

THINK ACT

BEYOND MAINSTREAM



January 2017

Iran's pharmaceuticals market

Rediscovering a sleeping giant

TILIA Corporation

Roland
Berger

THE BIG

3

SPECIAL

ROLAND BERGER
RATING OF MARKET
PARTICIPANTS

→ P.6

400 million

The number of people living in Iran and its
15 export-region neighbours.

Page 7

5.5%

The compound annual predicted growth rate
of Iran's pharmaceuticals market.

Page 4

-100

The number of Iranian pharmaceutical companies,
many of which offer attractive partnership potential.

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With most sanctions being lifted, international companies have a rare window of opportunity to tap into Iran's fast-growing economy.

Iran has one of the longest histories of medical practice in the world. The ancient Mesopotamians, for example, were carving diagnoses and prescriptions into stone tablets at least 4,100 years ago. Some still survive, as do some of the more rational treatments, such as the use of antiseptic plasters to cover wounds.

Much later, in around 300 A.D., the university at Gundeshapur became a recognized center for the teaching of evidence-based medicine, and it is thought Persians established the modern hospital system around the same time. The Canon of Medicine, a medical encyclopaedia completed in 1025 by the Persian philosopher Ibn Sina, remained an influential text in European universities until the 1650s.

In the modern era, however, Iran has fallen off the world's medical and pharmaceutical radar. Crippling international sanctions have restricted trade with Iran, severely affecting the pharmaceutical sector and resulting in price controls and a lack of transparency. But since January 2016, most international sanctions have

been lifted under the internationally agreed Joint Comprehensive Plan of Action (JCPOA). International exporters and investors are free to return, although some sanctions – for example relating to USD-related banking transactions – remain. These are under review, and in the meantime will likely have limited effect on healthcare companies which pay close attention to the remaining compliance requirements.

The political situation in Iran has also developed further. The reformist government that signed the JCPOA agreement has been working hard to maintain market stability and market openness and is actively seeking foreign investment. Indeed, the level of progress achieved already since lift of sanctions provides sizeable coverage against any deviation in course of policies following changes or transitions in administrations both inside as well as outside of Iran. As a result, early movers have the opportunity of gaining a head start in entering the Iranian market, provided they are aware of the risks and ambiguities and know how to mitigate them.

From its well-educated workforce to its dynamic competitive landscape, the Iranian pharmaceutical market has much to offer new entrants.

Five key factors stand in favour of market entrants seeking growth opportunities in Iran's pharma market:

1. POSITIVE MARKET DYNAMICS

Iran's economy is in good shape. Its nominal gross domestic product (at market price) is forecast to grow by around 12% annually, reaching a nominal GDP of USD 665 billion in 2020. → A Inflation has been halved since 2013 to a 25-year low of around 10%. These and other positive economic indicators explain why Goldman Sachs has identified Iran as having one of the highest growth potentials outside the BRIC nations.

The outlook for healthcare is particularly rosy. Spending is forecasted to grow at a similar rate to GDP, reaching nearly USD 40 billion (6% of overall spending) in 2020, driven by rising Ministry of Health and Medical Education (MOHME) expenditure.

Iran's population is also on the up. By 2020 it will have 84.2 million inhabitants – more than Germany. Roughly 30% will be aged 19 or under, 60% aged 20 to 59 and 10% aged over 60.

This represents a growing customer base for pharmaceutical products, with babyboomers of the 1980s now entering the workforce and fueling out-of-pocket spending. In addition, the proportionally high urban population enjoys good access to basic healthcare. In rural areas access is growing due to government reforms, further boosting potential. More than 90% of the population is covered by one of the four government-run health insurers.

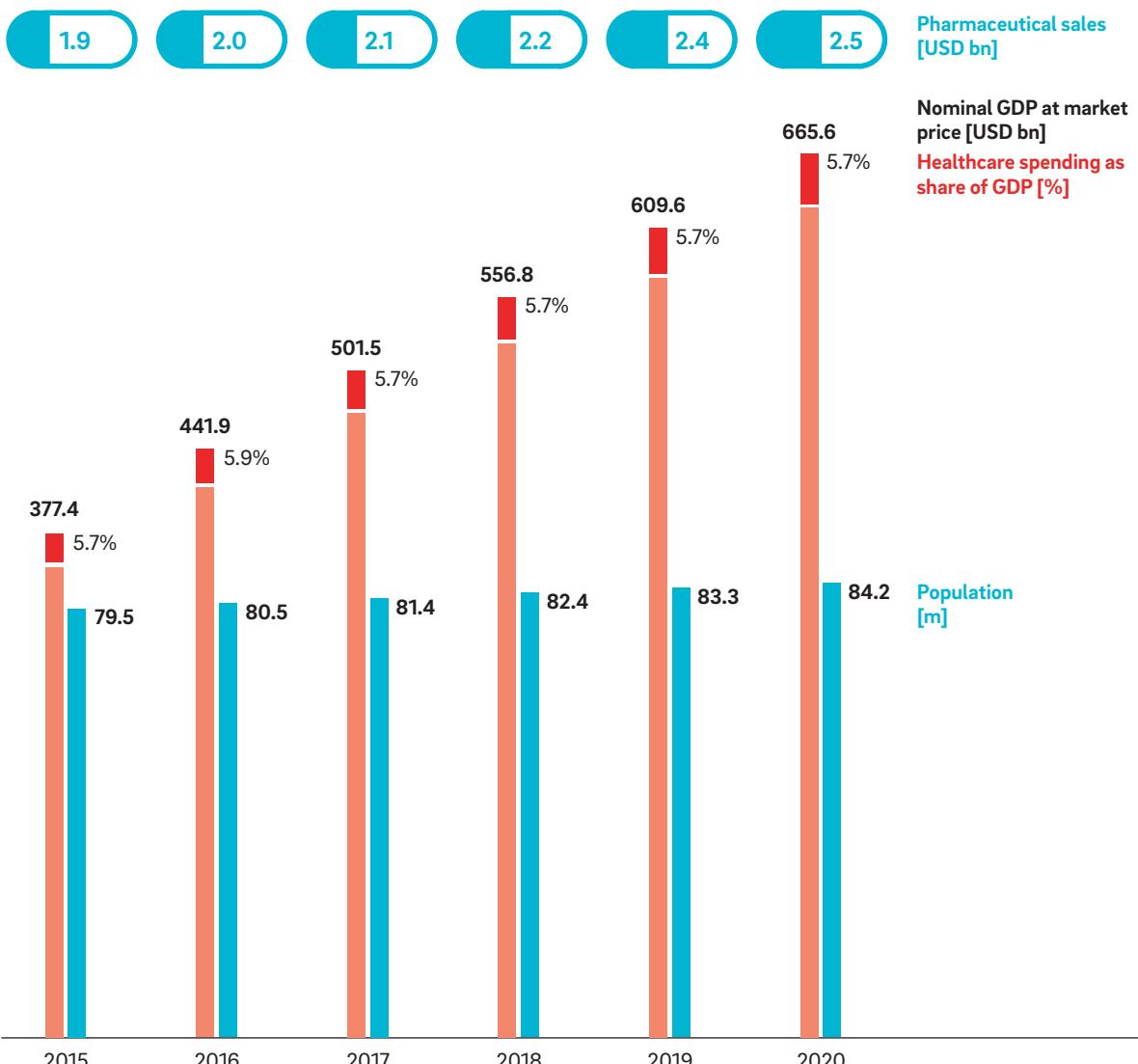
As a result, the Iranian pharmaceuticals market – valued by BMI Research at USD 1.9 billion in 2015 – is predicted to grow at a compound annual growth rate of 6%. By 2025, it will be the fourth largest in the Middle East and North Africa, after Turkey, Egypt and Saudi Arabia.

A

IRAN'S GROWING MARKET OFFERS HUGE BUSINESS POTENTIAL

In the next few years, Iran's rising GDP and customer base are likely to significantly increase demand for pharmaceutical products.

Development of pharmaceutical sales, GDP, healthcare spending, and population



Source: ILIA Corporation, Roland Berger, Roland Berger estimates based on IMF Data and BMI Research

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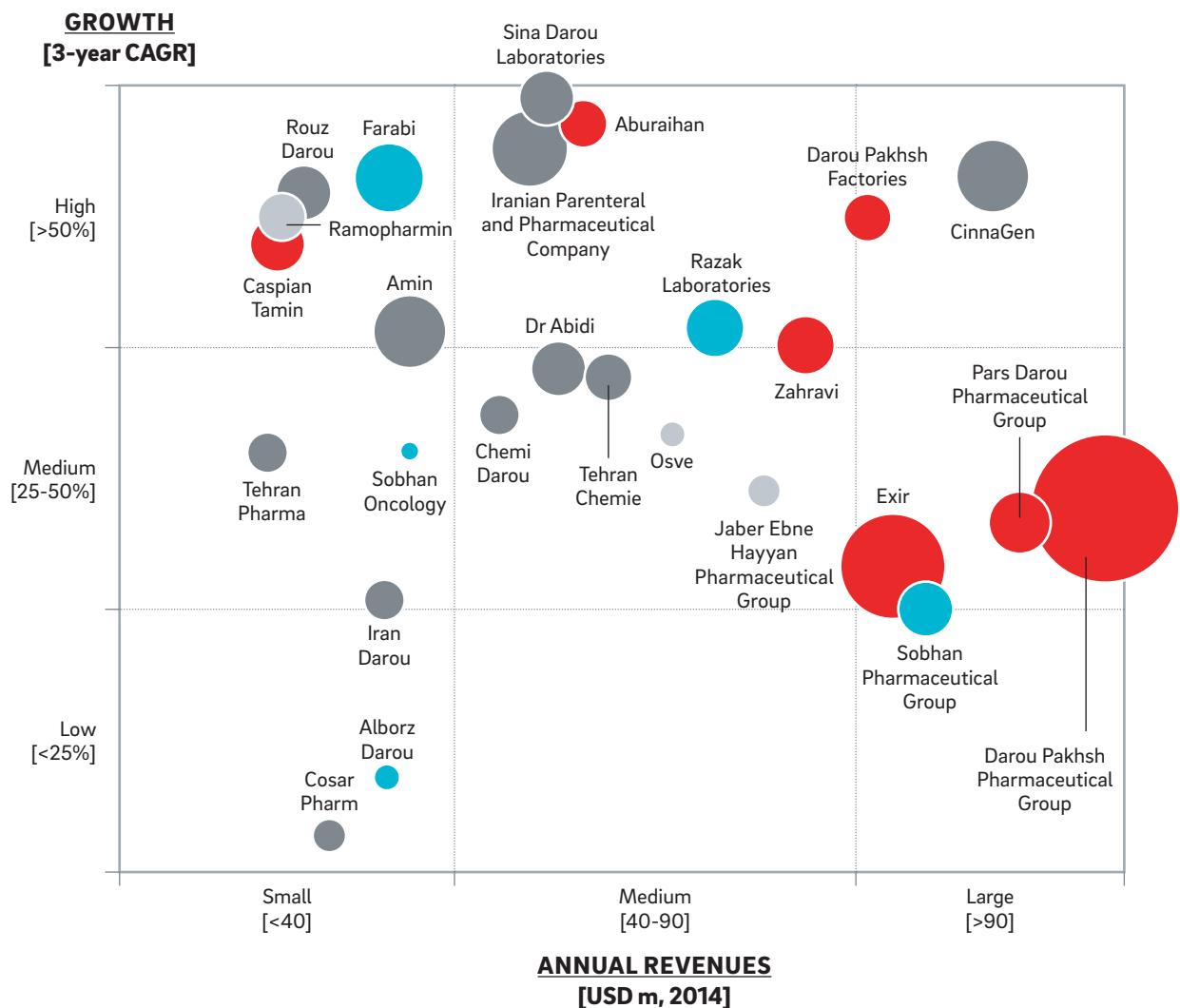
Iran's pharmaceuticals market

B

A LIVELY PHARMACEUTICALS MARKET

Iran's well-developed and networked pharma sector provides a ready platform for partnerships in areas such as licensing or co-promotion.

Competitive landscape of drug manufacturers (selection of largest players)



Portfolio size: # drugs in portfolio

Ownership: Ta'min Pharmaceutical Group Barkat Pharmaceutical Group Shafa Pharmaceutical Group Other/no large Group

Source: IMI 100, Iranian Stock Exchange, ILIA Corporation, Roland Berger

2. ESTABLISHED PHARMACEUTICAL INFRASTRUCTURE

Sanctions have forced Iran to build a substantial, largely self-sufficient drug production infrastructure. Some 60 plants produce almost 40 billion drug units each year, meeting 96% of domestic demand. Most do not meet international good manufacturing practice standards, but government initiatives are addressing this.

Research and development focuses mainly on new generic drugs, although investment in novel products is increasing: 12 new treatments for diseases including cancer and diabetes were launched in 2015, for example.

Iran's biotechnology capabilities are also improving. The country is queueing among the world's leading nation as for stem-cell research and has a considerable infrastructure of related facilities, e.g. for plasmapheresis (blood plasma treatment). The biggest biopharmaceutical company, CinnaGen, produces Biosimilars of leading immunology and cancer drugs, among others, and invests 20% of revenues in R&D.

In a nod to the global trend of establishing biotechnology hubs, Iran is also building a government-backed USD 2 billion "Industrial Pharmaceutical City" near Tehran. It will house incubators and startups under the same roof as research labs and biotech producers. Foreign investors will be exempted from taxes and it is hoped the venture will attract international experts.

3. SKILLED WORKFORCE

Some 80% of Iranians receive a secondary education, and the literacy rate is more than 98%, according to the UN. When it comes to science and medicine, its high standards of education appear to be paying off.

In 2012, the science database Scopus ranked Iran 17th in the world in terms of output of scientific papers, and it was 23rd in terms of highly cited medical articles in 2011. This indicates a significant research base, as evidenced by internationally recognized biomedical centers such as the Pasteur Institute of Iran.

In 2014, there were 0.93 physicians per 1,000 people according to BMI Research, about 2.5 times less than the US but more than South Africa. However, Iran has suffered from a brain drain in the recent years mainly because of low domestic incomes and market challenges.

4. COMPETITIVE LANDSCAPE

Iran has a lively pharmaceuticals market. The sector is made up of about 100 companies, → **B** with most focused on drug manufacturing. Some also carry out R&D, import non-locally produced drugs or provide distribution, offering ample potential for cooperation.

The largest producer is Darou Pakhsh Pharmaceutical Manufacturing, which also distributes drugs through its Darou Pakhsh Distribution subsidiary. The company generated revenues of over USD 700 million in 2014 and is listed on the Tehran Stock Exchange.

The sector is, however, largely consolidated. Most companies are owned by publicly controlled listed investors, such as the Ta'min Pharmaceutical Group (TPICO). Only a few private players, for example cosmetics company Dr. Abidi, exist.

5. A TRADE CROSSROAD

From the ancient Silk Road to China's new One Belt, One Road project, Iran has always enjoyed a prime position on international trade routes. Its geographic location also makes it an ideal export hub for Central Asia (especially Afghanistan, Russia, Syria, Iraq), a position enhanced by special economic zones and ready access to its 15 neighbours (population: 400 million) through trade agreements. → **C**

Iran's biotech and drug-making expertise has seen it win several large export deals. For example, Afghanistan sources 33% of its pharmaceutical products from Iran, and 11% of all Iran's pharma exports – worth a total of USD 159 million in 2014 – go to Syria under a contract agreement. Germany receives 16%.

As Iran ramps up production, its regional trade relationships are likely to grow and help it to expand its export horizons beyond the Middle East.

C

IRAN'S PHARMACEUTICAL TRADE

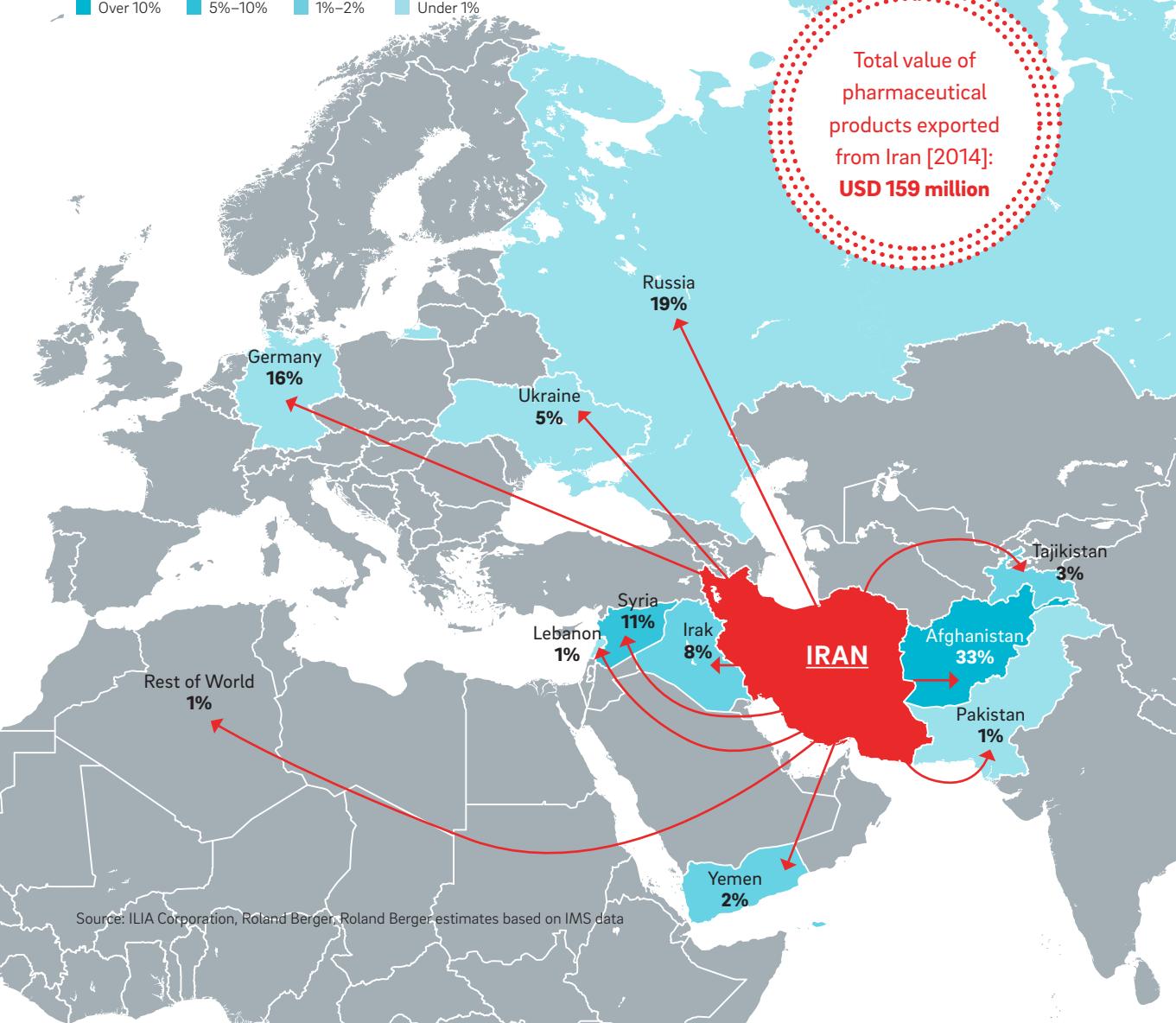
RELATIONSHIPS

Iran is strategically located between West and East and a gateway to a large trading bloc, making it an ideal hub to exploit export opportunities in the MENA region and beyond.

xx% = Share of Iranian pharma exports shipped to respective country

Share of domestic pharmaceutical consumption covered by imports from Iran

■ Over 10% ■ 5%-10% ■ 1%-2% ■ Under 1%



Pharmaceutical companies must have a thorough understanding of Iranian market conditions to maximize opportunities and avoid pitfalls.

1. ENTER – PREPARE WELL

A. UNDERSTAND THE MARKET

The Iranian healthcare system exhibits unique features that present both opportunities and hurdles for new entrants. Thorough preparation, including acquiring a deep knowledge of structure, decision makers and key stakeholders, is therefore essential, as is fostering good relationships with market players. →D

Regulators and funding bodies: Authorization from two government "gatekeeper" bodies is essential to successful trading in Iran. The first is the Food and Drug Administration of Iran (FDA), an agency that authorizes the import and manufacturing of all drugs, and controls the Iran Drug List (IDL). Only products listed on the IDL can be imported.

The import of generic drugs listed on the IDL but with a locally produced equivalent is not officially allowed. Exemptions are only rarely granted, for example during a drug shortage. However, physicians are not

currently prosecuted for prescribing non-IDL drugs, although this may soon change.

Currently, 70% of the active pharmaceutical ingredients (APIs) of the world's top-selling drugs are listed on the IDL. But there are notable exceptions, including Insulin lispro (off-patent), used in type-1 diabetes, and Aflibercept (patented), used in the treatment of macular degeneration and metastatic colorectal cancer.

The second gatekeeper is the Supreme Council of Health Insurance (SCoHI). It decides which drugs can have their costs reimbursed and at what level. The costs of most drugs in Iran are reimbursable, so securing this status ensures a strong competitive advantage. About 400 currently qualify for reimbursement, including some over-the-counter products. Insurers pay either 70% or 90% of costs.

Providers: Prescribed medicines account for about 90% of the sales value of drugs consumed in Iran. Prescribed medicines account for about 90% of sales value of drugs consumed in Iran, according to BMI research. This is

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Iran's pharmaceuticals market

comparatively high – the proportion in Russia, for example, is 53% – and means the prescribing physician is usually the key decision maker in the buying process.

Most physicians split their time between public and private practice. Public healthcare facilities include more than 17,000 health houses – the first point of contact for patients – and 6,000 hospitals. The four health insurers own or contract these services, covering the full cost of treatment for their members.

There are around 25,000 private general practices and 150 hospitals, which can usually only be accessed by those with private insurances.

Pharmacies: There are around 8,500 pharmacies in Iran according to various articles published in the Iranian Journal of Pharmaceutical Research. About 55% are linked to public institutions, enjoying a large market share due to their near-monopoly position in the provision of scarce and expensive drugs. The rest are privately owned. Online pharmacies are yet to have an impact, selling only around 1% of drugs. The influence of pharmacists on the buying decision is limited as 85% of patients present them with a predetermined

prescription, limiting pharmacists to the role of operator. But in the case of OTC drugs, which make up about 15% of total sales, pharmacists can advise patients on their buying decision.

This market is likely to expand in the future as growing numbers of OTC drugs lose their reimbursement status due to cost-cutting and become less attractive to prescribe, increasing the influence of pharmacists in the buying process.

Patients: As in most drug markets, patients are consumers of prescription medicines rather than selectors of them. This is particularly true in Iran, with its high proportion of prescription drug sales. But, as with pharmacists, they have a growing decision making power in the OTC market due to the fall in medicines with reimbursable status.

Existing market players: About 100 domestic pharma companies are active in Iran and can serve as accelerators for multinationals entering the market. Most are affiliated with government-backed investment companies, ensuring ready access to crucial public stakeholders such as the FDA.

D

REGULATORS AND FUNDING BODIES ARE OF UTMOST IMPORTANCE FOR INTERNATIONAL PHARMA COMPANIES

Market participants and their role and relevance for pharmaceutical firms.

Market participant	Role of market participant for international pharma companies	Relevance of market participant for international pharma companies
REGULATORS AND FUNDING BODIES	Gate keeper	
PROVIDERS	Decision maker	
PHARMACIES	Operator (+ advisor ¹)	
PATIENTS	Consumer (+ decision maker ¹)	
EXISTING MARKET PLAYERS	Accelerator	

1 Enhanced relevance for OTC drugs

Source: ILIA Corporation, Roland Berger



B. CONSIDER THE REGULATORY FRAMEWORK

Approval process: FDA authorization is a prerequisite for the sale of drugs in Iran, whether the product is imported or produced locally. The application process to introduce new drugs is not dissimilar to those in developed markets, but may be less transparent and more time consuming.

The first step involves registering the product by submitting drug data, import-export and authorization documents. Once certified by an Iranian consulate, these documents are passed to legal commissions for consideration. If successful, the drug is added to the IDL. The process usually takes about a year.

If approval is being sought for a drug already listed on the IDL, the imported version need only be approved by an FDA-accredited laboratory.

IP rights: There is little patent protection for drugs in Iran. Under current legislation, pharmaceutical formulae and compounds are not patentable, leading to extensive unauthorized production of generic medicines. However, with Iran currently seeking World Trade Organization membership, this is likely to change as the country will have to adopt the WTO's patent protection terms.

Pricing: Drug prices are determined by the FDA's Pricing Commission. It decides on the expenses incurred by producers and importers for each drug, and then fixes a price under the top-mark system, taking into account the upper range of cost.

Reimbursement: Health insurers pay 70% (outpatient dispensed) or 90% (inpatient dispensed) of the cost of drugs with reimbursement status. The remaining amount is paid by users. Most drugs, for example cancer medicines, have this status, but numerous drugs commonly used in the West do not, including pantoprazole, a treatment for excess stomach acid.

2. LAND – START SMART

A. DECIDE FOR LOCAL PRODUCTION OR EXPORT

New multinational entrants will first want to decide whether to make their product in Iran or export it to the country. There are benefits and costs to both. In the case of generic drugs already manufactured in Iran, local production has advantages because of the ban on, or heavy taxing of, imported equivalents. But both options are viable for new drugs or non-IDL listed generics. Imports of these face only the general 5% customs

tariff, and in selected cases this is even subsidized. Local production may also be cost efficient, either at owned facilities or via cooperation with in-country partners. It also affords rudimentary IP protection.

B. ESTABLISH BACK-END PROCESSES AND ROUTE TO MARKET

The setting up of backend functions, such as sourcing and manufacturing, will vary depending on the choice of local production or import. But in both cases the route to market is identical.

Sourcing: Half of the raw material used in drug manufacturing in Iran is imported. But local sourcing is on the rise, and a number of base materials required to make rare medicines have reportedly been produced since 2013.

Manufacturing: The government is planning to expand Iran's already considerable drug-making capacity. It wants to build on its mostly generics-producing base by branching out into the manufacture of patented medicines as part of its post-sanctions strategy.

But whether carried out at self-owned facilities or those of partners, manufacturing in Iran must abide by certain cultural rules. Selected medicines and dosage advice must be halal compliant, for example, and patient information must be provided in English and Farsi.

Imports: Finished pharmaceutical products are shipped in by importing companies, which are often subsidiaries of large local pharma groups. These offer significant opportunities to tap into local expertise.

Import taxes and custom tariffs range between 0 and 65% depending on whether the product has a locally produced equivalent.

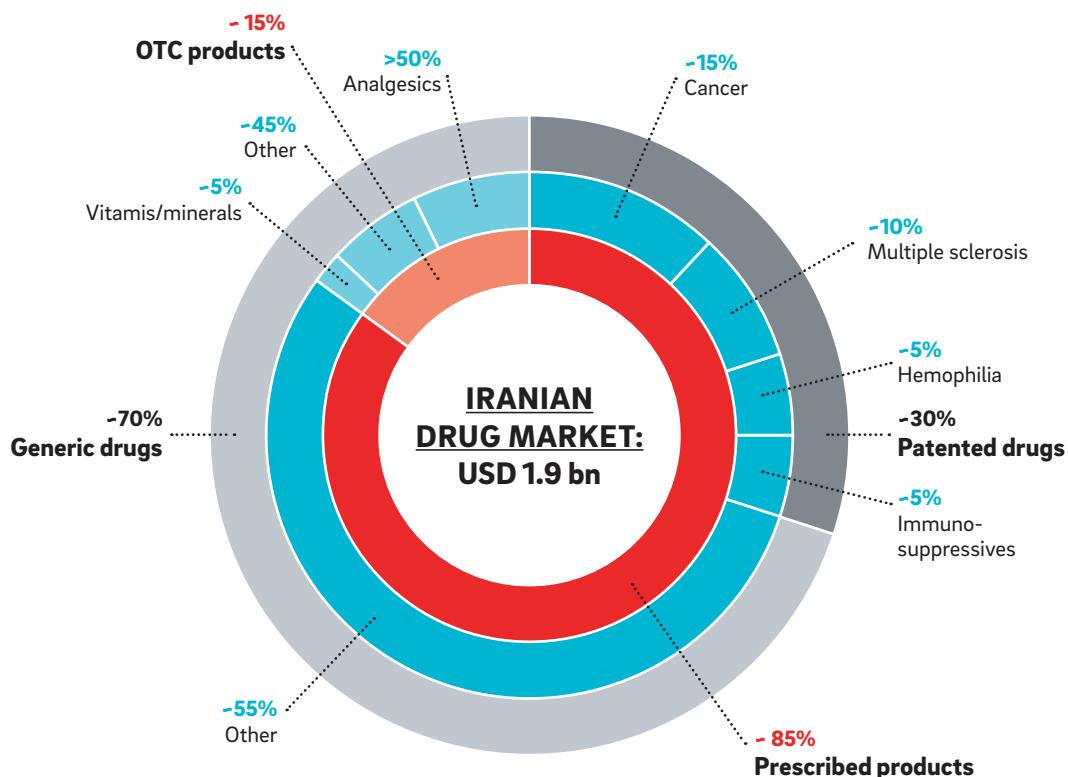
Distribution: Drugs are primarily distributed by six government-owned companies. But smaller private operators are increasing entering the market, with about 20 currently active. The state-backed Darou Pakhsh Distribution, which deals in both local and imported products, is the market leader with a 25% share.

Overall, the 10 largest distributors have a 75% market share. This level of consolidation makes the leveraging of existing local networks an attractive option. European operators, for example Dutch ingredients group Barentz, are already entering into such agreements.

Exports: Iran's government is keen to promote the export of medicines to help chip away at its negative trade balance. By 2025 it hopes to have balanced exports and

E**WHERE THE REAL VALUE IS HIDDEN**

Iranian pharmaceutical market split according to value.



Source: BMI Research, Science direct, ILIA Corporation, Roland Berger

imports of medicines; as such, drug export income is tax exempt, and initiatives are underway to improve manufacturing practices. Export licenses must be signed off by MOHME's Food and Medicine Deputy.

3. SUCCEED – WIN FAST**A. ADDRESS PROMISING MARKET SEGMENTS**

Several areas of unmet or growing demand exist in the Iranian pharma market. For example, although some 85% of all medicines consumed in Iran are prescribed by a physician, → E increasingly blurred lines between OTC and prescription drugs mean that a significant number of prescription medicines can be bought directly by users.

Analgesics account for most OTC purchases, due to high demand and their reimbursement status. As health awareness rises in the country, the market for vitamin and dietary supplements is expected to become another important area according to Euromonitor.

In the prescription sector, there are several supply gaps owing to the fact that many prescribed drugs cannot be produced locally. The largest are for oncology, multiple sclerosis and insulin drugs. An expected epidemiological shift towards chronic diseases is likely to crank up this demand further.

Large pharma companies are already moving to fill these shortfalls. For example, in 2015 Novo Nordisk announced it was building a USD 70 million insulin-manufacturing plant to exploit the fact that 65-70% of Irani-

an insulin is imported. This move took advantage of the Iranian government's efforts to attract companies that can satisfy domestic demand by producing locally.

Generic drug makers can also benefit from Iran's long tradition of favouring generic prescription medicines to keep down costs. Demand for low-cost generics in rural areas is particularly high, presenting opportunities for companies with scale advantages.

B. APPLY A SUCCESSFUL MARKETING MIX

Detailing visits by sales representatives are the primary marketing tool used by Iranian pharma companies, not least because they offer the best way to engage with providers, the key decision makers. Visits are usually undertaken once every two to five weeks, depending on the provider's prescription volume and their local population density.

Pharmacists, due to their lower prescription influence, receive much less attention. But this may change as more OTC products become available and their role in drug selection becomes more influential.

Other forms of drug marketing in Iran are little developed. While the Iranian Medical Council allows advertisements aimed at health care professionals, any direct-to-consumer marketing in public media is limited. The use of alternative marketing techniques, such as sampling and promotional mailing, is rare.

4. LEVERAGE – BENEFIT FROM PARTNERS AND COMPETITORS

A. ESTABLISH DOMESTIC PARTNERSHIPS

Collaboration with local players is the dominant strategy employed by international companies wanting to establish a foothold and grow in the Iranian pharma market. As mentioned, such partnerships offer new entrants access to infrastructure, distribution networks and key stakeholders.

Large Western pharma companies such as Pfizer, Merck, Novartis, Roche, Boehringer Ingelheim and Sanofi have all already employed this tactic. Several multinationals, for example, have partnered with Tehran-based Modava Pharmaceutical Company to facilitate distribution through its affiliate Shafayab Distribution. Novartis also sources secondary packaging from Modava, and is instituting API production, too.

Tie-ups with domestic companies have proven particularly beneficial for companies wishing to establish

import-export businesses, as local expertise can be tapped to help manage regulatory compliance.

B. LEARN FROM OTHERS

Foreign investment in the Iranian pharmaceuticals market is picking up pace and becoming increasingly ambitious. In addition to the partnership strategies being employed by the multinationals, most of which focus on distribution, other companies are establishing a bricks-and-mortar presence.

For example, the Indian generics manufacturer Cipla is planning a new production plant in Iran to take advantage of the growth in the generics sector, and Novo Nordisk's insulin-production facility is designed to exploit the growing demand for biologicals and biotechnology expertise. Additionally, Italian construction company Pesina Costruzioni is cooperating with MOHME to build five new hospitals in Iran as part of the government's strategy to upgrade its health infrastructure.

While foreign investment is on the up, history has shown that international companies must do their homework before entering the Iranian market. Several failed because they underestimated local competition, offering products that were expensive compared to local drugs. Others were tripped up by regulations or the now lifted sanctions.

Companies that have sought partnerships have fared best, with those prepared to go the extra mile and support local research doing best of all. Sanofi, for example, signed a Memorandum of Cooperation on research, helping it to secure government goodwill. → F

CONCLUSION

There is little doubt that Iran offers multinational pharmaceutical companies clear growth opportunities. But it is not a straightforward operating environment and its unique character presents risks rarely found in most developed or developing markets.

In order to mitigate these and prepare foundations for success, it is recommended that new players comprehensively investigate local market mechanics, the regulatory framework, business culture and domestic competition before entering. New entrants may also wish to consider partnering with local partners to smoothen their landing and enhance growth once operational. They should also closely study the actions of competitors. **Prevention, after all, is better than cure.** ♦

F

CASE STUDIES ON MARKET ENTRIES OF PHARMA PLAYERS

Other international pharmacos have already been granted market access by securing good relationships with authorities and cooperating with local manufacturers.

SANOFI

MARKET ENTRY INTO IRAN

Legal presence through representative office since 2006
Manufacturing collaborations for selected products since 2009
Engagement in significant **technology and know-how transfer**

MARKET DEVELOPMENT IN IRAN

Currently **55%** of Sanofi sales in Iran are generated by **locally produced drugs**, **45%** of sales are generated by **imports**
Further **strengthening of relationships with local representatives** through adoption of a Memorandum of Cooperation in January 2016
> Knowledge transfer with Iranian manufacturers
> Collaboration with the Ministry of Health on prevention and control of chronic diseases
> Alliances with laboratories to improve the availability of accurate, reliable, and meaningful epidemiological studies and registries

NOVO NORDISK

Legal presence through representative office since 2005
Production agreements with local pharma companies for all major medicines sold in Iran
Engagement in systematic **knowledge-sharing**

Engagement into various **voluntary activities in cooperation with local institutions**
> Launch of a **diabetes bus**, among others in cooperation with MOHME, in 2012
> Support of a **diabetes call center** for patient education
> Creation of a **national diabetes registry** in cooperation with MOHME
Cooperation with Barakat Pharmaceutical Company in 2016
> **Joint investment** of 70 million EUR in a **production plant** for prefilled insulin pens
> **Employment** of additional **160 workforces**

MAIN SUCCESS FACTOR

Secure a **good relationship with authorities and local manufacturing**
> Gradually enhance the degree of collaboration
> Offer significant knowledge transfer
> Make use of and enhance domestic expertise

Secure a **good relationship with authorities and local manufacturing**
> Engage in several initiatives and partnerships to boast domestic awareness of diabetes
> Show efforts to further develop the Iranian pharmaceutical infrastructure through cooperation, investment, and knowledge-sharing

ABOUT US

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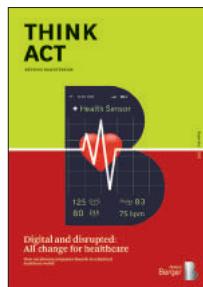
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FURTHER READING



HOW TO DO BUSINESS IN IRAN – SUCCESSFULLY
An overview of the benefits and challenges of doing business in Iran and how to prepare

At 1.6 million square kilometers, Iran is the 17th largest country in the world and its population of 78 million is similar in size to Germany. Remarkably, 41% of Iranians are below 25 years of age, offering a firm foundation for economic growth. Despite the sanctions and their consequences, Iran's GDP still stands at a sizeable USD 415 billion – almost equal with the United Arab Emirates.



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Publisher

ROLAND BERGER GMBH

Sederanger 1
80538 Munich
Germany
+49 89 9230-0

ILIA CORPORATION

Unit 2, Number 34, Ghasemi Street,
Gheytariyeh Park, Tehran, Iran
Office: +98 21 222 482 23
ilia-corporation.com

WE WELCOME YOUR QUESTIONS, COMMENTS AND SUGGESTIONS

DR. MORRIS HOSSEINI

Senior Partner
+49 30 39927-3342
morris.hosseini@rolandberger.com

DR. THILO KALTENBACH

Partner
+49 89 9230-8651
thilo.kaltenbach@rolandberger.com

HEIKO AMMERMANN

Senior Partner
+49 69 29924-6237
heiko.ammermann@rolandberger.com

PATRICK BIECHELER

Senior Partner
+34 91590-3144
patrick.biecheler@rolandberger.com

STEFAN HAID

Managing Director
Roland Berger International GmbH
+98 937 995 4384
stefan.haid@rolandberger.com

LENNART BÖSCH

Principal, Roland Berger GmbH

CLARA BRATFISCH

Consultant, Roland Berger GmbH

MARLON JÜNEMANN

Managing Partner, ILIA Corporation
juenemann@ilia-corporation.com

HODA HOSSEINIFAR

Consultant, ILIA Corporation

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