. Export base	What exports from Türkiye would add, market by market, to exports from the home country.	Per market: regulator's evidence named, whether a Turkish licence and TİTCK inspection meet it; export price allows for Turkish reference pricing; Iranian-party flows pass Stage 1; volumes rest on signed contracts or are labelled targets.	Holds a market until its regulatory route is known; a failing market is dropped without stopping the Turkish operation.	2017: export right to 20 countries reported; CEO said exports would, for now, be made from Iran; exports and EU approval not shown [28,48]
9. Review of scale, hold or exit	A standing, periodic decision to scale, hold or reduce commitment, with an orderly exit if chosen or forced.	Board sets triggers in advance, tied to earlier gates or product cases; reviews at fixed intervals and on Stage 1 change; licences and listings held by Turkish company; share-sale rules and approvals identified; hold defined.	Scaling returns to the changed stage, usually 4, 6 or 7; exit reruns Stages 1 and 5.	Turkish individual sole shareholder by July 2024; renamed Asena Biopharma, Yerlika Biopharma (2024), Yerlika İlaç (May 2026); private equity fund 55% by January 2026 [33]

Stage 0. Purpose and fit

The objective is a written statement of the role Türkiye is to play. That role can be a market for products made in Iran, a production site for the Turkish market, an export base for third markets, or these in sequence. The Uppsala sequence, from exporting through an agent to a sales subsidiary and then to production, is one such order [21]. The questions are which products the company would bring, how each fits the Turkish market, and what capability the company brings that the market lacks. Firms from emerging economies have also gone abroad to acquire resources that compensate for gaps in their capabilities, the strategy Luo and Tung call a springboard [5]. A company that seeks such gains in Türkiye names them as part of the role.

The market data of Section 3.1 frame the fit by product class. Imports are concentrated in originator and biotechnological products. In 2025, 68.8% of the value of originator medicines was imported, 99.4% of generic boxes were produced in Türkiye, and biotechnological medicines made up 45.8% of the value of imports [14]. Biotechnological medicines held about 21.1% of the market by value, and 42 biosimilar products of 11 brands were made in the country [14,51]. More than 80% of active ingredients are imported, in the AIFD/IQVIA account [13]. Price increases accounted for 90.6% of the growth of the audited market in 2024, while the number of boxes sold fell by 3.5% [13]. Sales are concentrated, with the 50 largest companies holding 86% of value in 2025 [14]. A maker of generics thus meets a market whose boxes are already made locally, and a maker of biologics meets one that

still imports much of what it spends [14]. On the home side, science-based Iranian companies were making biopharmaceuticals by 2012, and about six non-originator biopharmaceuticals had been registered in Iran since 2003 [4].

CinnaGen's stated purpose dates from January 2017. A press release relayed by Matriks announced that the group had chosen Türkiye as its new production and research base for local and regional markets, and put Europe first among the export markets [27]. Ekonomist reported that the Turkish company had obtained from the group the right to export to 20 countries, and that it was the group's first company outside Iran [28]. In November 2017 the group's chief executive gave cultural closeness, the size of the population, and an investment climate and incentives that inspired confidence as the reasons why Türkiye was the group's first choice for investment abroad [48]. In 2019 the plant was presented as the first in Türkiye to make medicines based on monoclonal antibodies, with rare and orphan drugs as its focus [29,90,91]. The company itself had been registered in June 2014, two and a half years before the first of these statements [33]. The gate of Stage 0 passes when the following conditions are met:

- The role of Türkiye, as a market, a production site, an export base or a sequence of these, is stated in writing, with the order of the steps.
- Each product proposed is placed in its Turkish product class (originator, generic or biosimilar; imported or made locally), with that class's place in the market as given in Section 3.1 [13,14].
- The capability the company brings for each product, and any capability it seeks to gain in Türkiye, is named.
- The board has approved the role and the product list as the basis for the stages that follow.

The gate holds while the role is agreed and the product list is not. It stops if no product fits the role chosen, and the company may then return to the choice of role, since commitment in the Uppsala view may stop as well as grow [22].

Stage 1. Compliance and banking feasibility

The objective is to establish, before any other commitment, that every flow of goods, technology and money the entry needs is lawful under each sanctions regime that binds a party to it. A second objective is that banks will process the payments with full knowledge of them. The stage comes first because payments connected with Iran are governed by US and EU sanctions law, which binds the parties within its reach and exposes foreign banks to US measures [40,41,63]. Firms in third countries weigh the risk of secondary sanctions when deciding whether to deal with a sanctioned economy [9]. French exporters that relied more heavily on trade finance were hit harder by the EU measures against Iran of January 2012 [10], and Iranian companies have had to pay cash in advance for imported medicines and raw materials [1]. The questions are which laws bind each party and each bank in the chain, which flows each law permits and on what conditions, and which counterparties are excluded.

The evidence is the text of each rule as in force on the date of the assessment, read by counsel in a legal opinion, a written statement of whether each planned act is lawful. The US general licence in section 560.530 of the Iranian Transactions and Sanctions Regulations, as amended in July 2026, covers medicine designated EAR99, shipped within 12 months of the contract, with the related financing and payment [40]. It excludes listed drug classes, which need a one-year specific licence, as well as military, intelligence and law-enforcement buyers and blocked persons [40]. It does not cover US technology or software used to manufacture medicine, and OFAC determines each year whether to revoke it [40]. Council Regulation 267/2012, in its text of 1 August 2026, binds EU persons and business done in the Union [41]. It allows healthcare transfers with banks domiciled in Iran, notified in advance

from EUR 10,000 and authorised in advance from EUR 100,000, and it counts linked transfers as one [41]. It also prohibits knowing and intentional participation in activities whose object or effect is to circumvent its measures [41].

The exposure of banks is evidence in its own right. OFAC designated a Türkiye-based bank on 4 September 2026, and on 5 October 2026 it alerted foreign financial institutions that those transacting with sanctioned Iranian banks could be targeted at any time without advance notice [62,63]. Restrictions on the US correspondent accounts of foreign banks are published in the Federal Register or on an OFAC list [64]. Türkiye's Ministry of Foreign Affairs stated on 14 February 2024 that Türkiye implements only sanctions decided by the UN Security Council. The same answer said that Turkish banks and companies borrow and lend abroad and that the Ministry informs them regularly about unilateral sanctions [76]. Türkiye's stated position therefore leaves the question of what a given bank will process to be answered bank by bank [76].

The record does not show how CinnaGen İlaç assessed sanctions or arranged its banking. It shows that the entry spanned changes in the US rules. The United States lifted its nuclear-related sanctions on 16 January 2016, ceased participation in the JCPOA on 8 May 2018 and re-imposed the sanctions on 5 November 2018 [85,86,87]. On that last date the Treasury stated that OFAC continued to maintain humanitarian authorisations for the sale of medicine to Iran [87]. The company was founded in 2014 and became multi-shareholder in 2016, and the opening of its plant was reported in June 2019 [29,33]. The registry states no reason for any of its acts [33]. The gate of Stage 1 passes when the following conditions are met:

- A written legal opinion from counsel qualified in US and EU sanctions law and in Turkish law covers every planned flow of goods, technology and money and every party to it. It finds each flow permitted or covered by a licence held, and finds that no element of the plan has the object or effect of circumventing a measure [40,41].
- Each product to be sold to Iran is classified against the conditions of the general licence, including EAR99 status, the excluded classes and the 12-month shipment condition, or a specific licence is held for it. No buyer is a military, intelligence or law-enforcement purchaser [40].
- Any US technology or software to be used in manufacture is identified, and the legal opinion states how its use is authorised [40].
- Every counterparty, including shareholders, board members, customers, suppliers, distributors and banks, has passed counterparty screening, a check against the US and EU lists of blocked, designated and frozen persons and the published restrictions on foreign banks, repeated before each new contract or payment [41,63,64].
- Each bank that will process the company's payments has been given full disclosure of the parties, the goods and the purpose of the payments, and has confirmed in writing that it will process them. Each payment meets the notification and authorisation thresholds that apply to it [41].

If any condition fails, the gate stops, and with it every stage that depends on the failed flow. It holds while an opinion, a licence application or a bank's answer is pending. The gate is opened again whenever a party, a bank or a rule changes, since OFAC decides each year whether to revoke the general licence and has stated that it can act without advance notice [40,63].

Stage 2. Market, price and reimbursement case

The objective is a case, product by product, that holds at the price Türkiye allows and at the amount SGK pays. Prices are set by the state, and SGK pays for more than 85% of medicine spending by value [36,42]. The questions are what maximum price each product would receive, whether and when SGK

would list it, what SGK would pay within its group, and how these amounts move with the euro value. The authors of a 2023 review state that the fixed shares and the euro value lower companies' margins and lead to fewer or more hesitant requests to enter the market [70].

The price evidence is the lowest ex-factory price, discounts excluded, of the reference product in France, Spain, Italy, Portugal and Greece, the reference countries named in the communiqué of 29 August 2026 [36,55]. That price is converted at the euro value, TL 29.1164 at a coefficient of 65% from 1 April 2026 [36]. The value was set by decisions of October 2024 and December 2025 before the 2026 decision [57,58], and the industry associations put it at 50.6% to 58.7% of the market rate on the dates they measured [13,14]. From the first generic, the original and all generics are capped at 60% of the benchmark reference price, with higher shares for first generics in their first three years [36]. Biosimilars, orphan products and several other classes are priced under separate Ministry rules, and a product made in Türkiye with no reference product can be priced on a cost card [36,55].

The reimbursement evidence is the product's group of equivalent products and its discount band. SGK pays up to the cheapest equivalent's discounted unit price plus 6%, counting the cheapest only if it held 1% of the group in one of the last five months [42,59]. In the band from TL 151.25, the public institution discount is 41% for a reference product with no generic and 28% for generics, in the communiqué as valid from 1 April 2026 [59]. Applications to the Drug Reimbursement Commission close on the last working day of March and of August, and only a firm holding a manufacturing or import authorisation may apply [37]. A first biosimilar priced at least 30% below the listed reference product is given priority, and a product at least 5% below the cheapest in its group can be listed in the weekly list [37]. A 2025 review, drawing on consultancy and industry reports, puts the average time from licence application to reimbursement at about three years [65]. The Competition Authority states that not being reimbursed can be an entry barrier where at least one medicine in the market is reimbursed [42].

Local production can bear on payment. SGK may create alternative payment models to encourage local production and the move of imported products to it [59]. The localisation requirement once removed reimbursement from products whose local-production commitments were not given, accepted or fulfilled, and in 2022 it was found inconsistent with GATT Article III:4 [43]. İEİS describes the localisation process as halted before it was complete, and reports that the Medium-Term Programme for 2025 to 2027 states that the domestic production strategy will be reassessed [14,51].

The record holds no price or reimbursement decision for any product of CinnaGen İlaç. In November 2017 the chief executive of CinnaGen İlaç told Sabah that the company had undertaken to the Ministry of Health to produce everything in Türkiye, the protein included [88]. The gate of Stage 2 passes, product by product, when the following conditions are met:

- A maximum price has been computed under the decision of 11 March 2026 from the five reference countries, with the euro value used and its date stated [36,55].
- The group of equivalent products, the price band and the public institution discount are identified, and the amount SGK would pay is computed [59].
- The case holds at the amount SGK would pay, and it does not depend on a rise in the euro value.
- The time to reimbursement in the plan follows the SGK application dates and is no shorter than the evidence of Section 3.1 supports [37,65].
- Any part of the case that rests on local production names the instrument that would reward it, such as an alternative payment model, and states whether that instrument exists on the date of the case [59].

The gate holds for a product whose case depends on a decision not yet taken, such as a cost-card price or an alternative payment model [55,59]. It stops for a product whose case fails at the reimbursed amount, and it stops the entry if no product passes.

Stage 3. Regulatory route

The objective is a licensing and inspection route for each product, with a dated plan that the rules allow. A licence can be applied for only by a natural person or trading company resident in Türkiye, which employs as its authorised person a graduate in pharmacy, medicine or chemistry entitled to practise there [34]. The questions are who will hold each licence, where each manufacturing step will take place, how GMP will be shown for each step, and how long the route will take.

For a product made in Iran, the Turkish applicant files the foreign licensor's document naming it the sole authorised representative, and GMP evidence for each step of the finished product [34]. TİTCK's GMP inspection of the Iranian site is applied for by an importer established in Türkiye, which carries responsibility for the file [35]. A site TİTCK has not inspected goes to an on-site inspection. The product must be seen in production, and the site's documents must also be available in English [35]. The certificate is valid for three years and can be extended to 12 years through risk-based reviews for a site in a country whose authority is a PIC/S member [35]. TİTCK's inspectorate and Iran's Food and Drug Administration are both listed by PIC/S with an accession date of January 2018 [15]. A critical deficiency leads to refusal and bars a new on-site application for six months [35]. In the AIFD/IQVIA account, licensing cannot be completed before a GMP certificate is issued [13]. The guideline states neither the fees nor the time within which TİTCK decides [35].

The licensing clock is set by the regulation. TİTCK starts the process only in February, May, August and November, after a completeness check of up to 30 days, 30 days to complete the file and a second check of up to 30 days [34]. It then concludes within 210 days of its start notice, or 90 days for applications that rely on earlier assessments by authorities of comparable standards, with the clock stopped while it waits for information it has requested [34]. The Competition Authority states that licences take longer than the law provides [42]. A reference product first licensed in the customs union of the European Union and Türkiye after 1 January 2005 has six years of data exclusivity from that licence, limited by any patent term in Türkiye [34].

The articles registered in June 2014 allowed CinnaGen İlaç to obtain medicine licences, to set up factories and to manufacture under contract [33]. The record does not show which licences the company applied for before its plant opened, or whether any product was first imported from Iran [33]. Yerlika's timeline lists licence applications for three further biosimilars in 2024 [50], and the 2025 interview lists five further products with marketing authorisations expected between 2026 and 2029 [30]. The gate of Stage 3 passes when the following conditions are met:

- A licence holder resident in Türkiye, with an authorised person who meets the regulation's conditions, is named for each product, whether it is the company's own Turkish subsidiary or a partner [34].
- For each product made outside Türkiye, an importer established in Türkiye has agreed to apply for TİTCK's GMP inspection, and the site can show the product in production, with its documents in English [35].
- GMP evidence of a kind the regulation accepts is on file, or planned, for every manufacturing step of the finished product [34].
- The dated plan treats TİTCK's start months and legal periods as the shortest possible times, and allows for clock stops and longer elapsed times [34,42].

- Data exclusivity and any patent term in Türkiye have been checked for each reference product on which the company's product relies [34].

The gate holds while a GMP inspection is pending, and for six months after a refusal [35]. It stops for a product that has no resident licence holder or whose site cannot meet the inspection conditions.

Stage 4. Entry mode

The objective is a choice of entry mode that fits the role set at Stage 0 and survives Stages 1 to 3. The options run from export through a Turkish importer and licence holder, through licensing or contract manufacturing at a Turkish plant, to a joint venture, an acquisition or the company's own plant [18,19]. The questions are how much control each option gives, what resources it commits, which local assets it secures and how hard it is to reverse.

Anderson and Gatignon frame the choice as a trade-off between control and the cost of committing resources, and low-control modes minimise the resources committed, often at the expense of returns [18]. A review of the empirical work found that no single mode performs best, while firms whose choices matched theoretical predictions performed better [19]. Hennart argues that the mode depends on how easily the local assets an entrant needs, such as distribution, permits and licences, can be traded [20]. Where a permit cannot be bought on its own, acquiring its holder or forming a joint venture with it may be the only route [20]. Contracts protect the parties poorly when one of them has better information or when the environment changes in unpredictable ways [84]. Once established, entry modes are difficult to change [19], and an acquisition is not necessarily a quick way to build a position in a foreign market [22].

The Turkish record leans to acquisition. Foreign acquirers made 71% of the 38 acquisitions in and around the sector that Kahraman and Uğurluoğlu compiled for 2006 to 2014 [77]. The purchases by Zentiva, Eczacıbaşı and Fareva brought plants, licences, marketing rights, customers and staff [46,47,78]. Amgen sold two products through its own affiliate from 2010 before it acquired a manufacturer in 2012 [44]. SK Plasma took 15% of a joint venture that is building a new plant, with technology fees and a part in management [82]. İEİS counted 111 manufacturing facilities in December 2025, among which a contract site or a target would be found [14]. Acquisitions in the sector pass through the Competition Authority. Since February 2026, transactions involving biotechnology, pharmacology and health-technology firms have been subject to an individual-turnover threshold of TL 250 million [42].

CinnaGen İlaç took the route of its own plant. The January 2017 release described a greenfield investment with a Turkish partner, without naming the partner or giving any shares [27]. The notices read for this study show the founder and the chief executive of CinnaGen İlaç as the company's two shareholders in April 2017 [33]. The plant was reported under construction in November 2017 and opened in June 2019 [29,48]. Yerlika now offers contract manufacturing and development services for other firms from the same facility [50]. The gate of Stage 4 passes when the following conditions are met:

- The modes open to the company have been compared on control, resources committed, the local assets each secures and the cost of reversing it [18,19,20].
- The local assets the entry needs, such as licences, a certified plant, distribution and staff, are listed, each with whether it can be bought or contracted for on its own [20].
- The chosen mode serves the role set at Stage 0 and uses only flows cleared at Stage 1.
- Where the mode is an acquisition or a joint venture, the need for Competition Authority clearance has been checked against the thresholds in force [42].

- Where the mode rests on a contract with a Turkish partner, the contract covers the know-how it transfers and what happens if the environment changes [84].

The gate holds while a partner or a target is sought. A mode that fails a condition is dropped and the comparison continues among the others, since no single mode performs best in the empirical work [19]. The gate stops the entry only if no mode passes.

Stage 5. Legal vehicle, ownership and control

The objective is a Turkish company whose ownership and control are documented, can be disclosed and can change in an orderly way. The vehicle in the record is the joint-stock company (A.Ş.), which a foreign parent can found alone [53]. The questions are who will own the company and through which entities, who will sit on its board and sign for it, and how ownership and control may change later.

The minimum capital is TL 250,000, or TL 500,000 of initial capital in the registered-capital system, after the presidential decision of 24 November 2023 [53]. At least 25% of cash capital is paid before registration into a bank account in the name of the company being formed, so a bank relationship cleared at Stage 1 is needed before the company exists [53]. The board may include legal persons, each acting through one registered natural person, and the Code sets no residency or nationality condition for board members [53]. A holder whose direct or indirect stake reaches or falls below 5, 10, 20, 25, 33, 50, 67 or 100% notifies the company and the authorities within ten days, and the rights attached to those shares are frozen until the notification is registered and announced [53]. Shareholders have a pre-emption right to new shares, which the general assembly can restrict only for justified reasons and with 60% of the capital in favour [53]. The foreign direct investment law gives foreign investors national treatment, asks only for notification of statistical information and allows profits, dividends and sale proceeds to be transferred abroad through banks [38].

CinnaGen İlaç was founded on 17 June 2014 by the CinnaGen group's chief executive alone, with the capital of TL 50,000 then printed in the Code as the minimum [33,53]. It continued with more than one shareholder from 20 October 2016, and in April 2017 the founder and the chief executive of CinnaGen İlaç were its two shareholders [33]. On 2 November 2018 Singapore Biotech Pte. Ltd. took over the founder's 90%, as notified under Article 198, and no notice read for this study shows who owns or controls that company [33]. In 2020 Singapore Biotech (Holdings) Pte. Ltd. chaired the board through a natural person, and from September 2020 the chief executive of CinnaGen İlaç held all the shares [33]. A Turkish individual was sole shareholder from July 2024 [33]. From December 2025 that individual and a private equity investment fund held the company, the fund with 55% by the notification of January 2026 [33]. The articles of December 2025 give each of two groups of shares board seats and require a member of each group to approve important board decisions [33]. Each change is visible in the registry by its date, and none by its reason [33]. The gate of Stage 5 passes when the following conditions are met:

- The ownership chain, from the Turkish company up to the natural persons who ultimately own and control each shareholder, is documented and ready to be given to the company's banks. The registry records shareholders, but the CinnaGen İlaç notices read for this study do not show who owns a corporate shareholder [33].
- An Article 198 notification is planned for every threshold that a planned or possible change of holding would cross, within the ten days the Code allows [53].
- The board, its chair and those with signing authority are named, and where ownership is shared the articles set out the nomination rights and the decisions that need the approval of each group [33,53].

- The shareholders have agreed in writing how control may change, by transfer of shares or by an increase of capital, and how pre-emption rights will be treated [53].
- Every shareholder and board member has passed the counterparty screening of Stage 1.

The gate holds until the documents exist. It stops if an owner or a controller cannot be disclosed to the company's banks, since every shareholder must pass the screening of Stage 1 against the published lists of blocked and frozen persons [41,62].

Stage 6. Financing

The objective is a financing plan that names the source, form and channel of each amount the company needs, from founding capital to the plant. The questions are how capital will be paid in, which amounts must cross borders and through which banks, and which state aid the project can obtain. The Code allows new capital in cash, in kind or from the company's own reserves [53]. An increase may also be paid by setting off a shareholder's receivable, in which case the board's declaration states that the debt exists, is valid and can be set off [53]. An increase lapses if it is not registered within three months of the decision [53]. Any amount that comes from abroad depends on a channel cleared at Stage 1, and the foreign direct investment law provides for transfers through banks [38,41].

State aid is set by the decision of 29 May 2025, which classes pharmaceutical manufacturing, NACE code 21, as high technology [39]. The minimum fixed investment is TL 12 million in regions 1 and 2 and TL 6 million in the others, and the TL amounts are revalued each year [39]. High-technology projects of at least TL 100 million can be considered under the Strategic Move Programme, whose criteria include own funds of 20% of the investment, and those of at least TL 500 million are priority investments [39]. Each project needs an incentive certificate, issued after a sectoral, financial and technical assessment, and applications are assessed until 31 December 2030 [39].

CinnaGen İlaç's shareholders financed it mainly by set-off from 2017 to 2020 [33]. Increases of TL 4,038,430 in April 2017, TL 54,452,370 in June 2020 and TL 90,000,000 in December 2020 were each paid by converting shareholders' receivables, established by accountants' reports, into shares [33]. Together they come to TL 148,490,800 of the TL 179,950,000 by which the capital grew from 2014 to 2020, and no notice read for this study records the remaining step [33]. The notices do not show how the receivables arose [33]. In December 2025 the capital was raised by TL 213,325,800 in cash, subscribed by the individual shareholder and the private equity fund [33]. The company's statements of 2017 to 2019 put the investment at USD 100 million in all, about USD 30 million of it physical and the rest technology transfer, and a 2019 profile in the company's voice put the two parts at EUR 30 million and EUR 70 million [29,48,91]. The chief executive of CinnaGen İlaç said in November 2017 that the project had been given priority-investment status, and no document of that status is in the record read for this study [48]. The gate of Stage 6 passes when the following conditions are met:

- Each tranche of capital and debt is named with its source, its amount, its form (cash, set-off or contribution in kind) and its date.
- Every amount that crosses a border has a bank channel cleared at Stage 1, and the bank has the disclosure Stage 1 requires [41].
- Where an increase is to be paid by set-off, the receivable exists, is documented and has an origin that can be shown to the company's banks [53].
- Any state aid the plan counts on is backed by an incentive certificate, or the plan holds without it [39].
- The plan states what the company does if a transfer is delayed or refused.

The gate holds while a certificate or a bank's answer is pending. It stops if the plan needs a transfer that no channel cleared at Stage 1 can carry, such as a transfer with a bank domiciled in Iran outside the categories the EU regulation allows [41].

Stage 7. Build, license, price, list

The objective is a product on the market, made at a certified site, licensed, priced and, where the case needs it, listed for reimbursement. The questions are whether to build a plant or use a contract site, in what order to seek certificates, licences, prices and listing, and what commitments on local production to make. A plant in Türkiye needs GMP evidence for each step it performs, which can be a TİTCK document [34]. A sales permit is required before a product is first marketed, and again when its manufacturing site moves from abroad to Türkiye [34]. A licence can be suspended if no commercial batch reaches the market within 30 months [34].

A product with no retail price cannot be sold in pharmacies, and first price applications are to be concluded within 90 days [36,55]. A newly listed medicine must show within five months that it is distributed, or it is made passive, and it is removed from the list at the end of the tenth month [37]. Under the localisation requirement, commitments were typically to be implemented within 18 months, and a company whose commitment was accepted had a year to change its marketing authorisation from import to local [60].

CinnaGen İlaç's building plans are on record in the company's words. In January 2017 it announced a plant to be founded that year at Çerkezköy, and Ekonomist reported operation from the third quarter of 2018 and a first product in 2019 [27,28]. In November 2017 test production was planned for September 2018 [48]. In December 2018 the chief executive said that the plant would become operational in the first half of 2019, with two bioreactors of 2,000 litres each [49]. The opening was reported from 11 to 13 June 2019 [29,89,90]. Yerlika gives the facility today single-use bioreactors of 10, 50 and 500 litres and a filling capacity of 2.5 million units a year [93]. Its timeline lists TİTCK GMP certificates for two molecules in 2021 and for seven in 2023, and the licensing and launch of a recombinant factor VIIa biosimilar in 2022 [50]. The 2025 interview lists eptacog alfa as approved in Türkiye in 2021 and marketed since 2022 [30]. The record does not show that product's price or its listing for reimbursement. The gate of Stage 7 passes, product by product, when the following conditions are met:

- The site, own or contracted, holds GMP evidence of a kind TİTCK accepts for every step it performs [34].
- The product has its licence, its sales permit and an approved price before launch, and a new sales permit is planned if its site moves to Türkiye [34,55].
- The first commercial batch is scheduled within 30 months of licensing [34].
- Where the Stage 2 case needs listing, the SGK application is filed, and distribution can be shown within five months of listing [37].
- Every commitment on local production made to a Turkish authority is written down, dated and matched to a production plan.

The gate holds a product until all its conditions are met. Commitment beyond the first products waits for the review of Stage 9, in line with the Uppsala view that the knowledge each further step needs is gained mainly by operating in the market [21].

Stage 8. Export base

The objective is to establish what exports from Türkiye would add, market by market, to exports from the home country. Türkiye exported pharmaceuticals worth USD 2.51 billion in 2025, 51.1% of them to Europe and 38.8% to Asia, and Iran was the fifth-largest destination in the İEİS table [14,51]. The questions are which markets accept Turkish licences and inspections as evidence, at what prices the company can enter them, and which flows involve Iranian parties.

Production in Türkiye brings a TİTCK licence and inspection by a PIC/S participating authority, which the Competition Authority calls important for proving the quality of medicines made in Türkiye [15,42]. PIC/S lists Iran's Food and Drug Administration with the same accession date as TİTCK's inspectorate, January 2018 [15]. Turkish prices can weigh on exports. In the İEİS view, export markets use Turkish prices as reference prices, so Turkish firms enter them at lower prices than they otherwise could [14]. Approval in Türkiye is also distinct from approval in the European Union. The editor of the 2025 interview noted that follow-on biologicals approved in Türkiye might not have been authorised under the European Union's process for biosimilars [30]. Cheraghali judged in 2012 that biosimilars developed outside the EU and the US had a very low chance of approval as biosimilars by the EMA or the FDA [4]. Foreign entrants have described Turkish plants as serving exports. Amgen described Mustafa Nevzat as having an export business, ADQ described Birgi Mefar as exporting to more than 30 countries, and Fareva gave efficient access to several international markets as a reason for its purchase [44,45,47].

CinnaGen İlaç's export plans are on record as plans. In 2017 Ekonomist reported its right to export to 20 countries, and its chief executive told Dünya that, for the time being, exports would be made from Iran on a re-export model [28,48]. The export target was USD 100 million, for 2023 or for each year, in most reports, and USD 150 million in the Hürriyet subheading [29,48,89,90]. The countries with signed agreements numbered between seven and twelve, depending on the report [29,89,90,92]. In December 2018 the chief executive spoke of three projects in preparation for submission to the EMA [49]. The record does not show the exports made or any EU approval obtained. Yerlika states that it was founded to take part in international markets [50]. The gate of Stage 8 passes, market by market, when the following conditions are met:

- The target market is named, with the evidence its regulator requires and whether a Turkish licence and a TİTCK inspection meet it.
- The export price case allows for the market's use of the Turkish price as a reference, where it does so [14].
- Every export or import flow that involves an Iranian party has passed the Stage 1 gate [40,41].
- Export volumes in the plan rest on signed contracts, or are labelled as targets.

The gate holds a market until its regulatory route is known. A market that fails is dropped without stopping the Turkish operation, a decline of commitment in one market of the kind the Uppsala authors allow for [22].

Stage 9. Review of scale, hold or exit

The objective is a standing decision, taken at set intervals, to scale, hold or reduce the commitment in Türkiye, and an exit that can be made in an orderly way if it is chosen or forced. The questions are what results would justify more commitment, what would justify a pause, and what an exit would require. The authors of the Uppsala model allow commitment to decline or cease when performance and prospects are not promising enough [22]. Hennart's account of Borden's exit from Japan shows a foreign footprint contracting as well as growing [20].

Firms already established abroad change course under sanctions. Of 22 Western multinationals with subsidiaries in Russia after February 2022, ten divested, four froze operations and eight stayed [12]. The pharmaceutical firm in that sample froze new clinical trials and new investment while keeping its operations [12]. In Türkiye, Amgen agreed in June 2022 to sell Gensenta, the former Mustafa Nevzat, to the Eczacıbaşı Group for USD 135 million, ten years after buying it, subject to the Competition Authority's approval [79,83]. After the purchase, the buyer's marketing subsidiary took over the sale of the 88 finished products for which Gensenta holds the licence [46]. Amgen stated that it would continue its activities in Türkiye [83]. Under the Code a change of owners is made by a transfer of shares or by new capital, and a holding that crosses a threshold is notified within ten days [53].

CinnaGen İlaç's owners and name changed from 2024, and its plant continued. A Turkish individual was sole shareholder by July 2024, and no notice read for this study shows how the shares came to that person or at what price [33]. The company was renamed Asena Biopharma in September 2024, Yerlika Biopharma in October 2024 and Yerlika İlaç in May 2026, under the same registry number [33]. The private equity fund held 55% by the notification of January 2026 [33]. Yerlika describes itself today as a Turkish contract manufacturer and developer of biological medicines working from Çerkezköy [30,50]. The CinnaGen group's website, as captured on 25 November 2026, names five companies of the group and no Turkish affiliate [97,98]. The gate of Stage 9 passes at each review when the following conditions are met:

- The board has set in advance its triggers, the results or events that call for a decision to scale, hold or reduce commitment. Each is tied to the outcome of an earlier gate or to a product case of Stage 2.
- The review is held at intervals the board has fixed, and also whenever a Stage 1 condition changes [63].
- Licences, certificates and reimbursement listings are held by the Turkish company, so that they stay with it if its shares change hands, as Gensenta's licences did [46].
- The articles and any shareholders' agreement set out how shares may be sold, including pre-emption rights, and the Article 198 notifications and any Competition Authority clearance a sale would need are identified [42,53].
- A hold is defined by what continues and what stops, for instance operations continuing while new investment is frozen, as in the pharmaceutical case Sawant and colleagues report [12].

A decision to scale sends the company back to the stage that the larger commitment changes, usually Stage 4, 6 or 7. A decision to exit runs through Stages 1 and 5 again, since a sale moves money and changes the owners [41,53].

The gates are linked. A stop at Stage 1 stops every stage that depends on the failed flow. Stage 1 is opened again whenever a party, a bank or a rule changes, since OFAC decides each year whether to revoke the general licence and has told banks that they can be targeted without advance notice [40,63]. Stages 2 and 3 can run in parallel, because pricing, reimbursement and licensing are separate procedures, although only a firm holding a manufacturing or import authorisation can apply to SGK [34,37]. Stages 4, 5 and 6 build on those results and on each other, since the mode decides the vehicle and the vehicle decides how capital is paid in [53]. Stage 7 begins when they have passed, Stage 8 follows it market by market, and Stage 9 recurs for as long as the company is in Türkiye [22]. The CinnaGen İlaç record shows the stages overlapping in practice. The company was registered in 2014 and its plant was announced in 2017. Most of the capital it held by 2021 was paid in by set-off in 2020, after the opening of the plant was reported [27,29,33].

5. Discussion

5.1 What the protocol adds

The protocol turns two general literatures into a sequence of decisions for one kind of entrant. Entry-mode theory explains why a firm chooses a mode, and staged internationalization explains in what order it commits [18,19,20,21,22]. The sanctions literature describes its own managerial guidance as limited [9]. Section 4 sets out an order of decisions for a manufacturer from a sanctioned home market, each closed by a gate whose conditions a board can mark as met or not met. Compliance and banking come first, at Stage 1. Every later stage moves goods, technology or money that US and EU sanctions law governs, and foreign banks are exposed to US measures [40,41,63]. A stop at Stage 1 therefore stops every stage that depends on the flow concerned. The stage is opened again whenever a party, a bank or a rule changes, since OFAC decides each year whether to revoke its general licence for medicine and has told banks that they can be targeted without advance notice [40,63].

The protocol also follows the order that Turkish rules impose. A licence can be applied for only by a person or trading company resident in Türkiye, and the GMP inspection of a site abroad is applied for by an importer established there [34,35]. Only a firm holding a manufacturing or import authorisation can apply to SGK [37]. A resident party is thus needed before a product can be licensed, inspected or listed, and Stages 3 and 7 are written around that party. The price is set from the lowest ex-factory price in five EU reference countries, converted at a euro value that has been set by three decisions since October 2024 [36,55,57,58]. Stage 2 accordingly asks that each product's case hold at the amount SGK pays and at the euro value in force, with no reliance on a future rise [36,59].

Ownership, control and financing are decided explicitly, at Stages 5 and 6, and documented in a form the company's banks can use. The Turkish Commercial Code requires a holder whose direct or indirect stake crosses one of eight thresholds to notify within ten days. It freezes the rights attached to the shares until the notification is registered and announced [53]. The registry records shareholders, while the CinnaGen İlaç notices read for this study do not show who owns a corporate shareholder [33]. The protocol therefore asks the company itself to document the chain up to the natural persons who own and control it. It also treats the form in which capital is paid as a decision in its own right. The record shows capital paid mainly by set-off from 2017 to 2020, each receivable established by an accountant's report [33]. Stage 6 asks that the origin of any receivable to be set off be documented and shown to the banks [53].

Review and exit are planned from the start, at Stage 9, because the comparator record shows a foreign owner leaving by a sale of shares, and the CinnaGen İlaç record shows owners changing. Amgen acquired Mustafa Nevzat in 2012 and agreed in 2022 to sell it, by then named Gensenta, to a Turkish group [79,83]. The licences for its 88 finished products stayed with the company [46]. The shareholders of CinnaGen İlaç changed several times between 2016 and 2025, its name changed three times under one registry number, and the company and its plant continue [33,50]. The protocol has the board fix its triggers, its review intervals and its share-sale rules before it commits, and define what a hold continues and what it stops [12,22,53].

5.2 The protocol and the theory

The protocol keeps the staging of the Uppsala model and changes what moves a firm from one step to the next. In the original model, commitment grows as the firm gains market knowledge by operating in the market [21]. The revised model allows commitment to decline or stop when performance and prospects are not promising enough [22]. In the protocol each step waits on a gate with written conditions, and the hold and the stop make that decline a decision taken at a known point. Much of

what the early stages need can also be known before operating. The rules on licensing, inspection, pricing and reimbursement are published texts [34,35,36,37]. Kostova and Zaheer argue that the regulatory domain is the easiest to read because it is formalised in laws, rules and regulations [100]. The entries differ in how closely they follow the Uppsala order. Amgen's affiliate sold two products from 2010 before Amgen acquired a manufacturer in 2012, a move from a sales organisation to production [21,44]. The CinnaGen İlaç record shows a company registered in 2014 and a plant announced in 2017. It does not show whether any product was sold in Türkiye before the plant opened [27,33].

The revised model also names a liability of outsidership, the disadvantage of a firm with no position in the business network of the market it enters, which its authors set beside the liability of foreignness [22]. Turkish rules make a measure of insidership a legal condition. The licence holder must be resident in Türkiye, and the GMP inspection of a foreign site begins with an importer established there, which carries responsibility for the file [34,35]. Stages 3 and 4 therefore ask early who that resident party will be. Johanson and Vahlne add that mutual trust and commitment rest on a common history of joint business experience more than on formal agreements [22].

Entry-mode theory frames the choice as a trade-off between control and the resources committed [18]. Brouthers and Hennart treat how much to own and whether to buy or build as separate decisions [19]. Stage 4 keeps both questions and adds the cost of reversing a mode, since modes once established are difficult to change [19]. Hennart's bundling argument fits the comparators closely. He holds that the mode depends on how easily the entrant's knowledge and the local assets it needs can each be traded [20]. The acquisitions recorded in Section 3.2, including the Turkish Eczacıbaşı Group's purchase of Gensenta, bought plants, licences, marketing rights, customer portfolios and staff together [46,47,78]. CinnaGen İlaç departs from that pattern. It built its own plant, announced as a greenfield investment, and in the company's account received its first TİTCK GMP certificates in 2021 and, in its timeline, licensed and launched its first product in 2022 [27,29,50]. Hennart argued in 1989 that contracts protect the parties poorly when one of them has better information or when conditions change unpredictably [84]. The argument bears on any transfer of know-how between a group and its Turkish company, such as the transfer of technology CinnaGen İlaç announced [49]. Dunning distinguishes market-seeking, resource-seeking, efficiency-seeking and strategic-asset-seeking entry, each pointing to different features of the host location [101]. The written role of Stage 0 does similar work, since it fixes what the entry is for before a mode is chosen.

Zaheer defines the liability of foreignness as all the additional costs that a firm operating abroad incurs and a local firm does not [102]. Among its sources he lists the home-country environment, with the example of US restrictions on high-technology sales to certain countries [102]. For an Iranian manufacturer in Türkiye, this source carries the sanctions exposure of the home country. The host's own law treats the investor equally, since the foreign direct investment law grants national treatment and draws no distinction by the investor's nationality [38]. The added cost falls instead on banking, payments and technology, through US and EU rules that bind the parties and banks around the company [40,41,62]. The protocol places that cost at Stage 1, before any resources are committed.

Kostova and Zaheer treat legitimacy, a subsidiary's acceptance by the institutional environment of its host country, as a problem separate from market entry. They argue that legitimacy issues can become salient at any point in a company's history [100]. The recurring review of Stage 9, and the re-opening of Stage 1 on any change of party, bank or rule, rest on the same view that the conditions of entry persist after it. Xu and Shenkar define institutional distance as the extent of similarity or dissimilarity between the regulatory, cognitive and normative institutions of two countries [103]. They propose that

a large regulatory distance favours lower-control forms such as a minority joint venture, and that a local equity partner can mobilise local legitimacy [103]. Eden and Miller argue that institutional distance drives the liability of foreignness and inclines a firm to an intermediate share of ownership [104]. They note that their propositions reflect the ownership strategies of multinationals from industrialised countries [104]. The protocol does not score distance. It meets the regulatory part through the written rules of Stages 1 to 3, and it leaves the share of ownership to the comparison of modes at Stage 4 [103,104].

The emerging-market views explain why a firm from a constrained home goes abroad. Luo and Tung's springboard centres on acquiring strategic assets and capabilities abroad to compensate for gaps at home [5]. Witt and Lewin, writing about advanced economies, describe outward investment as an escape from a home business system that no longer fits a firm's needs [6]. Mathews argues that latecomers gain resources through links with external firms, usually partnerships and joint ventures, and that such links can speed up the learning the Uppsala model describes [7]. The CinnaGen İlaç statements describe a flow in the other direction, from the home group to the host. The company announced the transfer of the group's technology to Türkiye, put at EUR 70 million in December 2018, and presented Türkiye as a production and research base for local and regional markets [27,49]. The group's chief executive gave cultural closeness, the size of the population, and the investment climate and incentives as the reasons for the choice [48]. These stated reasons concern the host location. The January 2017 release mentioned a Turkish partner without naming it, and the notices read for this study show the founder and the chief executive of CinnaGen İlaç as the two shareholders in April 2017 [27,33]. Cuervo-Cazurra and Genc's evidence concerns host countries among the least developed, a group to which Türkiye does not belong [8]. Stage 0 accommodates these views, since it asks the board to name both the capability the company brings and any capability it seeks [5].

The emerging-market pharmaceutical literature records entries in stages and by acquisition, as Section 1 showed for Indian manufacturers [23,24]. Athreye and Godley link the rise of Indian acquisitions abroad after 2000 partly to relaxed home rules on outflows of foreign exchange [23]. One Indian biosimilar maker sold in emerging markets before seeking approval in the US and Europe [25]. Stage 8 carries that market-by-market sequence, testing each export market against the evidence its own regulator requires. The Turkish case adds a host-side condition. The editor of the 2025 interview noted that follow-on biologicals approved in Türkiye might not have been authorised under the European Union's process for biosimilars [30]. Across 206 Indian firms, foreign technology and foreign finance went with a higher share of foreign sales [26]. For an Iranian entrant, foreign finance depends on bank channels cleared at Stage 1, and Stage 6 makes that channel a condition of its gate [41].

The sanctions literature describes the environment that Stage 1 tests. Meyer and colleagues report a wide range of firm responses to sanctions, and they conclude that a firm's reaction depends on the legal text of the sanctions and on the social support for them [9]. As Section 1 reported, the number of French firms exporting to Iran fell after the EU measures of January 2012, most among firms that relied on trade finance [10]. The protocol accordingly treats the decisions of banks, suppliers and partners as evidence to be obtained in writing. Dang and colleagues studied Vietnamese firms under the threat of US trade measures. Documentation and certification were among the responses they found, and they report that the documents firms provided were the only information that mattered to the US agencies [105]. In Russian firm data, Gaur and colleagues found that sanctions had no persistent negative effect on the turnover or employment of the firms targeted [106]. Their evidence concerns the targeted firms themselves. The protocol concerns the parties around an entrant from a sanctioned country, whose decisions determine which flows can be made.

Sawant and colleagues found that Western multinationals that stayed in Russia reconfigured their subsidiaries, and they describe a freeze as a pause in the subsidiary's resource development [12]. Stage 9 uses that distinction to define a hold. Witt and colleagues observe that international business theory developed mostly in an era when growing interdependence could be taken for granted [107]. The protocol starts from a setting in which a rule can change during an entry, as the US rules on Iran did in 2016 and 2018 [85,87]. Haidar's estimate that Iranian exporters redirected two-thirds of the export value lost after 2008 describes aggregate trade [11]. The protocol treats every flow that involves an Iranian party as a Stage 1 question, whatever its destination [40,41].

5.3 Lessons for Iranian manufacturers

Decide the role of Türkiye before choosing the vehicle. This lesson comes from Stage 0. A market for products made in Iran, a production site and an export base call for different products and different evidence, and the Turkish market sorts products by class [14]. In 2025, 99.4% of generic boxes were produced in Türkiye, while 68.8% of the value of originator medicines was imported and biotechnological medicines made up 45.8% of the value of imports [14]. CinnaGen İlaç was registered in June 2014, and its role was stated publicly in January 2017, as a production and research base for local and regional markets with Europe first among export markets [27,33]. Later statements gave export targets that differed from one source to the next [29,48,90]. A role and a product list approved by the board in writing give each later stage a fixed reference. The export part of the role can then be tested market by market at Stage 8, with volumes labelled as targets until contracts exist.

Clear compliance and banking before any other commitment, and keep them under review. This lesson comes from Stage 1. The rules on payments connected with Iran changed during the CinnaGen İlaç entry. The United States lifted its nuclear-related sanctions in January 2016 and re-imposed them in November 2018, between the company's founding in 2014 and the reported opening of its plant in 2019 [29,33,85,87]. The rules have continued to change. In September 2026 OFAC designated a bank based in Türkiye, and in October 2026 it warned foreign banks that those dealing with sanctioned Iranian banks could be targeted at any time without advance notice [62,63]. Türkiye's stated position, that it implements only sanctions decided by the UN Security Council, leaves the question of what a given bank will process to be answered bank by bank [76]. The company obtains a written legal opinion on every flow, uses licensed channels for every payment and gives every bank full disclosure before it commits further. The opinion is renewed whenever a party, a bank or a rule changes, since OFAC decides each year whether to revoke its general licence for medicine [40].

Build the price and reimbursement case at the amount SGK pays and at the euro value in force. This lesson comes from Stage 2. SGK pays for more than 85% of medicine spending by value [42]. Within a group of equivalent products it pays up to the cheapest product's discounted unit price plus 6% [59]. The euro value that converts reference prices into lira was set by decisions of October 2024, December 2025 and March 2026, and stands at TL 29.1164 from 1 April 2026 [36,57,58]. The industry associations put it at 50.6% to 58.7% of the market rate on the dates they measured, and before 2015 it had been frozen at TL 1.9595 since 2009 [13,14,66]. A case that holds only if the euro value rises rests on a decision the company does not take. Each product's maximum price, discount band and SGK payment are computed under the rules in force, and the product stays in the plan only if its case holds at those amounts. The CinnaGen İlaç record holds no price or reimbursement decision, so this lesson rests on the Turkish rules [36,37].

Plan the GMP route through a Turkish importer and PIC/S evidence, and date it from the legal periods as minimums. This lesson comes from Stage 3. A site outside Türkiye reaches TİTCK's GMP inspection only through an importer established in Türkiye, which carries responsibility for the file [35]. A site

not inspected before is inspected on site, with the product seen in production, and a refusal bars a new on-site application for six months [35]. Risk-based reviews can extend a certificate to 12 years for a site in a country whose authority is a PIC/S member, against 9 years for other sites [35]. PIC/S lists Iran's Food and Drug Administration with the same accession date as TİTCK's inspectorate [15]. The Competition Authority states that licences take longer than the law provides, and a 2025 review puts the average time from licence application to reimbursement at about three years [34,42,65]. In Yerlika's own timeline, the first TİTCK GMP certificates came in 2021 and the first licensed product was launched in 2022, after the opening of the plant was reported in June 2019 [29,50]. The importer and the PIC/S evidence for each foreign-made product are named early, and the plan counts TİTCK's start months and legal periods as the shortest possible times.

Choose the entry mode against the local assets that cannot be bought separately. This lesson comes from Stage 4. Foreign acquirers made 71% of the 38 acquisitions in and around the sector that Kahraman and Uğurluoğlu compiled for 2006 to 2014 [77]. The purchases brought bundles of assets. Zentiva's brought a plant, an active-ingredient company and marketing rights, the Eczacıbaşı Group's purchase of Gensenta brought 88 licensed products, and Fareva's a customer portfolio and nearly 750 staff [46,47,78]. Where a licence or permit cannot be traded on its own, acquiring its holder or forming a joint venture with it may be the only way to obtain it [20]. CinnaGen İlaç built its own plant, and Yerlika now offers contract manufacturing and development services for other firms from that facility [29,50]. The company lists the local assets its entry needs, marks which can be bought or contracted for on their own, and compares the modes on that list, on control and on the cost of reversal. An acquisition or a joint venture also needs a check against the Competition Authority's thresholds. Since February 2026, transactions involving biotechnology, pharmacology and health-technology firms have been subject to an individual-turnover threshold of TL 250 million [42].

Document ownership and control as the company's banks will need them, and plan every Article 198 notification. This lesson comes from Stage 5. A holder whose stake reaches or falls below 5, 10, 20, 25, 33, 50, 67 or 100% notifies within ten days, and the rights attached to the shares are frozen until the notification is registered and announced [53]. The CinnaGen İlaç record shows the instrument in use. Notifications under Article 198 recorded the founder's 90% taken over by Singapore Biotech Pte. Ltd. in November 2018 and the private equity fund's 55% in January 2026 [33]. No notice read for this study shows who owns or controls Singapore Biotech [33]. The articles of December 2025 show a division of control written down in full, with board seats for each of two groups of shares, decisions that need a member of each, and joint signatures for any single transaction above USD 100,000 [33]. The company documents the chain of ownership up to the natural persons who own and control each shareholder, in a form its banks can screen, and plans in advance the notification each change of holding would need.

Fund the company through channels a bank will process, and record how each amount of capital is paid. This lesson comes from Stage 6. The Code allows capital to be paid in cash, in kind or from reserves, and an increase paid by set-off needs the board's declaration that the debt exists, is valid and can be set off [53]. At founding, at least 25% of cash capital is paid before registration into a bank account in the company's name, so a bank relationship is needed before the company exists [53]. The capital of CinnaGen İlaç grew by TL 179,950,000 from 2014 to 2020. The notices read for this study record TL 148,490,800 of that as paid by set-off against shareholders' receivables, each established by an accountant's report [33]. In December 2025 the capital was raised by TL 213,325,800 in cash [33]. Any amount from abroad depends on a bank channel cleared at Stage 1. The EU regulation requires healthcare transfers with banks domiciled in Iran to be notified from EUR 10,000 and authorised from

EUR 100,000 [41]. Each tranche is named in advance with its source, amount, form, date and channel, and each receivable that becomes capital keeps a record of its origin that the company's banks can read.

Write down the rules for review, change of control and exit at the start. This lesson comes from Stage 9. Amgen acquired Mustafa Nevzat in 2012 and, ten years later, agreed to sell it as Gensenta to the Eczacıbaşı Group for USD 135 million, subject to the Competition Authority's approval [79,83]. The licences for its 88 finished products stayed with the company, and Amgen stated that it would continue its activities in Türkiye [46,83]. The shareholders of CinnaGen İlaç changed several times between 2016 and 2025. The company took three new names in 2024 and 2026 under the same registry number, and the company and its plant continue [33,50]. Its articles of December 2025 tie each group's right to nominate board members to a holding of 25%, and require 75% of the capital for the general assembly to meet and decide [33]. The board fixes at the start the triggers for a review, the intervals at which it is held, the rules for selling shares, including pre-emption rights, and the meaning of a hold, such as operations continuing while new investment is frozen [12,53]. Licences, certificates and listings are held by the Turkish company, so that they stay with it if its shares change hands, as Gensenta's did [46].

5.4 Implications for policy

For Turkish policy, the evidence bears on localisation and on the predictability of prices. The localisation policy tied SGK reimbursement to commitments to produce in Türkiye, with the aim of meeting 60% of domestic demand by value from domestic production [43,60]. The panel noted that about 40% was met in 2018 and 2019 [60]. The 2022 award left the requirement inconsistent with GATT Article III:4, and İEİS reports that the domestic production strategy is to be reassessed with international obligations taken into account [14,43,51]. SGK's communiqué still allows alternative payment models to encourage local production and the move of imported products to it [59]. Petricevic and Teece argue that host-state industrial policy and conditions of market access shape the strategies of foreign firms [108]. In the protocol, such an instrument enters a foreign manufacturer's Stage 2 case once it exists in a dated text [59]. The price side shows the same dependence. The euro value was raised by decisions of October 2024 and December 2025 and set again in March 2026, and its coefficient was 70% under the 2017 decision and is 65% under the 2026 decision [36,56,57,58]. The authors of a 2023 review state that the fixed shares and the euro value lead to fewer or more hesitant requests to enter the market [70]. The more of the euro value's path a company can compute in advance, the less of its Stage 2 case rests on a decision not yet taken.

For Iranian policymakers, the evidence bears on the regulatory standing of Iranian sites. Risk-based reviews extend a TİTCK certificate to 12 years for a site in a country whose authority is a PIC/S member, and to 9 years for others [35]. PIC/S lists Iran's Food and Drug Administration with an accession date of January 2018 [15]. That standing thus bears on the term of the certificates on which Iranian-made products reach the Turkish market. Home rules on payments abroad can also shape entry. As Section 5.2 noted for India, home rules on outflows of foreign exchange bore on acquisitions abroad [23].

5.5 Limitations

This study rests on a single case read from public documents. Flyvbjerg argues that one can often generalise from a single case, depending on the case and how it is chosen, and he leaves to large samples the question of how often a phenomenon occurs and how it varies [32]. The protocol is offered in that sense, as a sequence of decisions shown to arise in one entry and read against the

Turkish rules and other foreign entries. Eisenhardt names the risks of theory built from cases, among them theory that is modest and idiosyncratic or overly complex [31]. The protocol was derived from the record, the rules and the comparators, and it has not been applied to an entry and observed. The study holds no evidence on how entries that meet its gates perform.

The registry record was read in part. Of its 35 notices, 17 were read in full, and the other 18 are known by their date, issue and type [33]. The notices read do not record the capital step from TL 4,088,430 to TL 35,547,630, the passage of Singapore Biotech's 90% to the chief executive of CinnaGen İlaç, or the transfer of the shares to the Turkish individual [33]. The companies were not approached and no one was interviewed, so the record holds acts and statements without the reasons for them. Meyer and colleagues observe that, under sanctions, people in firms are unlikely to discuss their actions and motivations openly [9]. The company's statements of 2017 to 2019 are claims, and they give the investment and the export targets in different amounts [29,48,49]. The 2025 interview with Yerlika's chief executive was funded by Yerlika [30].

The market data come from AIFD and İEİS, which speak for the companies whose market they describe [13,14]. The estimate of about three years from licence application to reimbursement draws on consultancy and industry reports [65]. The record holds no outcome data. Profitability, volumes sold and exports achieved are not in it [30,33,50]. The rules were read as in force when the documents were collected, in November 2026, and several of them change often. The euro value has been set by three decisions since October 2024 [36,57,58]. OFAC decides each year whether to revoke its general licence for medicine, and it warned in October 2026 that it could act without advance notice [40,63]. The Competition Authority's report is preliminary, ahead of any decision of its Board [42]. A company using the protocol reads each rule again on the date of its own assessment, as Stage 1 requires [40,41].

Further research could apply the protocol to other entries into Türkiye, such as the acquisitions and the joint venture of Section 3.2, and ask whether their records show the same points of decision [77,82]. It could carry the protocol to other host countries, whose own rules on licensing, pricing and company law would change the content and order of Stages 2, 3 and 5. Eisenhardt treats the comparison of a framework built from cases with both similar and conflicting literature as a step that widens its generalizability [31]. Interviews with managers, bankers and regulators would add the reasons that documents do not hold, within the limits Meyer and colleagues describe for research under sanctions [9]. Kostova and Zaheer's view that legitimacy issues can arise at any point in a company's history also suggests following entrants beyond their first products [100].

6. Conclusion

An Iranian pharmaceutical manufacturer that looks to Türkiye as a market, a production site or an export base meets a regulated market and a sanctions environment at once. Türkiye's medicines inspectorate takes part in PIC/S, its prices are set by the state, and one public insurer pays for most medicine spending [15,36,42]. Payments connected with Iran are governed by US and EU sanctions law, which binds the parties within its reach and exposes foreign banks to US measures [40,41,63]. The literatures on entry mode and staged internationalization explain why a firm chooses a mode and in what order it commits [18,19,21,22]. They leave open the staged procedure, with decision gates, that such an entrant needs, and the sanctions literature describes its own managerial guidance as limited [9].

This article read the public record of CinnaGen İlaç, from 2014 to 2026, against Türkiye's rules on licensing, pricing, reimbursement and company law and against the routes by which other foreign manufacturers entered the same market. From that reading it derived a protocol of ten stages,

numbered 0 to 9, each closed by a gate of pass/fail conditions that a board can mark as met or not met. The company first states the role of Türkiye and clears compliance and banking. It then builds the market, price and reimbursement case, sets the regulatory route, and chooses the entry mode, the legal vehicle with its ownership and control, and the financing. The last stages build, license, price and list the first products, test Türkiye as an export base market by market, and review at set intervals whether to scale, hold or exit. Compliance and banking come first because every later stage moves goods, technology or money that sanctions law governs [40,41]. The later stages follow the order that Turkish rules impose, since a resident party is needed before a product can be licensed, inspected or listed [34,35,37]. Ownership, control and financing are decided explicitly and documented in a form the company's banks can use. Review and exit are planned from the start, before resources are committed.

For an Iranian manufacturer and its board, the protocol turns the entry into a series of written decisions taken in a known order. The role of Türkiye and the product list are fixed before the vehicle is chosen. The legal opinion and the banks' written answers come before any other commitment, and they are renewed whenever a party, a bank or a rule changes. Each product's case is computed at the amount SGK pays and at the euro value in force. The licensing plan names the resident licence holder and the Turkish importer, and it treats legal periods as the shortest possible times. The mode is chosen against the local assets that cannot be bought on their own. The chain of ownership is documented up to natural persons, every capital payment goes through a channel a bank will process, and the rules for review, change of control and exit are written down at the start. The CinnaGen İlaç record shows such conditions changing within one entry. US nuclear-related sanctions on Iran were lifted in 2016 and re-imposed in 2018, between the company's founding and the reported opening of its plant. Its shareholders changed several times between 2016 and 2025, and it took three new names in 2024 and 2026. The company and the plant continue [29,33,50,85,87].

The protocol is a structured way for a board to decide whether and how to enter, drawn from one case read in public documents and from the rules in force in November 2026. It was derived from the record, the rules and the comparator entries, and it has yet to be applied to an entry and observed. A company using it reads each rule again on the date of its own assessment. The next step is to test the protocol on other entries into Türkiye and to carry it to other host countries, whose own rules would change the content and order of its stages.

Declarations

Funding

This study was funded by KHESHT Investment Group.

Competing interests

The author works in the Department of International Operations of Ramopharmin Pharmaceutical Co., an Iranian pharmaceutical manufacturer owned by KHESHT Investment Group. Ramopharmin Pharmaceutical Co. founded and supports this journal (see About). The author has no relationship with CinnaGen, CinnaGen İlaç or Yerlika, and those companies were not approached for this study.

Ethical considerations

The study used public documents only: laws, regulations and decisions, official notices and reports, trade-registry notices, company statements, press reports and published research. It involved no human participants, no interviews and no patient or personal health data. Private individuals named in the registry notices are described by role and nationality only.

Data availability

All sources are publicly available and are cited in the reference list. The trade-registry notices can be viewed through the Türkiye Ticaret Sicili Gazetesi's notice search under İstanbul registry number 927931. Each web source was captured in November 2026, and the date of capture is kept with it.

Use of artificial intelligence

The author used an artificial-intelligence assistant (Claude, Anthropic) to collect and organise the sources, check numbers against them, prepare the figures and tables and draft text under the author's direction. The author reviewed the content and takes full responsibility for it.

Author contributions

Emre Altin is the sole author and is responsible for the whole of the work.

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Cite this article: Altin E. Entering Türkiye: a staged protocol for Iranian pharmaceutical companies, with the case of CinnaGen. J Pharm Enterp. 2026;1:e2026001. Available from: https://pharmenterprise.org/articles/turkiye-entry-protocol/
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