

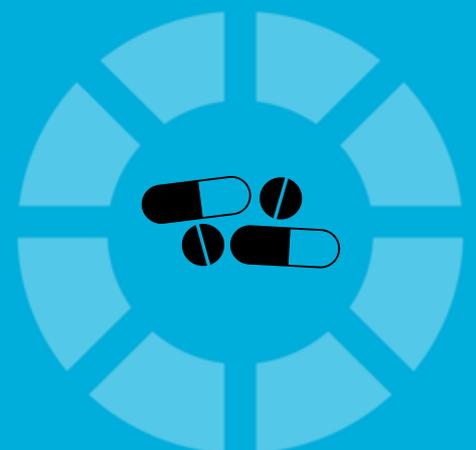
Q2 2016

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IRAN

PHARMACEUTICALS & HEALTHCARE REPORT

INCLUDES 10-YEAR FORECASTS TO 2025



Iran Pharmaceuticals & Healthcare Report Q2 2016

INCLUDES 10-YEAR FORECASTS TO 2025

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BMI Industry View

BMI View: *With sanctions lifted, Iran has improving prospects of opening up to a wider diversity of trading partners and providing strategic opportunities for multinational pharmaceutical companies. By reintegrating into the financial transaction system SWIFT, the import of pharmaceutical-related products will ease and prevent future drug shortages. Both innovative and generic drugmakers will look to gain a local presence within the country, given the growing demand for essential medicines and likely improvements to healthcare provision.*

Headline Expenditure Projections

- **Pharmaceuticals:** IRR69.55trn (USD1.93bn) in 2015 to IRR78.95trn (USD1.97bn) in 2016; +13.5% in local currency terms and -2.2% in US dollar terms. *Forecast upgraded from previous quarter.*
- **Healthcare:** IRR810.99trn (USD22.53bn) in 2015 to IRR923.35trn (USD23.08bn) in 2016; +13.9% in local currency terms and +2.5% in US dollar terms. *Forecast upgraded from previous quarter.*

Risk/Reward Index

Iran scores 38.0 out of 100 in terms of its attractiveness as a destination to launch innovative pharmaceuticals in Q216, up from 33.9 in the previous quarter, according to BMI's Risk/Reward Index. Iran's position in the regional rankings has risen one place in Q216 to 19th out of the 31 countries in the Middle East and Africa region. Its overall score is steadily approaching the regional average of 40.3.

Generally speaking, Iran benefits from a large and growing population and relatively widespread access to healthcare services. However, its regulatory regime - including intellectual property rights and economic situation - is highly questionable. Consequently, the country performs below the regional average in terms of risk despite improvements in the political situation.

Key Trends And Developments

- In January 2016, Sanofi signed a Memorandum of Cooperation (MoC) with Iran's government, aimed at boosting its presence in the country. This agreement falls in line with Sanofi's expansion activities across the Middle Eastern region in 2014 and 2015. The company is well-placed to benefit from the increasing demand for generic drugs and the currently favoured patented drugs segment.
- In January 2016, Italian group Pessina Costruzioni announced a deal to build five hospitals in Iran as companies scramble to steal a march on rivals with trade heating up. The Milan-based company signed an Memorandum of Understanding with Iran's Ministry of Health in Tehran, where three of the 1,000-bed hospitals will be built.

BMI Economic View

The outlook on the Iranian economy over the next five years is positive as the country benefits from major sanctions relief. Despite this, we believe much of the excitement about a sudden opening in Iran is hype and investment will take some time before it flows in.

BMI Political View

The rapid termination of sanctions represents a key victory for President Hassan Rouhani; however, the longer-term relationship between Iran and the US faces significant risks. With a new administration in the White House in January 2017, Iranian presidential elections in 2017 and concerns over the supreme leader's health, the confluence of moderates and pragmatists may be just a phase - posing risks to the longevity of the deal.

SWOT

Pharmaceutical SWOT Analysis

Strengths

- Large pharmaceutical market in regional terms, supported by large population.
- Popular regional destination for medical tourism.
- Wide-ranging public healthcare coverage, including in most rural areas.
- Requirement for registration of drugs under their brand names.
- Local manufacturing sector output comprising mostly inexpensive, basic medicines resulting in a market that is reliant on imports for hi-tech treatments.
- Anti-retrovirals are distributed free of charge.
- Acquisition of advanced medicine production capability.

Weaknesses

- Low per capita spending on healthcare and pharmaceuticals results in a focus on basic treatments.
- International investors are reluctant to get involved in Iran, especially given the economic sanctions.
- Relatively poor intellectual property standards.
- Strict government controls on the price of pharmaceuticals.
- Strict import regime favouring domestic companies.
- Around half of raw materials used by the local industry are imported.
- Over-the-counter (OTC) drugs are disadvantaged by the low prevalence of self-medication.
- Government's strategy for self-sufficiency with regards to pharmaceutical needs.
- Government corruption and underinvestment has left healthcare infrastructure weak.

Opportunities

- Low taxes on foreign-made drugs that are not manufactured locally.

Pharmaceutical SWOT Analysis - Continued

- Expanding public health insurance coverage boosting demand for generic medicines.
- Improved intellectual property and regulatory conditions to attract some investment in local facilities.
- Gradual modernisation of healthcare facilities.
- Plans to improve drug registration times.
- Improved international relations may increase confidence of multinational drugmakers to invest in the market.
- Increased investment in local pharmaceutical capacities.
- Rising interest in collaborative agreements with partners in select foreign markets.
- Removal of almost all economic sanctions

Threats

- Counterfeiting remains a serious issue.
- Availability of imported pharmaceuticals at risk due to financial sanctions.
- Exchange rate fluctuations, rising energy costs and inflation negatively impacting on profitability of drug production and also on final consumer prices.
- Underperforming economy to have a negative impact on government spending.
- Potential removal of OTC medicines from the reimbursement list.
- Trade in parallel imports threatening companies' performance.
- Regional instability linked to the proclamation of the Islamic State creating political and economic instability.
- Tense political relationship with the US.

Industry Forecast

Pharmaceutical Market Forecast

BMI View: *The removal of almost all sanctions on Iran's economy will herald a new era for the country and will see pharmaceuticals and healthcare markets benefit from greater multinational interest as foreign drugmakers look to expand their business operations for the long term. However, internal issues such as rampant corruption and years of underinvestment may prevent an immediate boom.*

Latest Updates

- Xbrane Biopharma has entered into a sales and distribution deal with the Swiss-based company Helvetic BioPharma for its lead ranibizumab biosimilar, *Xlucane*, which is to be launched in Iran. *Xlucane* is a biosimilar version of Genentech (Roche)'s *Lucentis*, used in the treatment of the wet form of age-related macular degeneration, and is expected to be launched during 2017.
- A pharmaceutical company, affiliated to the Social Security Organization, has used the latest technology in the production of beta-lactam antibiotics which are available in the market at 50% of the price of the imported medicines, which will help save USD5mn.

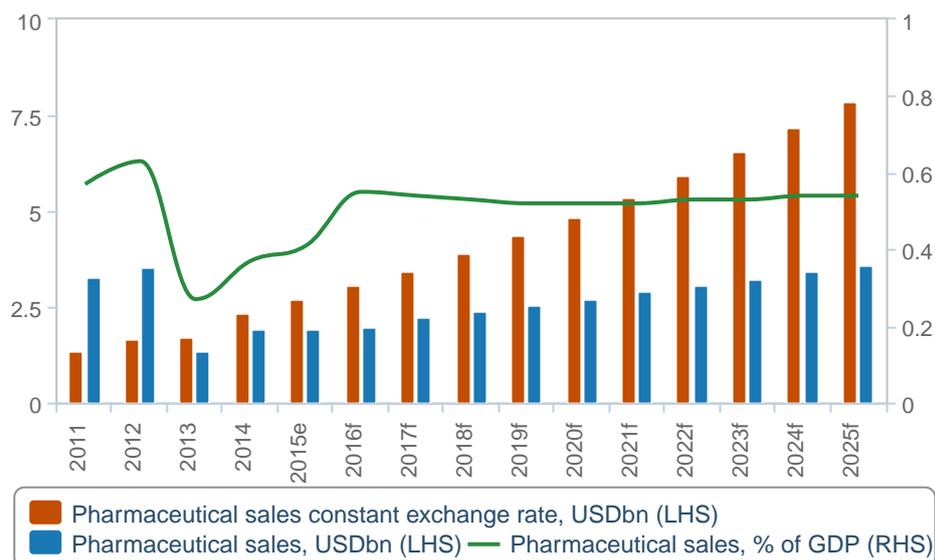
BMI continues to adjust its forecasts for Iran's pharmaceutical market to account for the lifting of sanctions in January 2016. Iran's diversified economy will enable the rial to largely weather the storm of depressed oil prices as it enters its post-sanctions period of stabilisation, and we expect the market in US dollar terms to rise by 2.2% in 2016. It is important to note that these monetary calculations remain based on extreme currency distortions.

The value of Iran's pharmaceutical market in 2015 was IRR69,545bn (USD1.93bn) and the market is forecast to increase to a market size of IRR125,142bn (USD2.72bn) by 2020, corresponding to a local currency compound annual growth rate (CAGR) of +12.5% (7.1% in US dollar terms, highlighting the severe impact of the depreciating rial). By 2025, the Iranian pharmaceutical market will be worth IRR202,891bn (USD3.59bn), corresponding to a local currency CAGR of 11.3% (6.4% in US dollar terms).

To generate pharmaceutical expenditure figures, **BMI** switched from the official IRR/USD exchange rate to the parallel (or black market) exchange rate, which reflects reality far better. We stress that these calculations have a high degree of uncertainty due to the volatile nature of the situation in Iran.

Pharmaceutical Market Forecast

2010-2024 (2011-2025)



f = BMI forecast. Source: UN Comtrade, National Sources, BMI

Structural Trends

In the aftermath of sanctions on the country's banking system in 2012, Iran's pharmaceutical sector faced severe difficulties for several years, despite medicines being exempt from sanctions. Due to restrictions on financial transactions, imports of pharmaceutical raw materials and finished products were affected, resulting in subsequent drug shortages. The scarcity of medicines was further exacerbated with the rial's significant depreciation, making imports even more expensive. Difficulties with money transfer increased the prices of medicines and many essential drugs were absent from the market completely.

Drug shortages for more sophisticated medicines became common, as many Western companies chose not to do business in Iran given the challenging operating environment. Given the more basic nature of domestic manufacturers, the shortages were unable to be accounted for by local companies.

More recently, the outlook for Iran's domestic pharmaceutical sector has been more positive, with Deputy Minister of Health and Chairman of the country's Food & Drug Administration, Rasul Dinarvand, claiming

in September 2014 that the drug supply crisis was over. He stated that medicine prices are now under control and customs clearance on imported medicine has resulted in an adequate supply. Nasser Riyahi, head of Iran's Drug Importing Union has stated that a large number of previously imported medicines are now manufactured by domestic companies, and the health ministry's policy is to restrict imports to further support the domestic industry.

Many previously imported pharmaceuticals are now produced locally, with domestic companies gaining a greater market share as a result of sanctions. Eight Iranian companies unveiled 12 newly produced drugs for the treatment of multiple sclerosis, cancer and diabetes in February 2015.

In January 2016, the US and Europe lifted oil and financial sanctions off Iran, immediately releasing over USD100bn of its assets after the International Atomic Energy Agency (IAEA) announced Iran had complied with its side of the July 2015 accord. This landmark agreement is potentially good news for a multinational pharmaceutical industry that has long recognised the commercial potential of tapping into the Iranian market, particularly as opportunities for growth in the West remain elusive

Although we caution that long-term forecasts remain at high risk owing to the still challenging situation in Iran, we expect steady growth of the market. The challenging regulatory environment which operates in favour of the local industry, weak patent protection and a low percentage of patented drug sales compared to the Middle East and North Africa region will provide significant challenges to multinationals wishing to operate in the Iranian pharmaceutical market, despite the clear demand for chronic disease drugs. Uptake of medicines in the short term is further risked by currency depreciation and hyperinflation of local medicine prices.

Key to the future development of the drug market in Iran will be the establishment of raw material production plants. This will enable local drugmakers to reduce costs and increase international competitiveness. It will also make domestic players less susceptible to currency fluctuations, which affect the prices of imports (including raw materials) and increase production costs. The continuing modernisation of local production facilities will gradually ensure compliance with international Good Manufacturing Practice standards and, therefore, boost export potential.

Table: Pharmaceutical Sales, Historical Data And Forecasts (Iran 2012-2020)

	2012	2013	2014	2015	2016f	2017f	2018f	2019f	2020f
Pharmaceutical sales, USDbn	3.516	1.340	1.909	1.932	1.974	2.229	2.389	2.553	2.721
Pharmaceutical sales, USDbn, % y-o-y	7.85	-61.89	42.47	1.20	2.17	12.93	7.19	6.85	6.56
Pharmaceutical sales, IRRbn	42,890	44,216	60,704	69,545	78,950	89,161	100,353	112,330	125,142
Pharmaceutical sales, IRRbn, % y-o-y	23.97	3.09	37.29	14.57	13.52	12.93	12.55	11.93	11.41
Pharmaceutical sales constant exchange rate, USDbn	1.660	1.712	2.350	2.692	3.056	3.452	3.885	4.349	4.845
Pharmaceutical sales, USD per capita	46.2	17.4	24.4	24.4	24.7	27.5	29.2	30.9	32.6
Pharmaceutical sales, % of GDP	0.63	0.27	0.37	0.41	0.55	0.54	0.53	0.52	0.52
Pharmaceutical sales, % of health expenditure	9.5	7.3	8.6	8.6	8.6	8.5	8.5	8.6	8.6

f = BMI forecast. Source: UN Comtrade, National Sources, BMI

Healthcare Market Forecast

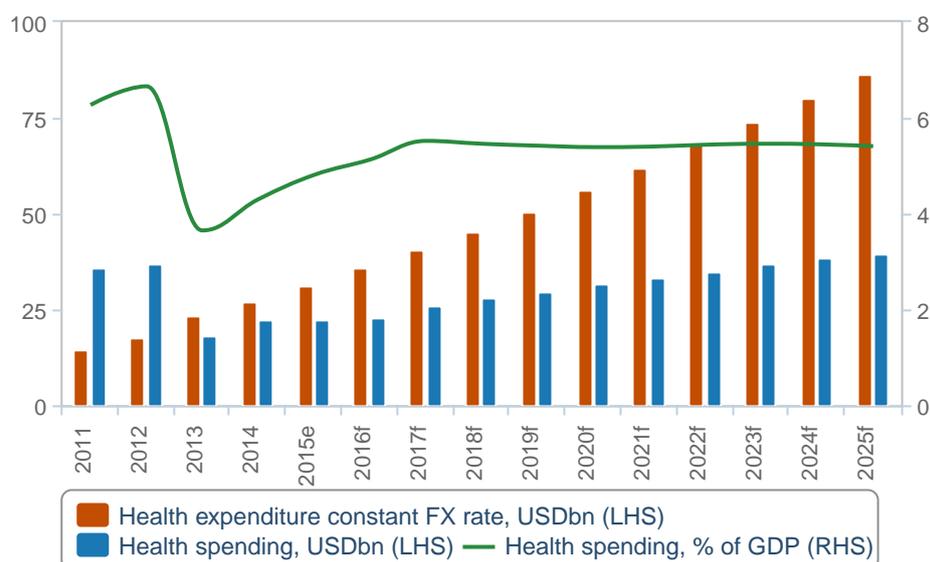
BMI View: *The fall of the sanctions has opened up the huge potential for investment in Iran's healthcare and health tourism, which will expedite government's attempts to extend public access to primary and preventative care. Both innovative and generic drugmakers will look to gain a local presence within the country, given the growing demand for essential medicines and medical equipment that will likely improve on healthcare provision.*

Latest Updates

- In December 2015, the Ministry of Health announced a swine flu outbreak had killed 42 people in southeastern Kerman province. The 600 people who contracted the virus were hospitalised, with the virus quickly being brought under control by the health authorities.
- In January 2016, the Ministry of Health announced an initial agreement with Italian group Pessina Costuzioni to build five 1,000-bed hospitals in Iran as part of a broad strategic cooperation strategy in the areas of hospital construction & equipment and medical tourism.

Healthcare Expenditure Forecast

2010-2024 (2011-2025)



f = BMI forecast. Source: World Health Organization (WHO), BMI

We calculate healthcare expenditure reached IRR810,988bn (USD22.53bn) in 2015. Our forecasts will remain at risk for as long as the political and economic uncertainty lasts; however, following a sharp contraction of the market in US dollar value-terms in recent years, we expect the rate of growth of healthcare spending to stabilise over the forecast period as inflationary pressures are stabilised. By 2020, **BMI** forecasts Iranian healthcare expenditure to reach IRR1.45trn (USD31.62bn), corresponding to a local currency compound annual growth rate (CAGR) of 12.4% (7.0% in US dollar terms). By 2025, we forecast Iran's healthcare market to reach IRR2.23trn (USD39.42bn), equating to CAGR of 10.6% and 5.8% in local currency and US dollar terms, respectively.

Structural Trends

Policy changes and other issues of national interest are rarely discussed with any degree of transparency, and decision-making is protracted and bureaucratic. However, on a cultural level, most patients are likely to seek a physician's advice rather than self-medicate. Being able to afford medicines is a separate matter, which may be part of the reason why over-the-counter drugs (OTCs) and prescription drugs overlap in sales.

The Iranian government has increasingly encouraged private sector investment in the pharmaceutical industry, which will continue to witness state divestments in drug importation, manufacturing and retail entities. The privatisation of the industry is likely to reduce the financial burden of healthcare and pharmaceutical provisions from state funds, although much will depend on the wider economic and political situation.

At the same time, it is possible that the growth of the industry will be boosted by improved universal access to basic health services, combined with institutional innovation and the broader involvement of communities and local governments in decisions regarding the rural health system. However, such developments will also greatly depend on political commitment.

Iran could be set to become a major health and medical tourism destination as a result of the political rapprochement with the US and other Arab nations in the post-sanctions period. The Iranian government is now providing health service training to employees of tourism agencies and also supports hospitals in opening international patient wards and centres.

Table: Healthcare Expenditure Trends, Historical Data And Forecasts (Iran 2012-2020)

	2012	2013	2014	2015	2016f	2017f	2018f	2019f	2020f
Health spending, USDbn	36.990	18.431	22.148	22.527	23.084	26.115	27.948	29.794	31.622
Health spending, USDbn, % y-o-y	2.44	-50.17	20.17	1.71	2.47	13.13	7.02	6.61	6.13
Health spending, IRRbn	451,236	608,217	704,313	810,988	923,349	1,044,610	1,173,797	1,310,939	1,454,594
Health spending, IRRbn, % y-o-y	17.75	34.79	15.80	15.15	13.85	13.13	12.37	11.68	10.96
Health expenditure constant FX rate, USDbn	17.468	23.545	27.265	31.395	35.744	40.439	45.440	50.749	56.310
Health spending, USD per capita	485.7	238.9	283.4	284.8	288.4	322.6	341.6	360.6	379.1
Health spending, % of GDP	6.66	3.65	4.30	4.81	5.13	5.52	5.46	5.42	5.39

f = BMI forecast. Source: World Health Organization (WHO), BMI

Table: Government Healthcare Expenditure Trends, Historical Data And Forecasts (Iran 2012-2020)

	2012	2013	2014	2015	2016f	2017f	2018f	2019f	2020f
Govt. health spend, USDbn	14.936	7.518	9.138	9.315	9.599	10.905	11.694	12.479	13.238
Govt. health spend, USDbn, % y-o-y	-4.08	-49.66	21.55	1.94	3.05	13.60	7.24	6.72	6.08
Govt. health spend, IRRbn	182,198	248,096	290,587	335,338	383,962	436,181	491,139	549,094	608,945
Govt. health spend, IRRbn, % y-o-y	10.25	36.17	17.13	15.40	14.50	13.60	12.60	11.80	10.90
Govt. health spend, % total health spend	40.38	40.79	41.26	41.35	41.58	41.76	41.84	41.89	41.86

f = BMI forecast. Source: World Health Organization (WHO), BMI

Table: Private Healthcare Expenditure Trends, Historical Data And Forecasts (Iran 2012-2020)

	2012	2013	2014	2015	2016f	2017f	2018f	2019f	2020f
Private health spend, USDbn	22.054	10.913	13.010	13.213	13.485	15.211	16.254	17.315	18.384
Private health spend, USDbn, % y-o-y	7.38	-50.52	19.22	1.55	2.06	12.80	6.86	6.53	6.17
Private health spend, IRRbn	269,038	360,121	413,726	475,650	539,387	608,429	682,657	761,846	845,649
Private health spend, IRRbn, % y-o-y	23.43	33.86	14.89	14.97	13.40	12.80	12.20	11.60	11.00
Private health spend, % total health expenditure	59.62	59.21	58.74	58.65	58.42	58.24	58.16	58.11	58.14

f = BMI forecast. Source: World Health Organization (WHO), BMI

Prescription Drug Market Forecast

BMI View: *We note that Iran's epidemiological profile highlights a rising demand for lung cancer, asthma and respiratory disease treatments, which are mostly available only on prescription. This situation will be further driven by the increased access to healthcare services financed by the government, and supported by the fact that hospitals continue to act as the main point of access to healthcare in the absence of a comprehensive primary care network.*

Structural Trends

The prescription drug market is estimated to account for between 85-90% of the total market, although we stress that Iran is a market for which it is extremely challenging to obtain exact figures. Additionally, the distinction between prescription and over-the-counter medicines is unclear, making the differentiation between sectors even more difficult. A significant number of prescription drugs are still available without a prescription, and this issue is expected to persist in the short-to-medium term at least, especially given the current economic and political situation. Similarly, the use of counterfeit drugs continues to be encouraged through the lack of intellectual property accords and poor enforcement, in addition to widespread poverty that is increasing the demand for low-cost treatments, regardless of their actual origin and legal status.

Antibiotics remain the most prescribed drugs in Iran, accounting for an estimated quarter of the market in volume terms. The low-cost nature of bulk antibiotics makes these products a popular choice for resource-starved public healthcare institutions. However, there is evidence that the misuse and overuse of antibiotics in Iran is itself causing health concerns - for example, *Acinetobacter baumannii*, a bacterium associated primarily with hospital-driven infections, has developed multiple drug resistance (MDR) and caused increased clinical problems as a result. Further, a 2013 report released in the Lancet also showed that antibiotics are inappropriately used: 993 (99%) of 1,000 patients received at least one antibiotic. Antibiotics were given to 85 (98%) of 87 patients for whom such treatment was not indicated, costing an average of US \$100 per surgical procedure.

As a result of these developments, the government is to introduce some restrictions on the use of antibiotics in public institutions, especially as the Social Security Organization has in the past been unable to meet all of its liabilities successfully, both to hospitals and to pharmaceutical manufacturers and distributors.

Patented Drug Market Forecast

***BMI View:** As the purchasing power for medicines is low, in the public and private sphere, we expect the development of the generic drug market to outpace that of its patented counterpart. Additionally, although we note the long-term market development will be predicated on the resolution of the current crisis, we expect that patent expirations will negatively affect the value of the patented drug segment. In the short term, the inability of domestic stakeholders to pay for the imported high-value medicines will also curtail the sales of patented drugs.*

Structural Trends

We estimate that patented medicines account for about one-third of the overall market's value. Clearly, growth will be difficult to assess accurately, due to the high volume of counterfeit trade and international patent infringement that will continue to blur market figures and trends. Given the potential of the highest profit margins, patented drugs remain among the most commonly counterfeited products. Generally speaking, cost-containment pressures and the government's intention to improve access to drugs to all sections of the population will play in favour of the development of the generic drugs market. Copy drugs, which are the staple of the local industry, are therefore expected to substantially expand their market share.

Iran is also keen to develop its own drug development industry and is seeing dramatically improved prospects for capital investment and technology transfer from foreign firms after the removal of the trade barriers in January 2015. Many previously imported pharmaceuticals are now produced locally, with domestic companies having acquired a greater market share as a result of the removal of the sanctions.

A 2014 Report by Scopus, the world's largest abstract and citation database, ranked Iran 21st in the world in terms of scientific productions in the field of biotechnology, by offering 3,957 products in the field of biotech.

Eight Iranian companies unveiled 12 newly produced drugs for the treatment of multiple sclerosis, cancer and diabetes in February 2015. Local companies manufacture sophisticated medicines using biotechnology and nanotechnology, with Sobhan Oncology producing seven nano-drugs. A total of 12 anti-cancer medicines were developed in Iran in 2014, making it unlike the majority of emerging markets which are reliant on importing the majority of drugs for chronic diseases.

Generic Drug Market Forecast

***BMI View:** The outlook for generic drug sales in Iran is favourable. With generic drugs habitually prescribed and the end of sanctions paving the way for increased foreign investment in drug production and infrastructure, we believe sales in this segment will increase. Economic factors and government initiatives should also have a positive impact on generic drug volumes. We estimate that generic medicines currently account for over half of the market by value, although the lack of reliable data will remain an issue with regard to our historical valuations and forecasts.*

Structural Trends

Access to basic healthcare in Iran is widespread, with about 90% of the rural population and almost the entire urban population covered. The outlook for generic drug sales in Iran is favourable, as a result of the habitual prescription of lower-value medicines and a reasonable level of public awareness. We believe sales in this segment will continue to increase. Opportunities exist for generic drugmakers in the Iranian pharmaceutical market, highlighted by Indian generic drugmaker Cipla's plans to set up a manufacturing facility in the country.

In May 2015, it was announced that Iran opened a production line for US and European branded generic drugs in Saveh, 100km southwest of Tehran. The plant was built with USD8mn of investment and produces 12 brands of drugs for treatment of diabetes, neurological diseases, inflammations and prostates. Five more products for special medical conditions will be added to the list in the next five years.

OTC Market Forecast

BMI View: *Driven by demand, analgesics will remain the leading component of the over-the-counter (OTC) market, although vitamins and minerals are also likely to experience relatively strong growth over the forecast period. However, as part of a health awareness drive, the authorities are likely to target misuse and overuse of OTCs - even though this situation has arisen from the lack of access to and availability of some types of medicines on the market, forcing the consumers to take what is available, rather than what is necessary.*

Structural Trends

Given that most products are still reimbursed, the legitimate over-the-counter (OTC) drug market in Iran is estimated to account for no more than 10-15% of the pharmaceutical market's total value. However, the distinction between OTC and prescription is still unclear - even at the point of sale at the pharmacy. OTC medicines are only available at pharmacies and are not marketed or heavily advertised, further restricting growth. Moreover, patients are more likely to consult a doctor than self-medicate as an initial means of treatment.

The key factor influencing future OTC growth is the Ministry of Health and Medical Education (MOHME)'s consideration of a programme to remove OTC medicines from the reimbursement list as part of the wider cost-containment drive. The MOHME plans to spend the money saved on OTCs, providing more important medicines that are not reimbursed. This could have an impact on the market value of consumer health products; however, a steady increase in private sector investment and buoyant GDP growth anticipated as a result of the lifting of sanctions may spare patients in rural populations from sharp price increases.

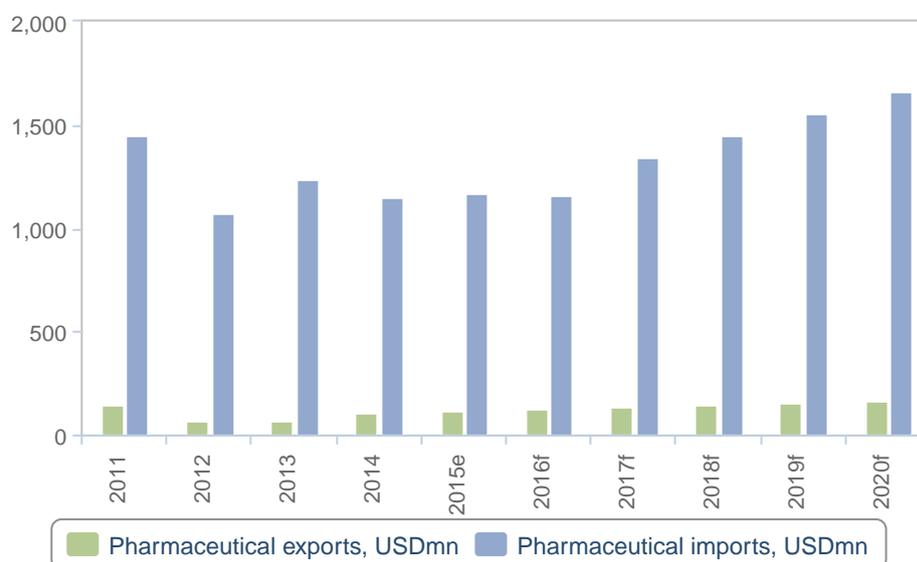
According to the Iranian Food and Drug Organisation, analgesics were the most consumed OTC drug in Iran over 2015 as Acetaminophen and acetaminophen with codeine accounted for more than half of the total market.

Pharmaceutical Trade Forecast

BMI View: The lifting of sanctions on Iran will result in increasing pharmaceutical imports from multinational drugmakers; however, the overall value of imports will stagnate over our forecast period to 2019 given government restrictions on drug imports. Sanctions on the banking sector in 2012 resulted in a 26.2% decline in the value of pharmaceutical imports as many companies chose not to do business in the country given the operating challenges. Imports have gradually increased since that time, but we do not foresee imports reaching pre-sanction levels for the remainder of our forecast period.

Pharmaceutical Trade Forecast

2010-2019 (2011-2020)



f = BMI forecast. Source: UN Comtrade, National Sources, BMI

Domestic Drug Manufacturing Sector

There are around 100 domestic pharmaceutical companies, 25 of which are listed on the Tehran Stock Exchange (TSE), according to Mehdi Pirsalehi, director general of Iran's Food & Drug Administration. The main stock market soared by 22% in a single month after sanctions were lifted in January 2016, and is up over 25% so far in 2016 as low valuations saw value investors flooding in an attempt to offset stagnating

performance in global markets. This has been good news for pharmaceutical companies who have also seen substantial valuation increases over up to Q216.

These companies have since voiced concerns that their sales could be negatively affected by an upswing in imports following the fall of sanctions; however, the government has implemented policies to control drug imports.

Drugs with domestically produced equivalents are not permitted to be imported, and given the well-developed domestic industry, which has made great strides in recent years, we hold the view that the majority of imported pharmaceuticals will come from multinationals in the form of innovative treatments. In 2014, 50% of imported drugs had a domestically available equivalent; however, from here on in, the only drugs to be imported will be those that cannot be produced domestically.

Pharmaceutical Trade Forecast

Pharmaceutical imports into Iran reached USD1.74bn in 2015, and despite the lifting of sanctions we forecast imports to decline for the remainder of 2016 before staging a rapid upswing in growth. By 2020, imports are expected to reach USD2.48bn, corresponding to a compound annual growth rate (CAGR) of 7.3% in US dollar terms. In line with our view with sanctions lifted, we believe the prospect of Iran opening up to a wider diversity of trading partners will improve and provide strategic opportunities for multinational pharmaceutical companies. By reintegrating into SWIFT, the financial transaction system, the import of pharmaceutical-related products will ease and prevent future drug shortages. As a result, over the long term, we believe that foreign drugmakers will be a lot more willing to operate in Iran.

Structural Trends

Most of Iran's basic pharmaceutical needs in volume terms are manufactured locally, so the majority of the population was not affected by the inability to buy foreign-made pharmaceuticals. A World Health Organization (WHO) consultant who visited Iran under sanctions said it drew well on its domestic resources and became almost self-sufficient in generic drugs - an impressive feat given the availability of drugs. Iran's highly developed pharmaceutical industry ensured strong generic production and distribution, able to serve the country's population through a comparatively loose generic prescription policy.

During the era of nuclear sanctions, medicines were in fact exempt from these trade sanctions on account of exemptions for essential drugs and other humanitarian goods. Hence Iran's pharmaceuticals and healthcare markets have remained fairly insulated from these economic barriers. However, restrictions on financial

transactions remained, which meant that imports of pharmaceutical raw materials and finished products were affected, often leading to drug shortages. This was particularly true for more sophisticated medicines, as many Western companies chose not to do business in Iran given the challenging operating environment.

For example, representatives from Merck & Co and Pfizer reported problems extracting money from the country when the Tejaret, the third-largest bank in Iran, was blacklisted as a result of it being the last legal route for financial transactions in the country. Given the more basic nature of domestic manufacturers, the shortages were unable to be accounted for by local companies.

Such transactions issues are likely to all but disappear with most of the banking restrictions removed and it is **BMI's** view that Iran's prospect of opening up to a wider diversity of trading partners will improve and provide strategic opportunities for multinational pharmaceutical companies. By reintegrating into the financial transaction system SWIFT, the import of pharmaceutical-related products will ease and prevent future drug shortages. As a result, over the long term, we believe that foreign drugmakers will be a lot more willing to operate in Iran.

For example, in September of 2015, Novo Nordisk signed a Memorandum of Understanding with the Food & Drug Administration of the Islamic Republic of Iran to build a manufacturing plant in Iran for *FlexPen* prefilled insulin injection devices. Novo Nordisk commented that the move signalled its long-term commitment to Iran, adding that the country has nearly 5mn people with diabetes, according to the International Diabetes Federation. The project is expected to last five years and represents a Novo Nordisk investment of around EUR70mn (USD78.6mn). The production will function in compliance with GMP and will create around 160 jobs. Novo Nordisk already employs some 130 people in Iran.

Further, in February 2016, a Pakistani business delegation visited Tehran to explore ways to broaden bilateral trade and economic relations. Trade between Iran and Pakistan is aimed to rise to USD5bn a year in three years and Almas Haiderm, the director of Industrial Development Corporation, said that 'members of my team are already looking to set up manufacturing plants or open offices in Iran, mostly in pharmaceuticals, plastics, as well as automation services.'

The government is pushing for structural modernisation of key medical facilities and technologies that will see an increase in advanced medicine, including antibodies and proteins. A number of substances that only few companies globally have the technical expertise to produce, including monoclonal antibodies and factor VIII, are already produced in Iranian laboratories, and the goal is to build on this foundation in order to make Iran a regional and international hub for medical innovation. Iranian experts have already made great

headways in using modern medical technology to cure a broad range of diseases inside the country in recent years, making Iran as a top destination for medical tourism.

Table: Pharmaceutical Trade Data And Forecasts (Iran 2014-2020)

	2014	2015	2016f	2017f	2018f	2019f	2020f
Pharmaceutical exports, USDmn	102.72	113.86	124.78	135.52	145.83	156.26	166.59
Pharmaceutical exports, USDmn, % y-o-y	56.63	10.84	9.60	8.60	7.61	7.15	6.61
Pharmaceutical imports, USDmn	1,153.89	1,167.73	1,158.05	1,342.57	1,445.85	1,552.07	1,661.68
Pharmaceutical imports, USDmn, % y-o-y	-6.93	1.20	-0.83	15.93	7.69	7.35	7.06
Pharmaceutical trade balance, USDmn	-1,051.17	-1,053.87	-1,033.26	-1,207.05	-1,300.02	-1,395.81	-1,495.09

f = BMI forecast. Source: National Sources, BMI

Table: Pharmaceutical Trade Data And Forecasts local currency (Iran 2014-2020)

	2014	2015	2016f	2017f	2018f	2019f	2020f
Pharmaceutical exports, IRRmn	2,653,445.43	2,941,143.86	3,993,115.64	4,743,270.07	5,395,879.35	6,093,962.00	6,830,111.21
Pharmaceutical exports, IRRmn, % y-o-y	125.01	10.84	35.77	18.79	13.76	12.94	12.08
Pharmaceutical imports, IRRmn	29,806,107	30,164,796	37,057,465	46,989,990	53,496,493	60,530,698	68,128,995
Pharmaceutical imports, IRRmn, % y-o-y	33.70	1.20	22.85	26.80	13.85	13.15	12.55
Pharmaceutical trade balance, IRRmn	-27,152,661	-27,223,652	-33,064,350	-42,246,719	-48,100,614	-54,436,736	-61,298,884

f = BMI forecast. Source: UN Comtrade, National Sources, BMI

Industry Risk/Reward Index

Middle East and Africa Risk/Reward Index - Q2 2016

***BMI View:** Geographic diversification may be a favourable strategy for multinational pharmaceutical companies, but it is vital that firms recognise both the rewards and the risks present in a market, whether developed or emerging. **BMI's Risk/Rewards Index (RRI) tool**, which provides a globally comparative and numerically based assessment of a market's attractiveness, was established to address this.*

In **BMI's** Q216 Pharmaceutical RRI, the Middle East and Africa region scores 41.3 out of 100, comparing poorly against Western Europe (70.2), Asia Pacific (52.3), Central and Eastern Europe (52.6) and the Americas (50.5). The indicators used to assess the attractiveness of a pharmaceutical market are now visible, improving the transparency of the index system and enabling the identification of regional or group outperformers across single indicators. A market's RRI score is made up of a sum of the Rewards score (Industry Rewards + Country Rewards) and the Risks score (Industry Risks + Country Risks).

The weight assigned to each subsector (such as Industry Rewards or Industry Risks) shows its influence within the final Rewards or Risks score and the final RRI score. The Rewards component accounts for 65% of the final RRI, while the Risks component accounts for 35%.

Q216 Middle East and Africa Pharmaceutical Risk/Reward Index

Rewards & Risks Scores

	Industry Rewards	Country Rewards	Rewards	Industry Risks	Country Risks	Risks	RRI	Ranking
Weighting	44	21	65	21	14	35	100	
UAE	27.6	11.0	38.6	14.7	9.2	23.9	62.5	1
Saudi Arabia	29.6	12.8	42.4	7.7	9.6	17.3	59.7	2
Israel	22.0	16.3	38.3	9.5	8.0	17.4	55.7	3
Kuwait	18.0	14.6	32.6	14.0	7.9	21.9	54.5	4
Qatar	18.4	13.3	31.7	11.9	10.0	21.9	53.6	5
Lebanon	20.0	15.7	35.7	9.5	7.6	17.1	52.8	6
Bahrain	16.4	12.3	28.7	13.3	10.0	23.3	52.0	7
Algeria	25.2	13.1	38.3	5.6	6.5	12.1	50.4	8
Oman	17.2	13.0	30.2	10.5	8.1	18.6	48.8	9
South Africa	18.0	10.5	28.5	11.2	9.0	20.2	48.7	10
Jordan	18.0	12.8	30.8	9.8	7.7	17.5	48.3	11
Morocco	16.8	10.2	27.0	10.5	8.0	18.5	45.5	12
Egypt	20.4	10.4	30.8	6.3	7.2	13.5	44.3	13
Mauritius	11.6	8.2	19.8	11.2	10.2	21.4	41.2	14
Botswana	14.0	10.4	24.4	7.7	8.1	15.8	40.2	15
Gabon	12.8	13.6	26.4	6.3	6.7	13.0	39.4	16
Ghana	11.6	10.9	22.5	7.0	8.7	15.7	38.2	17
Kenya	14.8	9.0	23.8	7.7	6.6	14.3	38.1	18
Iran	15.2	11.8	27.0	5.6	5.4	11.0	38.0	19
Namibia	11.6	10.1	21.7	7.7	8.0	15.7	37.4	20
Iraq	15.2	12.2	27.4	5.6	3.4	9.0	36.4	21
Cameroon	12.8	10.9	23.7	4.9	5.0	9.9	33.6	22
Tanzania	9.2	9.8	19.0	6.3	6.8	13.1	32.1	23
Sudan	13.6	9.3	22.9	4.2	4.3	8.5	31.4	24
Mozambique	10.4	9.8	20.2	4.9	5.9	10.8	31.0	25
Cote d'Ivoire	11.6	10.9	22.5	2.8	5.1	7.9	30.4	26
Uganda	8.0	8.2	16.2	6.3	6.6	12.9	29.1	27
Zambia	5.6	10.6	16.2	6.3	6.2	12.5	28.7	28
Angola	9.2	10.6	19.8	4.2	3.3	7.5	27.3	29
Nigeria	5.2	10.6	15.8	4.2	6.0	10.2	26.0	30
Zimbabwe	9.2	9.3	18.5	2.8	3.7	6.5	25.0	31
Regional Average	15.1	11.4	26.5	7.7	7.1	14.8	41.3	

*RRI scores out of 100, with 100 highest. Source: BMI.

The Industry Rewards, Country Rewards, Industry Risks and Country Risks subsectors are each made up of a number of indicators. The weighting of each indicator (such as market expenditure which is used to assess Industry Reward or economic diligence which is used to assess Country Risk) reflects its relative importance to the pharmaceutical industry and subsequently the relative reward or risk that each factor poses to drug companies. In Q216, the UAE is ranked as the most attractive market in the Middle East and Africa region (scoring 62.5 out of 100), followed by Saudi Arabia (59.7) and Israel (55.7). In the same quarter, Zimbabwe is ranked as the least attractive market in the region (scoring 25.0 out of 100), followed by Nigeria (26.0) and Angola (27.3).

With regards to assessing rewards, we identify industry-specific factors, such as the size of the pharmaceutical market, and country-specific factors, such as the size of the pensionable population, which represent opportunities to would-be investors. Focusing on the Rewards component of the index system, Saudi Arabia scores a total of 42.4 out of 65, the highest score in the subsector. Saudi Arabia's score is boosted by the country's large drug market (market expenditure score of 14.0 out of 20) and a rapidly growing population (population growth score of 4.0 out of 5), but dragged down by a relatively small pensionable population (pensionable population score of 1.6 out of 8). Meanwhile, Nigeria scores a total of 15.8 out of 65, the lowest score in the subsector.

Q216 Middle East And Africa Pharmaceutical Rewards

Industry Rewards & Country Rewards Scores

	Market Expenditure	Spending Per Capita	Sector Value Growth	Industry Rewards	Urban/Rural Split	Pensionable Population	Population Growth	Country Rewards	Rewards
Weighting	20	12	12	44	8	8	5	21	65
UAE	12.0	7.2	8.4	27.6	7.2	0.8	3.0	11.0	38.6
Saudi Arabia	14.0	6.0	9.6	29.6	7.2	1.6	4.0	12.8	42.4
Israel	10.0	6.0	6.0	22.0	8.0	4.8	3.5	16.3	38.3
Kuwait	6.0	6.0	6.0	18.0	8.0	1.6	5.0	14.6	32.6
Qatar	4.0	6.0	8.4	18.4	8.0	0.8	4.5	13.3	31.7
Lebanon	8.0	6.0	6.0	20.0	7.2	4.0	4.5	15.7	35.7
Bahrain	2.0	6.0	8.4	16.4	7.2	1.6	3.5	12.3	28.7
Algeria	12.0	4.8	8.4	25.2	6.4	3.2	3.5	13.1	38.3
Oman	4.0	4.8	8.4	17.2	6.4	1.6	5.0	13.0	30.2
South Africa	12.0	3.6	2.4	18.0	5.6	2.4	2.5	10.5	28.5
Jordan	6.0	4.8	7.2	18.0	7.2	1.6	4.0	12.8	30.8
Morocco	6.0	2.4	8.4	16.8	4.8	2.4	3.0	10.2	27.0
Egypt	12.0	2.4	6.0	20.4	4.0	2.4	4.0	10.4	30.8
Mauritius	2.0	4.8	4.8	11.6	3.2	4.0	1.0	8.2	19.8
Botswana	2.0	3.6	8.4	14.0	4.8	1.6	4.0	10.4	24.4
Gabon	2.0	2.4	8.4	12.8	7.2	2.4	4.0	13.6	26.4
Ghana	2.0	1.2	8.4	11.6	4.8	1.6	4.5	10.9	22.5
Kenya	4.0	1.2	9.6	14.8	2.4	1.6	5.0	9.0	23.8
Iran	8.0	1.2	6.0	15.2	6.4	2.4	3.0	11.8	27.0
Namibia	2.0	3.6	6.0	11.6	4.0	1.6	4.5	10.1	21.7
Iraq	8.0	2.4	4.8	15.2	5.6	1.6	5.0	12.2	27.4
Cameroon	2.0	1.2	9.6	12.8	4.8	1.6	4.5	10.9	23.7
Tanzania	2.0	1.2	6.0	9.2	3.2	1.6	5.0	9.8	19.0
Sudan	4.0	1.2	8.4	13.6	3.2	1.6	4.5	9.3	22.9
Mozambique	2.0	1.2	7.2	10.4	3.2	1.6	5.0	9.8	20.2
Cote d'Ivoire	2.0	1.2	8.4	11.6	4.8	1.6	4.5	10.9	22.5
Uganda	2.0	1.2	4.8	8.0	1.6	1.6	5.0	8.2	16.2
Zambia	2.0	1.2	2.4	5.6	4.0	1.6	5.0	10.6	16.2
Angola	2.0	1.2	6.0	9.2	4.0	1.6	5.0	10.6	19.8
Nigeria	4.0	1.2	0.0	5.2	4.0	1.6	5.0	10.6	15.8
Zimbabwe	2.0	1.2	6.0	9.2	3.2	1.6	4.5	9.3	18.5
Regional Average	5.2	3.2	6.7	15.1	5.2	2.0	4.2	11.4	26.5

*RRI scores out of 100, with 100 highest. Source: BMI.

With regards to assessing risks, we identify industry-specific dangers - such as approvals expediency - and those emanating from the state's political and economic profile - such as bureaucracy - which call into question the likelihood of anticipated returns being realised over the assessed time period. With regards to the economic and political assessment, only the aspects most relevant to the pharmaceutical industry are incorporated into the assessment. Focusing on the Risks component of the index system, Zimbabwe scores a total of 6.5 out of 35, the lowest score in the subsector. Compared to its peers, Zimbabwe's score is dragged down by industry characteristics such as weak patent respect (patent respect score of 0.7 out of 7) and approvals expediency (approvals expediency score of 0.7 out of 7). Meanwhile, the UAE scores a total of 23.9 out of 35, the highest score in the subsector, making it the least risky proposition for pharmaceutical product launch.

Q216 Middle East And Africa Pharmaceutical Risks

Industry Risks & Country Risks Scores

	Patent Respect	Policy Enforcement	Approvals Expediency	Industry Risks	Economic Diligence	Policy continuity	Lack of Bureaucracy	Legal Diligence	Business transparency	Country Risks	Risks
Weighting	7	7	7	21	3	3	3	3	2	14	35
UAE	5.6	3.5	5.6	14.7	1.7	2.7	1.8	1.7	1.3	9.2	23.9
Saudi Arabia	2.1	2.8	2.8	7.7	2.0	2.4	2.7	1.8	0.7	9.6	17.3
Israel	2.1	3.9	3.5	9.5	2.2	1.8	1.3	1.8	0.9	8.0	17.4
Kuwait	4.2	4.2	5.6	14.0	1.4	2.1	1.5	1.7	1.3	7.9	21.9
Qatar	4.9	3.5	3.5	11.9	1.4	2.7	2.6	2.0	1.3	10.0	21.9
Lebanon	3.2	2.8	3.5	9.5	1.9	2.1	1.5	1.3	0.9	7.6	17.1
Bahrain	4.9	3.5	4.9	13.3	2.0	2.7	2.3	2.0	1.1	10.0	23.3
Algeria	2.1	1.4	2.1	5.6	1.5	1.8	1.7	1.0	0.5	6.5	12.1
Oman	4.2	3.5	2.8	10.5	1.7	2.1	1.5	1.7	1.2	8.1	18.6
South Africa	3.5	4.2	3.5	11.2	2.1	1.8	1.8	1.8	1.5	9.0	20.2
Jordan	3.5	2.8	3.5	9.8	1.8	2.4	1.0	1.4	1.1	7.7	17.5
Morocco	4.9	2.1	3.5	10.5	1.7	2.4	1.8	1.3	0.7	8.0	18.5
Egypt	2.8	2.1	1.4	6.3	1.9	1.8	1.7	1.3	0.5	7.2	13.5
Mauritius	3.5	4.2	3.5	11.2	2.0	2.7	2.0	1.9	1.5	10.2	21.4
Botswana	2.8	2.8	2.1	7.7	1.1	2.7	1.4	1.5	1.4	8.1	15.8
Gabon	2.1	2.8	1.4	6.3	1.6	2.7	1.0	0.8	0.6	6.7	13.0
Ghana	2.8	2.1	2.1	7.0	1.7	2.4	1.5	1.6	1.5	8.7	15.7
Kenya	2.1	2.8	2.8	7.7	1.7	2.1	1.2	1.1	0.6	6.6	14.3
Iran	0.7	2.8	2.1	5.6	1.1	2.1	1.1	1.0	0.0	5.4	11.0
Namibia	2.1	2.8	2.8	7.7	1.5	2.1	1.3	1.7	1.5	8.0	15.7
Iraq	2.1	1.4	2.1	5.6	1.1	0.9	0.5	0.7	0.2	3.4	9.0
Cameroon	2.1	1.4	1.4	4.9	1.4	1.8	0.6	0.7	0.5	5.0	9.9
Tanzania	2.1	2.1	2.1	6.3	1.5	2.1	1.1	1.2	0.9	6.8	13.1
Sudan	0.7	1.4	2.1	4.2	1.2	0.9	1.3	0.8	0.1	4.3	8.5
Mozambique	2.1	1.4	1.4	4.9	1.3	2.4	0.7	0.8	0.8	5.9	10.8
Cote d'Ivoire	0.7	1.4	0.7	2.8	1.3	1.5	1.0	0.6	0.6	5.1	7.9
Uganda	2.1	2.1	2.1	6.3	1.6	1.8	1.5	1.0	0.7	6.6	12.9
Zambia	1.4	2.8	2.1	6.3	1.4	1.5	1.2	1.2	0.9	6.2	12.5
Angola	1.4	1.4	1.4	4.2	0.8	1.2	0.3	0.6	0.4	3.3	7.5
Nigeria	0.7	2.1	1.4	4.2	1.7	1.8	1.0	1.1	0.4	6.0	10.2
Zimbabwe	0.7	1.4	0.7	2.8	0.7	0.9	0.9	0.8	0.4	3.7	6.5
Regional Average	2.6	2.6	2.6	7.7	1.5	2.0	1.4	1.3	0.8	7.1	14.8

*RRI scores out of 100, with 100 highest. Source: BMI.

In the table below, the subsector scores (ie, Industry Rewards) and full component scores (ie, Rewards) have been expressed as a percentage of the total weight or as a percentage of the maximum score that can be

achieved. This allows for the identification of the sub-sector or component that will most positively or negatively affect a single market.

Q216 Middle East And Africa Pharmaceutical Risk/Reward Index

Rewards & Risks Scores As A Percentage Of The Maximum Score

	Industry Rewards	Country Rewards	Rewards	Industry Risks	Country Risks	Risks	RRI	Ranking
UAE	63	52	59	70	66	68	62	1
Saudi Arabia	67	61	65	37	69	49	60	2
Israel	50	78	59	45	57	50	56	3
Kuwait	41	70	50	67	57	63	55	4
Qatar	42	63	49	57	71	63	54	5
Lebanon	45	75	55	45	54	49	53	6
Bahrain	37	59	44	63	72	67	52	7
Algeria	57	62	59	27	47	35	50	8
Oman	39	62	46	50	58	53	49	9
South Africa	41	50	44	53	64	58	49	10
Jordan	41	61	47	47	55	50	48	11
Morocco	38	49	42	50	57	53	46	12
Egypt	46	50	47	30	51	38	44	13
Mauritius	26	39	30	53	73	61	41	14
Botswana	32	50	38	37	58	45	40	15
Gabon	29	65	41	30	48	37	39	16
Ghana	26	52	35	33	62	45	38	17
Kenya	34	43	37	37	47	41	38	18
Iran	35	56	42	27	38	31	38	19
Namibia	26	48	33	37	57	45	37	20
Iraq	35	58	42	27	24	26	36	21
Cameroon	29	52	36	23	36	28	34	22
Tanzania	21	47	29	30	49	38	32	23
Sudan	31	44	35	20	31	24	31	24
Mozambique	26	52	35	13	36	22	30	25
Cote d'Ivoire	18	39	25	30	47	37	29	26
Uganda	13	50	25	30	44	36	29	27
Zambia	21	50	30	20	23	21	27	28
Angola	21	44	28	13	26	18	25	29
Nigeria	12	50	24	20	43	29	26	30
Zimbabwe	24	47	31	23	42	31	31	31
Average	34	54	41	37	50	42	41	

*RRI scores out of 100, with 100 highest. Source: BMI.

Iran Risk/Reward Index

Iran scores 38.0 out of 100 in terms of its attractiveness as a destination to launch innovative pharmaceuticals in Q216, up from 33.9 in the previous quarter, according to **BMI**'s Risk/Reward Index. Iran's position in the regional rankings has risen one place in Q216 to 19th out of the 31 countries in the Middle East and Africa region. Its overall score is steadily approaching the regional average of 40.3.

Generally speaking, Iran benefits from a large and growing population and relatively widespread access to healthcare services. However, its regulatory regime - including intellectual property rights and economic situation - is highly questionable. Consequently, the country performs below the regional average in terms of risk despite improvements in the political situation.

Rewards

Industry and Country Reward scores are weighted and combined to form the Rewards indicator. Iran's score of 27.0 out of 65 is below the regional average, which stands at 26.5 for the quarter.

Industry Rewards

While Iran has low per capita pharmaceutical consumption in comparison with other markets in the region, the sheer size of its population will continue to stimulate the development of both pharmaceutical values and volumes. However, it is susceptible to shocks caused by funding shortfalls, exchange rate fluctuations and other one-off factors, such as natural disasters. In addition, the country has little foreign investment in the sector, with the pharmaceutical market further disadvantaged by government cost-containment measures. The patchy quality of primary care coverage continues to reduce patients' access to drugs and thus negatively affects the overall drug market's value and volume.

Country Rewards

Iran's score - which measures pensionable population, population growth and urbanisation - is slightly higher than the regional average. However, the score masks the prevalence of rural population, despite the fast-growing population numbers. Additionally, the country's ratio of pensionable to overall population is lower than in many of its more-developed Middle East and Africa peers.

Risks

Industry and Country Risks are weighted and combined to form the score for the Risks indicator. Iran's score is below the regional average (with its Country Risks situation considered as particularly problematic), indicating a substantial overall risk to potential returns for multinationals operating and wishing to operate in the country. Iran scores 11.0 out of 35 in Q216, lower than the regional average of 14.8.

Industry Risks

Industry Risk refers to a subjective assessment of the country's intellectual property laws, policy and reimbursement regimes, as well as to the speed and efficiency of the approvals process. The local operating environment is considered negative from the point of view of foreign research-based companies, which is evidenced in the country's low score for this variable. A lack of product protection, high registration fees, counterfeiting and bias towards local generic producers, continue to dominate the landscape.

Country Risks

Iran faces the increased level of risk associated with continuities in policy direction, the strength and balance of the country's economy, and the spread of corruption, among other components. The key rationale for the country's score is the excessive bureaucracy and presence of corruption, as well as the unstable political situation and rising inflation. Currency fluctuations create challenges for importers and exporters with regard to pricing. In the meantime, healthcare will continue to be under-funded in many regions, despite considerable oil revenues flowing into the country.

Regulatory Review

The main regulatory body in Iran is the Ministry of Health and Medical Education (MOHME), which operates a department exclusively responsible for medicines. All manufacturing, distribution and imports are supervised by the General Pharmaceuticals Bureau and require prior approval from the MOHME.

A local agent is required to register a product in Iran. If the imported drug is already included in the Iran National Formulary (INF), the import is only subject to the approval of the MOHME's accredited laboratories. Otherwise, the importer has to follow the process of getting the drug registered.

The following documents are required for product registration:

- Legalised authorisation letter;
- Legalised Certificate of Pharmaceutical Product;
- Legalised list of importing countries or free sale certificate;
- Drug master file (for active pharmaceutical ingredients, or APIs), otherwise registration dossier;
- Certificate of analysis (for APIs);
- Drug importing application form.

The Consulate of Iran must certify the documents. These are then forwarded, together with the quality control certificate from the manufacturer of the imported batches to the MOHME. A specific commission then decides whether the product may be imported. Officially, registration takes up to one year. However, in reality, the process might take significantly longer.

Although the registration process might appear straightforward and the requirements might contain the basics of those stipulated in more developed markets, they are far from transparent and could hold many difficulties for foreign companies. The provision of a drug master file often poses a major problem. Producers are wary of supplying the MOHME with enough data to make copying possible.

At the same time, firms are unlikely to risk the application's success by providing insufficient information, which can act as a barrier to market entry. In the case of new and unregistered companies, the MOHME inspects the manufacturing facilities in order to evaluate its suitability in terms of good manufacturing practices (GMP). However, if the manufacturing facility holds accreditation from the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA), then the GMP audit by the ministry will be waived.

The drug registration fee is quite high for the region, at USD6,000 per product. Imported drugs must display their Iran Registration Code (IRC) and have both English and Farsi on leaflets and packaging. The Farsi leaflet requires approval from the MOHME.

The National Drug Selection Council (NDSC) is responsible for approval of medicines based on their pharmacoconomics. All drugs must be approved by the NDSC before being listed on the National Drug List (NDS). There were 2,400 drugs registered by the ministry of health as of 2008. Of these, 3,370 were locally produced, 465 were imported and 357 were herbal medicines.

However, around 50 were recently examined under a drug quality control programme, with the review board concluding that only three quarters met the required standards. Clearly, this is one area that needs to be improved.

From November 2015, the MoH announced that it will be tightening rules to monitor pharmaceutical companies' compliance with international standards.

Registration Of Imports

All drug imports need prior approval from the MOHME. The first batch of an imported drug must pass the batch release process by the Quality Control Laboratory of the MOHME before the product can be legally distributed. Further batches are also subject to random testing for importation.

In the past, all drug imports were undertaken via four state-owned government companies, while distribution within Iran was via six government firms. In total, there were only around 100 products that were imported by multinational companies. In more recent years, the rules have been relaxed, with drugs now also imported through a local office. Furthermore, all state-owned companies that import medicines were required to be privatised or to terminate their activities by March 2007, with the development likely to encourage the eventual privatisation of the pharmaceutical supply chain.

Taxes on domestically produced drugs are high. Previously, import duty was 90% for products that also have a local manufacturer. However, in March 2008, this was reduced to 65%. In addition, there is a 4% customs duty for all imported drugs. The importing company must also assign a technical supervisor, who is responsible for all technical and formal aspects of drug registration and importation and must ensure adherence to good storage practice (GSP) and good distribution practice standards.

Iran's FDA formed an expert council to identify and mandate new drugs for import in September 2015. The council consists of natural and legal entities including insurance organisations and healthcare practitioners, and experts and researchers in different fields. The council will decide on what new drugs can be imported into the domestic market. Imported medicines that have domestically-produced cheaper equivalents will not be allowed into the country, while new drugs that may not be available domestically will be imported but only within the framework of national policies.

Intellectual Property Regime

Little patent legislation exists in the country, given the basic nature of the market, which acts as a major deterrent to market entry. According to Article 28 of the Law of Registration of Marks and Patents in Iran, pharmaceutical formulae and compounds are not patentable, but a patent may be filed for processes related to the manufacture of pharmaceuticals. However, according to specially devised legislation, pharmaceutical products - whether produced in Iran or imported - are required to have a registered trademark.

Iran is presently seeking WTO membership, which would improve its IP climate, although it also requires economic liberalisation. The country would have to discard its protectionist trade policies and review its intellectual property laws, which contravene the terms of the WTO's Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement. This is likely to put production of unauthorised generic medicines under pressure.

However, Iran's WTO membership is unlikely to be achieved within the coming five years at least, given the magnitude of the current political obstacles. In late 2009, the Iranian commerce minister said that the country would join the organisation by 2017, provided political obstacles were removed. In the meantime, Iran remains outside the list of countries featuring in the annual Special 301 submission by the Pharmaceutical Research and Manufacturers of America (PhRMA) to the Office of the US Trade Representative (USTR). This is due to its lack of strategic importance as a pharmaceutical market for US companies, rather than due to the high level of IP protection in the country.

In February 2016, it was announced that Switzerland would assist in matters of legal security, economic cooperation and intellectual property in order for Iran to obtain full membership to the WTO. The announcement was made at a press conference after a landmark meeting between Iranian President Hassan Rouhani and Swiss President Johann Schneider-Ammann. A series of bilateral agreements were discussed, including the activation of Swiss bank in relation to the Central Bank of Ira; export insurance; industry, agriculture and cooperation in the fields of academia; science; research; and technology. Generic drugs have traditionally been encouraged in Iran, and until recently, drugs could be registered only under their generic

name as opposed to their brand name. However, Iran has recently significantly changed its policy on generic medicines. According to the National Pharmaceutical Scheme, all medicines are required to be distributed under a 'special generic system'.

There are four approval tracks based on the number of licensed producers of the product. Drugs on the NDJ that do not currently have a local producer are able to apply for Track 1 (the fastest track). It generally takes four months to review the dossier for this track. Registration time for other tracks ranges from six to 24 months, depending on the number of licence-holders for the product.

Counterfeit Medicines

Counterfeit medicines also pose a problem in Iran. It is estimated that illegal, smuggled and fake drugs are worth more than twice the value of legitimate domestic production, though the definition of illegal is open to interpretation. According to the Iranian Pharmacists Society, fake drugs worth between USD200mn and USD250mn are imported into the country annually. The Society claims that the value of fake exports stands at around the same figure. As well as posing a significant health risk to the population, this trade further discourages foreign drugmakers from investing in the country.

Measures such as checks on imported goods carried out by Iran's Standards and Industrial Research Institute (ISIRI) will help reduce the number of counterfeit drugs circulating in the country, as well as cutting down on the quantity of damaged or sub-standard medicines entering Iran. In 2004, Iran set up a specialised office belonging to the general prosecutor, with the aim of handling criminal cases relating to trademark infringements more efficiently. The office has given companies much greater opportunity to enforce their rights against counterfeiting and forgery, and is able to collect and secure evidence against alleged offenders within a few days of the complaint.

Currently, under Iranian law, it is possible to take criminal action against counterfeiters under Articles 529 and 530 of the country's penal code. Anyone who is found to have committed forgery or who uses a forged trademark is eligible - in addition to paying damages - to be imprisoned for a period between three months and two years. A complete criminal prosecution usually takes around one and a half years.

However, some experts in the country believe that the price of medicines needs to be lower in order to discourage pharmaceutical trafficking. Other suggestions for reducing the size of the problem include the proposal that insurance companies pay the difference between the set price and the cost to the consumer. Officials are currently in talks with insurance companies over the establishment of such a price setting mechanism.

Nevertheless, a lack of IP accords and poor enforcement remain prime reasons for the counterfeit trade, while widespread poverty means that the demand for low cost treatments is high. Patented and prescription drugs remain the most commonly counterfeited drugs as they offer the highest margins.

Pricing & Reimbursement Regime

The pricing of pharmaceuticals in Iran is handled by the Pricing Commission, which operates under the Organisation for Supporting Consumers and Producers' Rights and the MOHME. Prices are set according to the expenses incurred by producers or importers. All foreign-made pharmaceuticals have a 4% tax imposed on them, while those that are manufactured locally incur an additional 65% levy.

The Pricing Commission makes a decision regarding the expenses incurred and the prices are fixed under the mark-top system, which takes the upper range of cost into consideration. Since most of the domestically produced medicines are generic, they are priced according to expense analysis, although the commission often negotiates with the producer or importer to settle the price. The commission also dispenses subsidies in order to protect the interests of producers and importers. Currently, the commission dispenses subsidies only to importers, mainly impacting comparatively hi-tech medicines.

Essential drug production is centralised. Essential drugs are officially estimated to reach more than 90% of the population. Drugs are subsidised by the government, and those covered by health insurance (around 80-85% of the population) have to pay only 30% of drug costs. However, the Iranian Pharmaceutical Association, which represents drug retailers, believes that payments by patients for medicines are too high and should be reduced.

According to a report authored by Dr Akbar Abdollahiasl from the MOHME for the WHO, the average mark-up for locally manufactured generic drugs is 29-37%, including an IRR5,000 (USD0.5) dispensing fee charged by pharmacists regardless of drug price. However, the mark-up for imported pharmaceuticals ranges between 63 and 174%, although the study admitted that it did not have a sufficiently large sample size to make a reliable prediction of average mark-up value.

Pricing And Reimbursement Developments

The exchange rate has been a major factor affecting drug supply. In July 2013, Iran raised the prices of its domestically manufactured drugs by 40% and that of imported drugs by 90%. The move comes after the increase in the exchange rate of the US dollar, which the country uses for importing raw materials. The

government earlier allocated the US dollar at the official exchange rate of IRR12,260 for the import of drugs but now the rate has gone up to IRR24,000.

Consumers may also soon be forced to share a greater burden for drug costs, as the MOHME is debating whether to remove OTCs from the reimbursement list. It is likely that the MOHME will use the funds currently spent on OTCs to finance more important medicines that are currently not covered. However, no progress has been reported in either direction, although we expect that overall accessibility of OTCs - both in the public and private spheres - has been significantly worsened by the international sanctions.

Drug availability in remote rural areas of the country can also be problematic, with pharmacies in these areas often suffering shortages. Shortages for more sophisticated medicines became common, as many Western companies chose not to do business in Iran given the challenging operating environment. Given the more basic nature of domestic manufacturers, the shortages were unable to be accounted for by local companies. Shortages were reported for multiple sclerosis drugs *CinnoVex* (interferon-beta) and *Extavia* (interferon-beta 1b), marketed by **CinnaGen** and **Novartis**, respectively. There were also noted deficiencies of cancer treatments *Erbix* (cetuximab), marketed by **Bristol-Myers Squibb** in the US and Canada and **Merck KGaA** elsewhere, and *Remicade* (infliximab), marketed by **Schering-Plough** (a subsidiary of Merck & Co) outside of the US, Japan and China.

In general terms, there is a need to improve consumer awareness of the need to use pharmaceuticals more rationally and effectively. Around 8% of annual hospital admissions are thought to be a result of the misuse of medicines.

According to Mehdi Pirsalehi in August 2015, the Iranian FDA has been working on setting price caps on drugs for two years in a bid to stabilise the pharmaceutical sector. The FDA along with the government has taken several measures, including negotiations with foreign pharmaceutical firms, prompt action to supply medicines, reasonable pricing of imported drugs, fixing prices of domestic drugs and preventing import of domestic medicines by imposing import tariffs. The medicine shortage in the country has dropped by about 88% over two years to 30 drugs from 270 types of pharmaceuticals reported in 2013, added Pirsalehi.

Market Overview

Iran's pharmaceutical market is garnering significantly more attention in light of the removal of almost all sanctions, with the country's pharmaceutical expenditure valued at IRR69,545bn (USD1.93bn) in 2015. A lack of quality and reliable information is a problem associated with assessing Iran's pharmaceutical market, and there is no data available regarding the split between patented and generic medicines. However, given the issues in recent years regarding international sanctions, generic medicines will still command the highest market share. Per capita spending on pharmaceuticals was a mere USD24 in 2015, among the lowest regionally.

As of 2015, Iran's healthcare market was valued at IRR810,998bn (USD22.53bn) with public spending accounting for 41% of the market in value terms. Healthcare expenditure per capita stood at USD285, accounting for almost 5% of Iran's economy in the same year. Out-of-pocket payments fund half of overall healthcare expenditure.

Iran's epidemiological profile is dominated by non-communicable diseases, which represent three quarters of all deaths. According to the World Health Organization (WHO), cardiovascular diseases (46%) were the leading cause of deaths in 2014, followed by cancers (13%) and other non-communicable diseases (11%). **BMI's** Disease Database estimates that 7.6mn disability-adjusted life years (DALYs) were lost to non-communicable diseases in 2015 - a much greater burden in comparison to the 1.6mn DALYs lost to communicable diseases.

Iran's domestic pharmaceutical manufacturing sector is among the most developed in the Middle East and North Africa (MENA) region with 89 local drugmakers present. These pharmaceutical producers upped their capacity during the period of sanctions and now produce many sophisticated products for the treatment of cancers, diabetes and multiple sclerosis among others, with the government's pro-domestic company stance limiting market access opportunities for Western drugmakers. Leading domestic companies include Darou Pakhsh, Sobhan Oncology, Tofigh Daru, Farabi Pharmaceutical and Zahravi Pharmaceutical. Iran's law does not allow any FDI unless it enters the country through a joint venture or other corporate strategy (such as the establishment of a local office), which has been used by some pharmaceutical companies to gain market access. Indeed, in October 2014, India-based generic drugmaker **Cipla** signed an agreement with its existing Iranian distributor to set up a manufacturing facility in Iran.

Healthcare Sector

The Iranian government has invested substantially in the development of the healthcare system, with investments paving the way for an increase in the number of doctors and hospitals in the country, although quality issues have yet to be resolved. The government has attempted to improve public access to primary and preventative care, particularly in the rural areas where more than 35% of the population reside. In 2005, a rural insurance scheme was implemented, which has led to significant falls in infant mortality among these at-risk groups. The measures have improved basic health indicators to some extent, and life expectancy has been rising steadily in recent years.

All Iranians are eligible for community-based preventive public health and limited curative health services, financed and provided through the primary healthcare network, which is funded entirely by the national government. This system was established to improve rural access to healthcare and reduce the gap between rural and urban health outcomes. Although the Social Security Organisation (SSO) guarantees a minimum level of care for those who meet their insurance obligations, it also gives added benefits to those who volunteer to pay higher premiums.

Medical students and employees do not have access to experienced doctors from Western countries, which negatively affects the quality of care. The health of the population is threatened by the unhygienic disposal of wastewater and sewage, along with the limited availability of clean water, especially in rural areas. Despite investments in healthcare, the infant mortality rate is estimated to be much higher than in the developed world.

Healthcare Spending

Iran's government committed around one-sixth of its budget to healthcare-related functions for the financial year April 2008-March 2009, according to the Ministry of Health and Medical Education (MOHME). Approximately IRR70trn (USD7.5bn) was used to fund the ministry health, government insurance schemes, public medical centres and medical universities.

This level of funding is expected to encourage growth already seen in the public hospital sector and to allow the expansion of healthcare in rural areas to continue. The improvement of Iran's per capita health indicators is further aided by sluggish population growth, of less than 1% per annum.

Absolute spending levels have risen steadily in recent years, despite government attempts to control costs. Nevertheless, the government accounts for a progressively smaller percentage of the overall spending on

health (which fell to an estimated 37% in 2012, from some 45% in 2007), even though the country's private healthcare coverage remains fragmented. Although the private sector - including out-of-pocket spending - accounts for the majority of healthcare expenditure, private health insurance comprises only 2-3% of total expenditure.

Primary Care

Primary care is provided by clinics known as health houses, which employ community workers known as behvarzes. Tasks performed by the health houses include record keeping and data collection; public health education and promotion of community participation; antenatal, prenatal and postnatal care; care of children; family planning services; immunisation; and disease control services. The second and third levels in the hierarchy of the rural health network provide backup for the rural health houses and offer diagnostic and treatment services. These organisations also have urban counterparts.

The primary healthcare system relies on three components:

- Establishing a simple, but integrated, health information system.
- Establishing health houses in remote and sparsely populated villages.
- Staffing health houses with health workers recruited from local communities.

The expansion of the primary healthcare system has achieved remarkable results. Steps taken by the system have been responsible for reducing infant and child mortality, eradicating major infectious paediatric diseases and improving post-natal health. However, there are weaknesses in the system, and some facilities do not meet the required standards. Also, there is insufficient support from the institutions at the second and third tiers of the system, with salaries received by medical professionals similarly considered inadequate.

Secondary Care

In addition to the health houses, the country's largest healthcare delivery network is owned and run by the MOHME through its network of health establishments and medical schools. Other parallel organisations, such as Medical Service Insurance Organisation (MSIO), have been established to act as relief foundations, as well as insurance firms.

According to the census undertaken by the Statistical Centre of Iran in 2003, Iran had 730 medical establishments, of which 488 were directly affiliated and run by the MOHME, 120 were owned by the private sector and the rest belonged to other organisations such as the Social Security Organisation (SSO).

Most private hospitals are better equipped than their public equivalents. The government has been planning to privatise some of the state-owned hospitals as the demand for private hospitals has increased and the occupancy rate of state-owned hospitals has decreased to about 56%.

In general terms, there is a need to improve consumer awareness of the importance of using pharmaceuticals more rationally and effectively, as around 8% of annual hospital admissions are thought to be a result of the misuse of medicines. In fact, according to 2010 statements made by the director of pharmaceutical affairs of Zanzan University of Medical Sciences, as many as 30% of patients treated for renal failure are suffering due to the incorrect or uncontrolled use of medicines, especially painkillers, which can have dramatic side-effects on the gastrointestinal system.

Iran is becoming a destination for Islamic and regional medical tourists as a result of its geographical position, reasonable prices and advanced medical facilities. According to a member of Majlis Health Commission, Shahin Mohammad Sadeqi, in July 2015, Iran has around 270 hospitals with special wards specifically for foreign medical tourists which are all ready to operate once the Ministry approves their compliance with international standards. Low-cost offerings and high quality healthcare in the country are attracting medical tourists from neighbouring Islamic nations who feel more comfortable there than in certain Arab or Asian countries. Iran generates between USD400mn-500mn annually from medical tourism and aims to reach USD2.5bn in the coming years according to the head of Iran's Cultural Heritage, Handicrafts and Tourism Organization (UCHHTO), Masoud Soltanifar.

Table: Healthcare Resources (Iran 2010-2015)

	2010	2011	2012	2013	2014	2015
Hospitals, total	820	832	845	857	870	883
Hospitals, public	685	695	706	717	728	739
Hospitals, private	135	137	139	140	142	144
Hospitals, beds	122,683	124,287	125,911	127,557	129,224	130,913
Hospitals, beds, per '000 population	1.65	1.65	1.65	1.65	1.65	1.65

Source: BMI

Table: Healthcare Personnel (Iran 2010-2015)

	2010	2011	2012	2013	2014	2015
Physicians, total	67,549	68,816	70,134	71,487	72,849	74,202
Physician, per '000 population	0.91	0.92	0.92	0.93	0.93	0.94
Nurses, total	222,773	262,792	310,122	366,025	431,909	509,405
Nurses, per '000 population	3.00	3.50	4.07	4.74	5.53	6.44
Dentists, total	13,982	14,157	14,340	14,528	14,714	14,896
Dentists, per '000 population	0.19	0.19	0.19	0.19	0.19	0.19
Pharmacists, total	14,816	15,000	15,213	15,432	15,650	15,864
Pharmacists, per '000 population	0.20	0.20	0.20	0.20	0.20	0.20

Source: BMI

Table: Healthcare Activity (Iran 2010-2015)

	2010	2011	2012	2013	2014	2015
Public inpatient admissions, '000	4,508.65	4,658.76	4,815.77	4,978.73	5,146.07	5,316.46
Public inpatient admissions, per '000 population	60.72	61.96	63.23	64.53	65.85	67.20
Hospitals, average length of stay, days	4.5	4.4	4.4	4.3	4.3	4.3
Surgical procedures, '000	1,532.94	1,583.98	1,637.36	1,692.77	1,749.66	1,807.60
Outpatient visits, '000	304,461.92	316,676.76	329,511.60	342,912.11	356,778.68	371,026.33
Outpatient visits, per '000 population	4,100.31	4,212.01	4,326.74	4,444.60	4,565.68	4,690.05

Source: BMI

Healthcare Insurance

Iran has a compulsory health insurance system managed by the SSO. The public sector guarantees a minimum level of care for those who meet their insurance obligations but gives added benefits for those who volunteer to pay higher premiums.

Membership of the SSO is mandatory for all employed, who pay 7% of their salaries as premiums. These are mostly topped up by the employer, with a small proportion also provided by the government (3%). Self-

employed citizens have to contribute voluntary premiums of around 15% of their income. Most private healthcare insurance is also operated by state-owned companies.

The SSO is the largest single purchaser of healthcare services in the country. The organisation provides direct coverage to insured people (including pensioners) through 67 hospitals and about 270 clinics. Indirect coverage is provided on contract with approximately 840 clinics and polyclinics, 670 hospitals and over 28,500 doctors and dentists. The insured people using those facilities pay a fraction of the cost, while the full cost of the treatment is borne by patients using facilities not contracted by the SSO.

The health insurance organisation encourages generic substitution, agreeing to pay the cost fixed at the level of the lowest-priced medicine using the same molecule, regardless of the actual price of different drugs. However, insurance covers only 70% of the pharmacy and 80% of the hospital value of products, and then only if included on the positive reimbursement list. Therefore, patients who wish to use imported drugs have to cover the difference, which can be significant and even unaffordable when higher-cost medicines are involved.

The government still provides approximately USD240mn in subsidies for drugs and infant milk per year. The medicine subsidies are primarily for older oncology drugs, plasma derivatives and multiple sclerosis products. Although some over-the-counter drugs (OTCs), including paracetamol, continue to be subsidised, local reports suggest that this is likely to change in the near future.

Low capacity and investment in public hospitals are the leading problems facing the state healthcare sector, as wealthier Iranians tend to opt for 'private' healthcare or travel abroad for treatment. Despite the fact that the government subsidises pharmaceutical production and drug imports, most households spend more than 19% of their healthcare expenditure on pharmaceuticals.

According to Jam-e-Jam reports from February 2010, the SSO owed IRR3,800bn (USD385mn) to the hospitals with which it held contracts. Additionally, reimbursements to pharmaceutical companies were also delayed, causing friction between the SSO and the industry. At the same time, SSO's outstanding liability to pharmacies was reported to be in the range of millions of US dollars. While some of those debts are likely to have been repaid since, their sheer size would have prevented full resolution in a timely fashion.

In March 2014, Iranian President Hassan Rouhani launched a medical insurance plan called RouhaniCare, apparently inspired by ObamaCare, to insure 5mn of the 12mn Iranians who cannot afford premiums. The Financial Times reported Rouhani as saying: 'The first step will be taken in the next Iranian calendar year starting on March 21 2014 to gradually bring everyone under medical insurance coverage and lower

people's share of medical cost.' Health experts have welcomed Rouhani's insurance plan, but say the high costs for patients have been compounded by the near bankruptcy of the country's 555 state hospitals, which provide most inpatient services.

International Healthcare Collaboration

In June 2014, Syrian Health Minister, Saad Naif signed a contract with Iran on the supply of medicines, equipment and ambulances. The contract includes medicines, medical equipment and 50 ambulances, according to the Syrian Arab news agency. Syria recently concluded several agreements with Iranian and Belarusian companies to provide drug and medical supplies.

Iran and Oman expanded their bilateral cooperation in medicine and pharmaceuticals, according to a statement by Iran's Health Minister Seyed Hassan Hashemi during a meeting with his Omani counterpart Ahmad bin Muhammad bin Obeid Saidi in Tehran in April 2014. The two countries will also co-invest in the construction of a pharmaceutical factory in Oman, which will provide opportunities for Iranian investors, Hashemi added. The medicaments produced at the factory will be exported to the Gulf states. Hashemi clarified that Iran plans to promote private investment in hospital construction in Oman.

In November 2016, the United Nations mission in Iran announced that the Iranian government would extend its Salamat Insurance Scheme to all of its registered refugees. The insurance extension - which is a collaboration between the Ministry of Interior, responsible for immigrant affairs; the Iranian Health Insurance Organization; and the United Nations High Commissioner for Refugees (UNHCR) - is aimed at Iran's substantial Afghan and Iraqi refugee population who will receive access to a health insurance package for 'hospitalization and temporary hospitalization', as available to Iranian nationals. Half of the coverage for the program will come from the Iranian government, while the UNHCR will contribute USD8.3mn.

Traditional Herbal Remedies

Iran is stepping up its efforts to produce and export herbal medicines. The country exports 120 such products, which is a considerable advance on a decade ago, when there were only 10 exports in this area. All locally manufactured herbal products are completely non-synthetic. According to official estimates, herbal medicines have the potential to contribute as much as 30% to the pharmaceutical sector's exports. Currently, herbal medicines exports are valued at around USD30mn per annum.

Local newspaper Tehran Times reported in April 2010 that Iranian exports to the Association of Southeast Asian Nations (ASEAN) increased by 31% y-o-y in the 12 months to the end of March 2010. According to

the statistics from the Trade Promotion Organisation of Iran (TPOI), volumes reached 1.3mn tonnes, which was valued in excess of USD1bn. In addition to petrochemicals and citrus fruit, key exports to ASEAN included medicinal herbs.

The country operates a Traditional Medicines Research Centre, which is engaged in the development of the traditional herbal medicines sector in Iran, as well as promoting the industry abroad. In recent years, the country has made its mark on the international scene. The government is also planning to create links with various other research institutes operating in different Islamic countries.

According to the WHO, there are around 30 traditional herbal medicine producers in Iran. The country has significant potential in this field given its geographical and climatic diversity, with about 1,800 plants able to be used for medicinal purposes. The government requires all herbal medicines to be manufactured to the standards applied to all pharmaceutical products.

In September 2011, Iran's President Mahmoud Ahmadinejad emphasised the high potential of different natural herbs for the treatment of different diseases, seeking a revival of traditional medicine during a meeting with WHO regional director Hassan Abdolrazzaq Jazayeri. Ahmadinejad said the country may import more drugs and medicines unless traditional medicines are revived. Iran's geographical diversity offers favourable conditions for the growth of more than 7,500 plant species, according to reports by Fars News Agency.

Research & Development

In Iran, only a few pharmaceutical companies have R&D capabilities. These are mainly aimed at developing new formulations and dosages of existing products, rather than creating original drugs. Firms in Iran are dependent on research institutes and universities for R&D-related activities. Even large enterprises in the pharmaceutical industry rely on research institutes for process development to manufacture generic drugs, which is a major limitation.

Iran's scientific community is not world-renowned for quality or impartiality. Indeed, the country topped a 90-country 'brain-drain' league table produced by the IMF in 2006. The study on which the table was based found that more than 150,000 educated young people leave Iran every year, creating a chronic shortage of skilled workers.

The country maintains three important facilities for disease research, namely the Pasteur Institute, the National Research Centre of Genetic Engineering and Biotechnology (NRCGEB) and the Razi Institute for

Serum and Vaccines, which focuses on diseases affecting animals and humans. The NRCGEB's research into recombinant DNA technologies, genetic engineering and DNA vaccine production has the potential to be used to produce treatments for a number of pathogens.

Four basic materials required for the production of rare medicines have reportedly been developed and produced for the first time in Iran. The statement - cited by Fars News Agency - was made by the public relations official of the Pharmacology College of the Tehran University of Medical Sciences, Mansour Rastegarpanah. The Iranian government announced on March 31 2013 that the country's pharmaceutical research and production facilities produced the materials required for chemotherapy, pulmonary hypertension and blood coagulation medicines. The materials were sold to Iranian pharmaceutical firms after being developed, with the aim of entering the pharmaceutical industry, following the completion of scientific and legal procedures, Rastegarpanah added. Iran, therefore, continues to be committed to its goal of self-sufficiency in terms of pharmaceutical demand, with this goal coming to the fore, especially in the light of international sanctions.

It was reported in September 2015 that nearly 41% of domestic knowledge-based firms (95 companies) are focussed on producing pharmaceuticals. For example, **Barakat Pharmed** has acquired 14% of the domestic pharmaceutical market and produces more than 420 products through its subsidiaries including **Sobhan Darou, Iran Daru, Tolid Daru** and **Alborz Darou** among others. Several measures have been taken to enable the innovating firms to grow including tax exemptions on imported equipment for knowledge-based companies from early 2015.

Biotechnology

In early 2010, the MOHME announced that it is developing the country's biotechnology industry over the long term to ensure self-sufficiency in the pharmaceutical sector. This assertion is of particular relevance to high-value medicines, including cancer drugs and other complex therapies.

According to Iranian Deputy Health Minister for Research and Technology, Mostafa Ghanei, Iran is striving to be the biggest producer of biosimilars or follow-on biologics. The country reportedly already ranks first regionally and fifth in Asia in terms of biotechnology medicine manufacturing. In 2012, a report found that Iran was making significant advances in manufacturing biosimilars, referred to as biogeneric products in the country, with plans to start producing 24 additional biogeneric products drugs by the end of 2012.

Similarly, in January 2012, Payvand Iran News reported that the country's Ministry of Health and Pasteur Institute commenced a programme for the local development of a cervical cancer vaccine. The vaccine is

expected to become available in Iran within the next three years. According to Ghanei, Iran was expected to start domestic production of other vaccines by 2013, with products covering flu, rabies and haemophilus virus.

Ghanei was also quoted as saying that Iran 'would be the biggest producer of biosimilars or follow-on biologics in the next two years', with the country reportedly already ranking first regionally and fifth in Asia in terms of biotechnology medicine manufacturing. However, no progress has been reported in this area, while we also believe that the international sanctions have had a detrimental effect on the project.

Still, Iran's biotechnology and pharmaceutical industry has had to develop rapidly - largely because the trade embargo severely restricted its choice of trade partners. As it has a strong higher education system in place and several domestic biotech firms established, the country stands a realistic chance of advancing the sector. The ministry also said that in the last few years the country had developed and promoted biotechnology, particularly as the industry has been incorporated into the cancer care programme.

The MOHME said 95% of the drugs consumed in Iran are manufactured in the country, suggesting that its ambitious plans to become 100% self-reliant in four years may not be totally unrealistic, although the figures are unlikely to be entirely reliable. Moreover, we believe Iran's unattractive regulatory environment is a major obstacle to such progress.

Intellectual property (IP) protection and similar laws are not strictly adhered to by drugmakers in the country, while proper pharmacovigilance over more complex medicines derived from biotechnology is either extremely elementary or totally non-existent. While the trade embargo has limited the number of global markets to which the country's biotech firms could export, firms in Iran should be ensuring that international manufacturing regulations are met to maximise potential for overseas sales in the long run. According to government ministers, plans have been put in place to ensure the quality of domestically produced drugs.

However, while Iran's commitment to advance its manufacturing capabilities in the biotechnology sector will see the country maintain a strong position in this area in the region, we believe that domestic drugmakers underestimate the difficulty of developing and producing complex biosimilars against a backdrop of increasingly stringent regulations. Local biotechnology company Pooyesh Darou will struggle to contend with large global generic drug industry players like Sandoz - which is currently carrying out late-stage clinical trials for a biosimilar to Amgen's *Neulasta* (pegfilgrastim) in preparation for its patent expiry in 2015. Should the trial results yield a successful biosimilar, we expect Sandoz to continue to focus its marketing strategy on developed states. However, entrance into the Iranian market will occur in the

medium-to-long term. The company already has an import presence through a biosimilar of Merck Serono's *Rebif*.

According to IRI Broadcasting, Pooyesh Darou started to manufacture two new types of drugs - thrombolytic reteplase and neutropenia drug pegfilgrastim - in early 2013. The drugs were initially marketed as branded biologics in the US and EU markets. Pegfilgrastim was co-developed, produced and marketed as *Neulasta* by Amgen and as *Neulastim* by Roche, both of which are currently under patent. Reteplase was developed and produced as *Retavase* by Boehringer Mannheim, which has since been bought by Roche. The complexity of replicating the large, intricate structures of protein-based molecules, however, has meant that few biosimilars have entered the market since the patent expiration of reteplase.

International Biotechnology Collaborations

In December 2014, Iranian Minister of Health and Medical Education Hassan Hashemi and his Tanzanian counterpart Suleiman Mohammed Rashid signed a Memorandum of Understanding (MoU) in the field of health and medical cooperation. Hashemi stressed the importance of an effective relationship and technology transfer between the two countries in the health sector. Iran's private sector is willing to cooperate with and invest in the Tanzanian health industry, said Hashemi. 'Since 96% of Iran's drugs are produced domestically and are consumed by regional countries, we hope to distribute Iranian-made drugs across the African region,' said Hashemi (Mehrnews). Rashid urged Iranian investors and companies to cooperate in building a pharmaceuticals plant in the country.

Iran and Cuba have also agreed to cooperate in the field of biotechnology, with the latter planning to open a biotech plant in Tehran, which will predominantly manufacture vaccines. Cuba and Iran have been entering into biotechnology agreements since the early 1990s. Cuba transferred the technology and necessary equipment for manufacture of the hepatitis B vaccine, erythropoietin (EPO), interferon and streptokinase, as well as a number of other biotechnology products to Iran, and also provided training for Iranian scientists. The state-controlled Pasteur Institute of Iran established its biotechnology department in 1993, the year of the first biotech accord between the two countries. In 1996, Cuba's Centre for Genetic Engineering and Biotechnology (CIGB) formed the joint venture firm Noavaran Tec Kish with the Pasteur Institute. The joint venture is valued at around USD60mn and, at the time, was considered one of the more advanced facilities of its kind in the Middle East.

Countries with less advanced pharmaceutical technologies are reportedly interested in Iran's know-how. To this end, in October 2012, Belarus was in official discussions with Iran over the possibility of purchasing

patents and technology for biotechnology medications, according to statements made by Belarusian Deputy Healthcare Minister Gennady Godovalnikov. The pharmaceutical market of Iran is extremely promising as 97% of demand is met by medicines produced locally, Godovalnikov said. Of the 8,000 drugs Iran produces, about 1,000 are of vegetable origin, he added, and local factories in Iran are constructed in accordance with the global good manufacturing practice standards.

Clinical Trials

Iran does not have a domestic contract research organisation (CRO) to carry out clinical trials. Hospitals have small groups that take care of clinical trials, with about 178 studies currently ongoing across the country, according to ClinicalTrials.gov in November 2014. The promotion of CROs should provide opportunities for learning by attracting global drug firms to conduct trials in Iran and also help domestic firms to carry out multi-centre trials all over the country with centralised control.

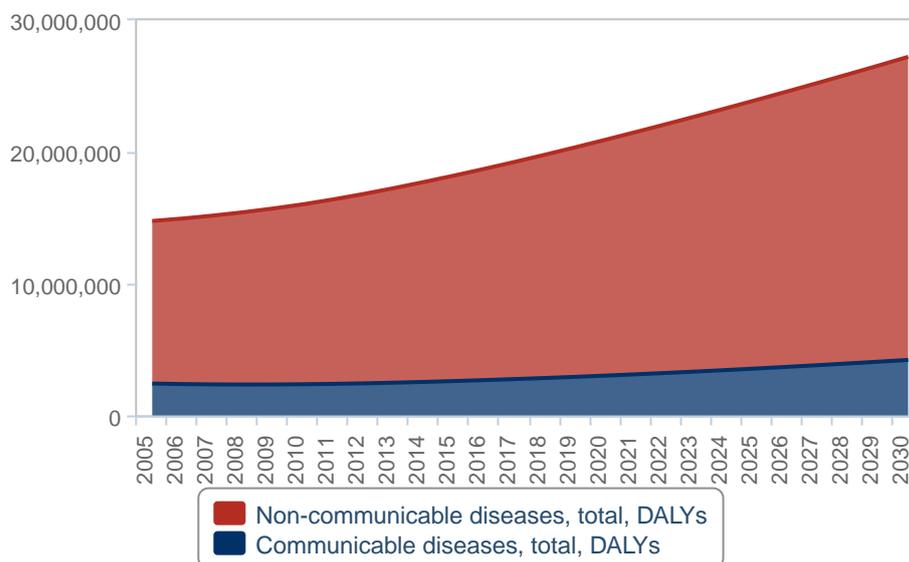
Nevertheless, Iran does have a not-for-profit organisation for the registry of clinical trials, which is affiliated to the WHO. The registry's creation has been assisted by the MOHME. Its function is to provide public information about ongoing studies, increase public awareness of clinical trials in general and implement the mandatory registration prior to patient enrolment.

Epidemiology

According to **BMI's** Disease Database, the number of DALYs lost to disease or injury in Iran is expected to increase from around 12.8mm in 2015 to over 14.9mn by the end of 2030. Underlying this trend is the burden of non-communicable disease, which is expected to increase by an average of 1.5% y-o-y, due to an increasingly affluent and aging population. The burden of communicable disease (including conditions such as malaria and cholera) is expected to fall due to improved healthcare.

Burden Of Disease Projection

(2005-2030)



Source: BMI, World Health Organization (WHO), BMI's Disease Database

The prevalence of respiratory diseases and cancers in Iran is increasing at a significant rate, according to the Tehran Times. BMI notes that the Iranian capital is exposed to higher risk factors than other regions. These include the geographical situation, climate and congestion, which all increase the levels of air pollution in the city. As none of these causes are likely to change within the short-to-medium term, we expect multinational drug firms that focus on respiratory related diseases to find Iran an attractive market to boost revenues in the Middle East. This view is also supported by the fact that respiratory diseases are estimated by the World Bank to cause losses to the economy in excess of USD640mn annually, which is likely to prompt the authorities to deal with the issue.

During 2007-2008 the Behesht-e Zahra Organisation conducted a demographic study in Tehran to determine the scale of the problem. During this period, 762 people died from lung cancer in Tehran, while 291 people died from respiratory diseases. Over two-thirds of those dying from respiratory-related disease in the capital were men. A further 401 people died from lung cancer during 2008-2009, with more expected to be added to this number pending a consensus on figures.

Public awareness of the dangers that air pollution poses to health is increasing, although this is not entirely due to government intervention. As the incidence rates of asthma and other respiratory illnesses increase, physicians have begun advising patients not to venture outdoors during peak traffic periods and at midday during the summer. **BMI** believes that early diagnosis and management of respiratory diseases must also be encouraged to reduce the morbidity rate.

Additionally, diabetes is emerging as a public health issue. According to the December 2010 diabetes awareness survey across 10 countries in the Middle East and North Africa (Algeria, Egypt, Iran, Iraq, Jordan, Lebanon, Morocco, Saudi Arabia, Tunisia and the UAE), 40% of the respondents were at risk of developing diabetes. The survey found that over half of the people questioned were unaware of the medical repercussions of the disease, while 37% had never been screened for it. Novo Nordisk appointed Ipsos Emirates Health to conduct the survey as part of its contribution to World Diabetes Day 2010.

In December 2012, it was reported that a large-scale healthcare project in Iran, which has secured approval from the Iranian president, will be carried out in the near future, according to Iran's Nursing Council Chief Ghazanfar Mirzabeygi. Under the project, the nursing community will perform free-of-charge medical tests on about 50mn people aged 20 years and above. The tests will be carried out for extra weight, blood pressure and blood sugar concentration by about 40,000 nursing students and some 100,000 registered nurses within one month, Mirzabeygi added.

HIV/AIDS

Iran is a major transit route for narcotics coming from the neighbouring countries of Afghanistan and Pakistan but destined for Europe, Central Asia and the Gulf region. There is an estimated total of 2mn drug users in Iran, with around 200,000 said to be injecting themselves intravenously. Medical experts fear that the country is facing an explosion of HIV/AIDS cases, with the government urgently focusing on the resources for the discovery of effective treatments to combat the disease.

In a positive development, the authorities are attempting to address the problem. Currently, around 1.2mn people are tested annually in Iran for HIV/AIDS. Testing includes those deemed high-risk or who travel frequently abroad. Patients receive anti-retroviral drugs free of charge, a policy that will be sustainable as long as the number of cases remains low. In early 2008, the government also began distributing a controversial IMOD (immuno-modulator drug) herbal remedy to AIDS patients.

The government has started a telephone counselling service and has distributed 10mn brochures on HIV. There are more than 154 sites for voluntary testing in the country and 600 sites for counselling. A television

campaign aiming to raise awareness of the disease was recently launched. Iran also runs a programme of blood screening for HIV/AIDS, in an attempt to ensure safe blood transfusions.

HIV/AIDS Prevalence In Iran

	Estimated number of HIV cases
Adults (15-49)	73,000
Women (15-49)	9,300
Estimated number of deaths due to AIDS	4,100

Source: UNAIDS Global AIDS Report 2014

Iran has taken several important steps in the delivery and expansion of HIV/AIDS services throughout the country in recent years. In 2014, however, the Iranian health minister, Hassan Hashem, expressed concerns over the sharp rise in the number of people with HIV in the country and that the taboo is preventing patients from receiving treatment. According to Hashem, fear of AIDS is running very high in Iran due to the spread of misinformation and unscientific claims, which are directly fuelling an 80% increase in the number of AIDS cases year-on-year.

Iran's HIV treatment and prevention programmes suffered a series of setbacks under the previous administration with the authorities jailing two pioneering AIDS doctors and preventing activists from publishing AIDS awareness leaflets for students. It is estimated that 70% of those with HIV in Iran do not know they are infected.

Competitive Landscape

Research-Based Industry

Iran has more than 56 pharmaceutical plants, with an equal number in the dependent industries such as production of raw materials and manufacturing of packaging devices. Iran also boasts around 30 producers of herbal medicines. Pharmaceutical companies in Iran are mainly focused on the production of generic medicines and copies of foreign products. The largest drugmaker in Iran is currently Darou Pakhsh Pharmaceutical Manufacturing.

The Iranian pharmaceutical sector is made up of 89 local drugmakers and 93 pharmaceutical importers. Given the large number of local drugmakers, with the top 10 only accounting for approximately 45% of the total consumption of locally produced medicines, the domestic industry is in need of consolidation. By contrast, three pharmaceutical importers, Cobel, Akbarieh and Behestan Darou, hold more than 10% of the total market of imported medicines consumption, while the top 10 account for approximately 73% of the market. Given their relative dominance, **BMI** believes Cobel, Akbarieh and Behestan Darou stand to benefit the most from increased import reliance and will eliminate smaller players from the market.

Considering the scale and duration of the economic sanctions against it, Iran has been remarkably self-sufficient in terms of pharmaceutical supply, with local production satisfying more than 90% of the local demand in volume terms - albeit with a declining proportion in value (under 65%). Moreover, around 50% of all raw ingredients for pharmaceutical production by local companies are imported. In 2008, some 31.3mn units of pharmaceuticals were sold in Iran, in contrast to under 7mn consumed two decades earlier. However, by international standards, its pharmaceutical manufacturing business is still a small player, with its sales reaching USD79mn in the year ending March 2008, according to the Tehran Stock Exchange (TSE).

Since the Islamic revolution, drugs have been produced and distributed by state-owned companies and supplied to consumers at subsidised prices. New drug development is virtually absent, owing to the local industry's limited R&D capabilities. Nevertheless, Iran has one of the most advanced biotech industries in the early developing world, which could help the market to develop in the long term. The country reportedly ranks first regionally and fifth in Asia in terms of biotechnology medicine manufacturing.

Iranian pharmaceutical producers are increasingly forming joint ventures with foreign players in order to enter overseas markets for the production of specific drugs, and the recent lifting of almost all trade sanctions will only serve to accelerate this process. Meanwhile, the authorities are keen to invest in

biotechnology and other leading areas of research, as well as to attract foreign players through contract manufacturing and similar ventures. The Ministry of Health and Medical Education (MOHME) has also encouraged multinational drug makers to set up manufacturing units in Iran, either independently or in partnership with local firms. In order to persuade foreign firms to invest, MOHME has stressed that Iran is an attractive contract-manufacturing location, due to its low labour and energy costs.

Although the direct presence of multinational pharmaceutical companies in Iran has hitherto been minimal, the willingness of multinational drugmakers to invest in Iran is likely to increase as relations with the West improve.

Novartis, Roche, Boehringer Ingelheim and Sanofi are all present through partnerships with domestic drugmakers. Both GlaxoSmithKline and Novo Nordisk are reportedly in the process of establishing manufacturing units in the country before economic sanctions on Iran were enacted. As sanctions are eased, the willingness of innovative drugmakers to do business in Iran will improve. Novo Nordisk's investment in Iran was confirmed in September 2015 - announcing it will build a EUR70mn plant for insulin production. Currently, 65-70% of insulin is imported, and spending on insulin represents around 3% of pharmaceutical expenditure in Iran.

The government is pushing for structural modernisation of key medical facilities and technologies that will see an increase in advanced medicine, including antibodies and proteins. A number of substances that only few companies globally have the technical expertise to produce, including monoclonal antibodies and factor VIII, are already produced in Iranian laboratories, and the goal is to build on this foundation in order to make Iran a regional and international hub for medical innovation. Iranian experts have already made great headway in using modern medical technology to cure a broad range of diseases inside the country in recent years, making Iran a top destination for medical tourism.

This MOHME's renewed push for more sophisticated medicines is a direct result of them remaining in short supply caused by the sanctions. Drug shortages for more sophisticated medicines have become common, as many Western companies chose not to do business in Iran given the challenging operating environment. Given the more basic nature of domestic manufacturers, the shortages were unable to be accounted for by local companies. Shortages were reported for multiple sclerosis drugs *CinnoVex* (interferon-beta) and *Extavia* (interferon-beta 1b), marketed by CinnaGen and Novartis, respectively. There were also noted deficiencies of cancer treatments *Erbix* (cetuximab), marketed by Bristol-Myers Squibb in the US and Canada and Merck KGaA elsewhere, and *Remicade* (infliximab), marketed by Schering-Plough (a subsidiary of Merck & Co) outside of the US, Japan and China

Despite the furore for the recent nuclear deal, the Iranian pharmaceutical market is clearly a difficult proposition for multinationals, largely as a result of restrictive government controls. The regulatory system currently operates firmly in favour of the local industry, while areas such as patent protection remain inadequate by international standards.

The most promising strategy for local involvement in Iran's pharmaceutical industry appears to be through a tie-up with a domestic manufacturer. Indeed, in October 2014, India-based generic drugmaker Cipla signed an agreement with its existing Iranian distributor to set up a manufacturing facility in Iran, according to a stock market disclosure. The Indian pharmaceutical company will invest INR2.25bn (USD36.5mn) for a 75% stake holding in the proposed unit. Its planned contribution over the next three years includes the supply of equipment, machinery and technical expertise to the manufacturing facility.

There is a strict import regime in Iran, in addition to a 65% import tax on imported drugs when locally produced alternatives are available, and a 4% customs duty for all imported drugs. Setting up a local manufacturing facility in Iran will offer Cipla a route around these high tax rates and difficult import regime. A manufacturing facility will allow the company to avoid the implications of the current sanctions in Iran, which have badly hit medicine imports into the country and resulted in drug shortages. Sanctions against Iranian banks and obstacles to transfer money to and from the country have had major implications for the importation of medicines. Having a local presence in the country will allow Cipla to better navigate issues should sanctions continue over the long term.

Japan-based Astellas is also planning to cooperate with a domestic producer and announced in November 2015 that it will export technology for the production of three widely used medicines by kidney and liver patients, in collaboration with Iranian pharmaceutical companies. The implicated drugs are *CellCept* (mycophenolate mofetil), *VESIcare* (solifenacin succinate) and *Flomax* (tamsulosin hydrochloride).

Table: Multinational Company Activity

Company	Operations
Novartis	<p>Its products are distributed through domestic firms, with Novartis having no direct manufacturing presence in Iran, although it reportedly has a business centre there (a Novartis Pharma Services Inc. branch office).</p> <p>There have been notable shortages of <i>Extavia</i> (interferon-beta 1b), marketed by Novartis in Iran in recent years, due to exchange rate fluctuations and international sanctions that have impacted on the financial system.</p> <p>In 2012, Novartis sold rabies and flu vaccines worth EUR1.5m to an affiliate of the Iranian health ministry, generating net profits of EUR441,000. The company signed an official memorandum of understanding in 2010 in order to accelerate sales, allowing it fast-track registration, market exclusivity, end user subsidies and exemptions from customs tariffs on sales via third party</p>

Multinational Company Activity - Continued

Company	Operations
	<p>distributors within the country. The company has an agreement with a local company for licensing and manufacturing in Iran; however, the western sanctions on Iran resulted in the flow of medicinal and life-saving products to Iranian patients being severely affected if not fully ceased, according to a company spokesperson. Novartis re-affirmed its commitment to providing access to medicines for its patients in full compliance with US, EU and Swiss trade sanctions and regulations in December 2013.</p>
Pfizer	<p>The largest global pharmaceutical company, Pfizer, is present in Iran only through imports, which are dealt with by domestic distributors. The company does not have any local manufacturing facilities or a representative office. Pfizer merged with compatriot Wyeth in 2009, which marketed some nutritional health products and infant formulas in Iran and across the Gulf Cooperation Council region.</p> <p>Iran is likely to remain of marginal interest to Pfizer, given the prevailing operating and political conditions. Some of Pfizer's medicines, such as <i>Viagra</i> (sildenafil) remain among the most commonly illegally copied and traded pharmaceuticals worldwide.</p>
Roche	<p>Roche is present in Iran through a partnership with domestic company Zahravi Pharmaceutical Company. The company has a representative office in Tehran.</p>
Sanofi	<p>French drug major Sanofi mostly operates in Iran through local distribution agents, although it has its own sales force. The company does have a local presence in Iran through a contract manufacturing partnership with Dr Abidi Pharmaceuticals, a local drugmaker with ISO:9001 certification.</p> <p>The company has managed to penetrate the Iranian market for prescription drugs, also offering some generic products. Sanofi is likely to take a cautious approach and concentrate on few high-demand products, supported by strong marketing and promotional activities.</p> <p>Sanofi's revenue in Iran was USD13.9mn in 2012.</p> <p>In January 2016, Sanofi signed a Memorandum of Cooperation with Iran's government, aimed at boosting its presence in the country. This agreement falls in line with Sanofi's expansion activities across the Middle Eastern region in 2014 and 2015, and the company is well placed to benefit from the increasing demand for generic drugs and the currently favoured patented drugs segment.</p>
Merck & Co	<p>It is represented in Iran by Merck Serono and is present in Iran only through imports, which are dealt with by domestic distributors. The company does not have any local manufacturing facilities. In late 2009, Merck & Co merged with compatriot Schering Plough, which also has a limited presence in Iran.</p> <p>Merck & Co is unlikely to increase its interest in Iran in the short-to-medium term. However, the need to expand into emerging markets over time may see the company pushing to capture a share of the prescription market in Iran, depending on the wider political and economic conditions and also on the success of the country's drive to secure self-sufficiency in pharmaceuticals.</p> <p>There have been notable shortages of <i>Remicade</i> (infliximab), marketed by Schering-Plough in Iran in recent years, due to exchange rate fluctuations and international sanctions that have impacted on the financial system.</p>
Johnson & Johnson	<p>The company does not have a local presence and has a poor exposure to Iran's pharmaceutical market. Products are imported.</p>
GlaxoSmithKline	<p>UK major GlaxoSmithKline is present in Iran through imports, mostly of patented and branded prescription products, which are dealt with by domestic distributors. The company does not have any local manufacturing facilities, although it is reportedly considering establishing a plant in Iran in the near future. GlaxoSmithKline does not have an office in Iran.</p> <p>In 2012, GlaxoSmithKline reported sales of GBP19.7mn (USD30.8mn) in Iran with profits of GBP2.8mn (USD4.4mn).</p>

Multinational Company Activity - Continued

Company	Operations
AstraZeneca	AstraZeneca's sales in Iran totalled USD14mn in 2012. AstraZeneca's products are imported - the company does not have a local presence.

Source: Pharmaceutical companies, BMI

Generic Drugmakers

Table: Leading Drug Manufacturers, Iran - To March 2009

Rank	Company	Estimated Revenue in Iran (USDmn)
1	Darou Pakhsh	75
2	Farabi	70
3	Zahravi	60
4	Exir	50
5	Pars Darou	45
6	Alborz Darou	37
7	Jabar Egn Hayan	33
8	Pharmieco	30
9	Tehran Shimi	29
10	Sina Darou	25

Source: Local news sources, TSE, BMI

Traditionally, Iranian government policy has supported self-sufficiency in the production of medicines. By volume, Iran produces around 97% of its medicines domestically, while about 50% of the necessary raw materials for producing those medicines are imported. This reflects a marked increase in domestic production, as only 25% of drugs used in the country were produced domestically before the 1979 Islamic Revolution.

To date, the sector has been distinguished by its under-investment in R&D, poor intellectual property (IP) protection and isolation from global scientific developments. This has resulted in the production capabilities of the local industry falling short of the state's medical needs. Therefore, some foreign investment is now required for the development of the local pharmaceutical sector. Local production by multinational companies is permitted under licence in Iran, as is contract manufacturing.

55 companies meet over 95% of the country's needs for medicines, although many of the formulations are basic, and the local industry lacks the expertise to produce more high-tech treatments. However, domestic drug production is gradually expanding, with the Iranian authorities recently granting manufacturing licences for 20 vaccines and sera products to local private companies. Iran's improving manufacturing capabilities are evidenced by the announcement from Dinarvand in January 2015 that 12 types of anti-cancer drugs will be produced in Iran within two months that were previously imported. Multiple sclerosis drugs *Tecfidera* (dimethyl fumarate) and *CinnoVex* are also now produced in Iran, according to scientific secretary of the 11th International MS Congress, Shekoofeh Alaie. In addition, three locally produced medicines to treat renal failure produced by Soha Pharmaceutical Company were introduced into Iran's market in May 2015.

The exchange rate has been a major factor affecting drug supply and there have been isolated reports of drug shortages despite attempts to meet domestic demand internally. In July 2013, Iran raised the prices of its domestically manufactured drugs by 40% and that of imported drugs by 90%. The move came after the increase in the exchange rate of the US dollar, which the country uses for importing raw materials. The government earlier allocated the US dollar at the official exchange rate of IRR12,260 for the import of drugs but now the rate has gone up to IRR24,000.

In recent years, Iranian pharmaceutical companies have produced versions of well-known drugs domestically. Iran will open a production line for branded generic drugs licensed by European and US companies, according to Press TV in May 2015. The plant, located about 100km southwest of Tehran, was built with an investment of USD8mn, according to Behestan Pharmaceutical Company's CEO Mehdi Balochestani. The plant will initially produce 12 brands of drugs for treatment of diabetes, neurological diseases, inflammations and prostates. The manufactured drugs are expected to be on pharmacy shelves in the coming two months, Balochestani noted. Five more drugs for special medical conditions will be added to the list in the next five years. 'The products will be available under insurance coverage with better quality and a 10% price discount,' Balochestani said.

Iran will produce a generic version of Gilead Sciences' Hepatitis C drug *Sovaldi* (sofosbuvir) from September 2015, according to Deputy Minister of Health, Reza Malekzadeh. The drug will be offered at USD10, one tenth the price of the originator version.

Glatiramer acetate, an immunomodulator drug used for the treatment multiple sclerosis (MS) has been produced locally since 2012. In 2013, the Fars News Agency - citing Haleh Hamedifar, manager of an Iranian drug manufacturing company - reported that Iran would begin exporting its domestically

manufactured MS medication to Russia, Armenia and Syria from February 2013. While the drug is registered in Syria, Armenia and Russia, other countries have also requested the Iran-made MS drug, Hamedifar said.

In October 2013, Iranian drugmaker Osvah Pharmaceutical Company launched the production line of active pharmaceutical ingredient fingolimod, according to local news source Khabar Online. Fingolimod is an oral medication for the treatment of MS. The drug is a copy of Gilenya, produced by Novartis, which reached blockbuster status in 2012, when its global sales reached USD1.2bn.

Other local players appear to be targeting foreign markets. Farabi Pharmaceutical Company announced plans to launch its products in Oman in January 2015. The company manufactures 90 antibiotics and non-antibiotics items, used to treat mental, cardiovascular and digestive diseases, according to Ahmad Ali Sharifani, marketing and sales manager of Farabi. In another export-related development, Iran announced it is planning to export domestically produced hepatitis and BCG vaccines to Syria in August 2015. The Iranian Ministry of Health aims to increase medicine exports to at least USD500mn over the next three years, according to General Director of Iran's FDA Mahdi Pirsalehi.

Similarly, in December 2012, Head of Iran's Razi Vaccine and Serum Research Institute (RVSRI) Hadi Famil Qadakchi was reported to have announced that Iran is ready to export vaccines to Ukraine. These vaccines will assist in prevention of foot-and-mouth disease or brucellosis in Ukraine, Qadakchi said in a meeting with Ukraine's Deputy Minister of Agriculture and Food, Alexander Vasilyevich.

In November 2012, the US government eased sanctions on the sale of medicines and medical supplies to Iran. The move came after Iran protested that the sanctions imposed by the US are harming its ordinary citizens. The sanctions have resulted in the shortage of medicines for diseases such as haemophilia, cancer and MS, according to Fatemeh Hashemi, the head of the Charity Foundation for Special Diseases.

A month later, India started seeking opportunities to export additional pharmaceuticals to Iran amid sanctions imposed by the UN Security Council. In this context, a large Indian business delegation visited Iran in mid-December 2012 to explore business opportunities, particularly with a view to identifying the demand for several drugs in Iran, which had traditionally been purchased as active pharmaceutical ingredients (APIs) or bulk drugs from Europe. The delegation visited Iran under the government's marketing development activity (MDA) scheme. India recorded a marginal increase of USD1mn in bulk drug exports to Iran during FY11/12. The two countries have also reached an accord to make the Indian rupee the official currency for trade. India's UCO Bank will serve as the official bank for transactions in pharmaceutical exports in the future. By early January 2013, Indian pharmaceutical companies Ranbaxy

Laboratories, Cipla, Glenmark and Ind-Swift Laboratories were reported to have agreed to supply lifesaving drugs to Iran.

Iran's Bayer Aflak Pharmaceutical Factories Company commenced commercial production of veterinary medicines in June 2014, according to Fars News Agency. The plant is capable of manufacturing veterinary penicillin, syrup and sterile ointment. Eventually, the company aims to also produce human medications. The plant's second phase of development, which will enable it to manufacture human medicines, is around 40% complete. The plant is expected to eventually have 12 production lines for a variety of medicines.

Pharmaceutical Distribution

Until the early 2000s, the government was responsible for wholesale activities in Iran through six state-owned firms. The sector has since been liberalised. Leading distributors include Darou Pakhsh, which reportedly controls 25% of the market, Darou Gostar Razi, Pakhsh Razi and Pakhsh Hedjrat.

About 70 companies are engaged in importing activities, with their number growing in recent years. Leading importers include Cobel Darou, Behestan Darou and Akbarieh. Importers' and distributors' mark-up margins are 10-13% each, with retail pharmacies charging an additional 15%, on average.

Hospitals in Iran faced facing severe drug shortages due the unilateral sanctions imposed by the US, the EU and their allies. These sanctions indirectly affected Iran's supply of medicines despite the fact that medicines were exempt from these trade sanctions on account of exemptions for essential drugs and other humanitarian goods. As a result, Iran's pharmaceuticals and healthcare markets have remained fairly insulated from these economic barriers. However, restrictions on financial transactions remained, which meant that imports of pharmaceutical raw materials and finished products were affected, often leading to drug shortages. This was particularly true for more sophisticated medicines, as many Western companies chose not to do business in Iran given the challenging operating environment.

For example, representatives from Merck & Co and Pfizer reported problems extracting money from the country when the Tejaret, the third largest bank in Iran, was blacklisted as a result of it being the last legal route for financial transactions in the country. Given the more basic nature of domestic manufacturers, the shortages were unable to be accounted for by local companies.

Such transactions issues are likely to all but disappear with most of the banking restrictions removed and it is **BMI's** view that Iran's prospect of opening up to a wider diversity of trading partners will improve and provide strategic opportunities for multinational pharmaceutical companies. By reintegrating into the

financial transaction system SWIFT, the import of pharmaceutical-related products will ease and prevent future drug shortages. As a result, over the long term, we believe that foreign drugmakers will be a lot more willing to operate in Iran.

Table: Leading Distributors, Iranian Year To March 20 2008

Rank	Company
1	Darou Pakhsh
2	Pakhsh Razi
3	Pakhsh Hedjrat
4	Pakhsh Ferdous
5	Pakhsh Alborz
6	Pakhsh Ghasem
7	Darou Gostar Razi
8	Darou Behdasht Shafa Arad
9	Armaghan Darou
10	Mahya Darou

Source: Local news sources, BMI

Pharmaceutical Retail Sector

In 2007, there were 7,400 pharmacies operating in the country, of which 650 operated 24 hours a day. According to local sources, as of 2010, the number of pharmacies currently in the region of was 9,000.

It is estimated that about 150 pharmacies are still needed in deprived areas, and it is hoped that fresh pharmacy graduates will be in a position to fill the gap. Also, a number of pharmacies lack certain pharmaceutical products. This can be explained by recent laws, which oblige state hospitals to function as financially independent entities. As a result, many institutions are indebted to pharmaceutical companies, which have subsequently stopped supplying them with medicines.

Western sanctions imposed on Iran's nuclear programme indirectly drove up the cost of drugs and treatment in the country. The sanctions limited regular supplies to hospitals and pharmacies, which in turn helped black market pharmaceutical peddlers to flourish across the country. In Iran's slumping economy and elevated inflation, the cost of certain imported medicines and supplies had almost doubled. Although the sanctions did not block medicine and humanitarian supplies, damage from the sanctions had been felt at almost every level of Iranian healthcare.

Table: Tehran Stock Exchange - Listed Pharmaceutical Companies As Of November 2015

Company	Symbol	Market Capitalisation (IRR)
Darou Pakhsh	DPAK1	2,567bn
Loghman Pharm	DLGM1	616.5bn
Pars Darou	PDRO1	2,169.5bn
Dr Abidi Laboratories	ABDI1	1,590.8bn
Amin Pharm	AMIN1	1,573bn
Abouraihan	DABO1	1,982.2bn
Alborz Darou	DALZ1	5,013.4bn
Jaber Hayan	DJBR1	3,209.6bn
Kowsar Pharm	DKSR1	869.8bn
Osvah Pharm	DOSE1	4,355.5bn
Rasak Laboratories	DRZK1	5,846.2bn
Sina Darou	DSIN1	3,010bn
Sobhan Pharm	DSOB1	5,242bn
Zahravi Pharm	DZAH1	4,322.9bn
Exir Pharm	EXIR1	1,229.4bn
Iran Pareneral	FTIR1	1,476.6bn
Iran Darou	IRDR1	623.7bn
Rouz Darou	ROZD1	1,511.4bn
Tehran Chemical	THSH1	5,632.9bn
Farabi Pharm	DFRB1	2,307.7bn
Chimidarou	KIMI1	1,487.8bn
Damioran Pharm	DAML1	703.2bn

Source: TSE, BMI

Company Profile

Caspian Tamin Pharmaceutical Company

- Strengths**
- One of the leading local drug companies.
 - Some indigenous R&D.
 - Strong export portfolio.
 - Strong emphasis on consumer rights and green practices.
- Weaknesses**
- Iran's underdeveloped healthcare system.
 - The company's domestic market growth potential is restricted by the low spending capacity of Iran's population.
 - Around half of raw materials used in local production have to be imported.
 - The company's growth is limited by the basic nature of its output, as it is unable to compete in more hi-tech product markets.
- Opportunities**
- Domestic market competition is minimal, with major foreign company representation virtually non-existent.
 - Large population and low drug consumption is providing considerable scope for expansion.
 - Opportunities to further increase European sales, given the rising demand for generic medicines there.
 - Recent addition of the drug IMOD to the government's AIDS/HIV programme, despite the lack of scientific proof.
 - Diversification of African export portfolio could boost revenues.
 - Lifting of sanctions likely to dramatically improve trading climate with Western world.
- Threats**
- Unstable trade relationship with the West will potentially have a negative impact on the company's growth potential.

- Underdevelopment of the country's healthcare system is continuing to threaten domestic market potential.
 - Rampant inflation and currency fluctuations are hampering the company's ability to make future purchases of raw materials from abroad.
-

Company Overview The Iran Pharmaceutical Development & Investment Company, established in 1983, is now known as Caspian Tamin, as an affiliate of the Tamin Pharmaceutical Investment Co (TPICO). Tamin is a private joint-stock company owned by the Iranian Social Security Organisation (SSO) (74.5%) and the Iran Social Security Investment Company (25.5%).

As a holding company, Tamin also assumes managerial and supervisory responsibilities for its affiliated companies Pars Darou, Atra, Shivin Daron, Antibiotics Sazi Iran Company (ASICO), Hedjrat Distribution Company and Farabi Pharmaceuticals, which manufacture antibiotics such as amoxicillin, ampicillin and cloxacillin. Together with the Iran SSO, Farabi is one of two main shareholders of antibiotics manufacturer ASICO.

The company has a production plant, the Sterile Pharmaceutical Laboratory, located on Rasht Industrial Estate in the Guilan province near the Caspian Sea. It produces various pharmaceutical dosage forms such as small volume parenterals (ampoules), creams, ointments, gels, syrups and bulk solids. Development of other divisions, such as freeze-dried and liquid vials, is under process. The plant is an affiliate of TPICO, the country's leading pharmaceutical holding company.

The company's portfolio comprises 89 products, most of which are exported to more than 12 countries around the world. Fifteen products are manufactured exclusively by Caspian Tamin.

Strategy In order to improve its global operations, the company is looking for cooperation with foreign drug manufacturers, such as the local formulation of drugs under licence. Currently, the company is in the registration process for products in a number of markets including Sri Lanka, Uzbekistan, Kazakhstan, Russia, Ukraine, Egypt, Ethiopia, Philippines, Vietnam and Yemen. The company also recently exported 500,000 ampoules of anti-convulsive drug phenytoin to Cuba, becoming the first Iranian drug maker to export products to Cuba. The company is currently exploring broadening its exportation strategy, with plans to expand into Africa in the advanced stages of planning.

Developments

2016

- In January 2016, the company announced that it has commenced exporting its products to Oman with a 3000-unit shipment of the *Medroxyprogesterone acetate* injection.

2015

- In October 2015, Caspian Tamin announced the registration of two new products in Sri Lanka, *Gentamicin Sulfate* and *Diclofenac Sodium*.

2014

- The company launched two new pharmaceutical products - *Cimetidine Ampoule* and *Ketorolac Ampoule* - into Iran's pharmaceutical market.

2013

- In April 2013, Caspian Tamin launched a new product, *Sodobica* (sodium bicarbonate 8.4% ampoule) into the Iranian market.

2008

- In 2008, Caspian Tamin launched two new products - *Sodobica* (sodium bicarbonate) and *Ipocort* (hydrocortisone). By the end of September 2008, it also added *Ranica* (ranitidine), *Lignodic-D* (lidocaine decstrose), *Ipacalcin* (calcitonin), *Pamidat* (pamidronate) and *Andron* (testosterone) to its portfolio.
- Also in 2008, Iran's Ministry of Health announced that it would begin reimbursing Tamin's HIV/AIDS medicine *IMOD* (immuno-modulator drug). Controversially, *IMOD* is a herbal remedy without proof of efficacy to international scientific standards.
- Caspian Tamin was awarded the government's Green Management price in 2008.

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Darou Pakhsh

Strengths

- Sales expanded beyond the domestic market, with exports to 20 countries.
- Strong domestic infrastructure with 10 different drug companies in Iran.
- Well-placed to remain the leading pharmaceutical company in the country.
- Some indigenous R&D.

Weaknesses

- The company's domestic market growth potential restricted by the low spending capacity of Iran's population.
- Around half of raw materials used in local production have to be imported.
- Currency fluctuations make it challenging for company to compete in export markets.

Opportunities

- Joint venture with Western company Biotest to expand its domestic market presence.
- Domestic market competition minimal, with major foreign company representation virtually non-existent.
- Large population and low drug consumption providing considerable scope for expansion.
- Development of a new cancer drug with researchers from the University of Tehran, which is reported to be in the final stages of clinical trials.
- Key involvement in government sanctioned economic cooperation projects, including Azerbaijan.

Threats

- Unstable trade relationship with the West will potentially have a negative impact on the company's growth potential.
 - Underdevelopment of the country's healthcare system is continuing to threaten domestic market potential.
 - Rampant inflation is hampering the company's ability to make future purchases of raw materials from abroad and is eroding its pharmaceutical market value.
-

Company Overview

Claiming to be the largest Iranian pharmaceutical company, the Darou Pakhsh Holding Corporation - a holding company of pharmaceutical manufacturer, Darou Pakhsh Manufacturing Co - operates 10 different drug companies in Iran, and is involved in the production and distribution of medicines and pharmaceutical raw materials, in addition to running a large R&D department. The holding company also covers Exir Pharmaceuticals and Aburaihan Pharmaceutical, among others, and is affiliated with Tamin Pharma Investment Company.

The company, established in 1956, is listed on the Tehran Stock Exchange, but the Social Security Organisation owns a majority of the company. The company has exported 70 products to 20 countries such as Canada, Switzerland, Romania, Russia, Pakistan and Brazil. The holding company also has a distribution arm, Darou Pakhsh Distribution Co, which reportedly holds a 25% share of the market.

Strategy

Darou Pakhsh is one of the leading importers of finished pharmaceutical products in Iran, which it distributes through its wide network. The company has agreed to partnerships with a number of foreign firms and currently imports drugs worth USD30-40mn per year. Those partnerships are likely to expand, in the light of the rising demand for pharmaceuticals in general, and especially with regards to those drugs that cannot be manufactured locally - although the wider political environment will also play a part in the development of such import deals.

The company is also developing a new cancer drug in partnership with researchers from the University of Iran. The medicine, which is called Spinal-Z, is indicated to treat gastrointestinal tumours and is derived from two medicinal plants. The drug, which is currently reported to be in the final stages of clinical trials, is likely to be substantially cheaper than similar foreign brands and thus likely to be more widely used.

Developments

2016

- Having previously negotiated establishing a joint pharmaceutical factory in Azerbaijan's Sumgait City, the Iranian Ministry of Health announced that Darou Pakhsh will cooperate on the project. The factory is expected to produce dozens of essential drugs to be used for treatment of heart diseases, contagious disease and several types of antibiotics and painkillers, with EUR35mn of investment required at the initial stage.

2013

- In October 2013, Darou Pakhsh announced their status as a publicly traded company on the Tehran Stock Exchange under the ticker symbol of 'drug' in the pharmaceutical products group. The IPO was made on the November 3rd.

2009

- In 2009, Biodarou delivered 6,000 litres of donated plasma to Germany's Biotest Pharmaceutical. The shipment will be used for the production of albumin, immunoglobulin and Factors VIII and IX. The blood products would then be returned to Iran. Once Iran is capable of harvesting 200,000 litres of plasma each year, it will be able to produce the specialised blood products itself. Nevertheless, Iran is still the only Middle East country capable of gathering plasma through plasmapheresis.

Company Details

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- Website: www.dppharma.ir

Exir Pharmaceuticals

Strengths

- One of the largest domestic drug manufacturers.
- Ability to innovate.
- Product portfolio includes over-the-counters.
- Solid track record of successful international expansion.

Weaknesses

- Reliance on imported active pharmaceutical ingredients.
- Iran's underdeveloped healthcare system.
- Counterfeiting remaining a major threat to innovative pharmaceuticals.

Opportunities

- Export to growing Central and Eastern European markets.
- Dominance of the domestic insulin-producing market.
- Government's focus on the development of domestic pharmaceutical production.
- Strong competition from other global generic-based players, especially India and China.
- Lifting of sanctions likely to dramatically improve trading climate with Western world.

Threats

- Iran's political situation limiting foreign direct investment.
- Rampant inflation is hampering the company's ability to make future purchases of raw materials from abroad.
- Difficulties securing adequate healthcare and pharmaceutical funding.

Company Overview Established in 1988, Exir Pharmaceuticals has grown to become one of Iran's leading drugmakers, with a growing reputation for innovation. It is involved in the manufacture,

import, export and distribution of pharmaceuticals, the latter through the Exir Distribution Co.

Domestically, Exir is reportedly the only Iranian producer of insulin. Exir's products are exported to a number of central and eastern Europe markets including Armenia, Turkmenistan, Azerbaijan, Yemen, Afghanistan, Russia, Belarus and the Ukraine. The company also has registered products in the Philippines and Vietnam.

Exir has a portfolio of more than 70 drugs including antibiotics, central nervous system drugs, cardiovascular drugs and vitamins. Its key products are anti-bacterial agents *Cefazex* (dephalosporin) and *Lorikacin* (amicacin).

The company is listed on the Tehran Stock Exchange. The Social Security Organisation, which controls 20 pharmaceutical companies in Iran, is a major stakeholder in Exir, through the DP Holding Company.

Strategy

In 2008, Exir began producing interferon gamma under the brand name *Gamma Immunex*. Shortly after, Exir's R&D team was named the best R&D division of the year by the Ministry of Mining and Industry. The award was largely thanks to the development and launch of *Immunex*, indicating the company's potential for product development.

In the meantime, the company is targeting new export markets. Future markets identified by the company include Kazakhstan, Venezuela, Brazil and other South American countries.

In North America, Exir established ExirPharma Inc. in which it is a shareholder, and is developing new brands in Canada, such as *Mixnatural* and *Maximed*.

Developments

2011

- In 2011, Exir Pharmaceuticals was nominated as the 'exemplary exporter of the year' for the fourth time - the only Iranian pharmaceutical company to have done so.

2010

- In May 2010, Exir forged a link with the faculty of pharmaceutical science at Tehran University. The cooperation will strive to improve scientific research in particular areas of focus of Exir, such as diabetes.
- In September, Exir registered one of its products in Vietnam. While distribution does not appear to have commenced, Exir is aiming to expand the number of its international registrations, with a number of drugs already undergoing registration in markets as diverse as the Philippines, Sweden, Venezuela and Algeria.

Company Details

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- Website: www.exir.co.ir

Pars Darou

- Strengths**
- One of the leading local drug companies.
 - Some indigenous R&D.
 - Antibiotics remain widely demanded in Iran.
 - Strong credentials on the environment and sustainability.
- Weaknesses**
- The company's domestic market growth potential is restricted by the low spending capacity of Iran's population.
 - Around half of raw materials used in local production have to be imported.
 - Basic nature of its output makes it unable to compete in more hi-tech markets.
- Opportunities**
- Domestic market competition is minimal, with major foreign company representation virtually non-existent.
 - Government push for self sufficiency in medicine production.
 - Large population and low drug consumption is providing considerable scope for expansion.
 - Investment in capacity and product portfolio expansion to meet new demands.
- Threats**
- Unstable trade relationship with the West will potentially have a negative impact on the company's growth potential.
 - Underdevelopment of the country's healthcare system is continuing to threaten domestic market potential.
 - Rampant inflation and currency fluctuations are hampering the company's ability to pay for active pharmaceutical ingredient imports.
-

Company Overview Pars Darou was originally established as Bayer Pharma Iran in 1962, the first subsidiary of a multinational pharmaceutical company in Iran. The company was renamed Pars Darou in 1981. Since 1995, the company has been listed on the Tehran Stock Exchange, with more than 14,000 shareholders. Currently, the company employs about 200 staff. In July 2012, the company was awarded ISO10004: 2010 certification.

Pars Darou was the founder of antibiotics manufacturer Farabi Pharmaceuticals in 1993 and is still a major shareholder, with 52.46% of the shares. It also has an 18.80% stake in the Hedjrat Distribution Company and a 16.0% stake in the joint venture (JV), Amin Pharmaceuticals.

The company has its plant in Tehran and is fully approved by the Iranian Ministry of Health. Annual capacity and available dosage forms are as follows: tablets: 600mn, capsules: 150mn, creams: 10mn, suspensions: 2mn and solutions: 1mn.

Its product portfolio features about 60 drugs, including brands such as tricyclic antidepressants imipramine and amitriptyline; corticosteroid for inflammation and eczema, betamethasone; anti-fungal treatment fluconazole; antibiotic metronidazole; and malaria treatment primaquine.

Strategy The company is also looking to expand, with an emphasis on rationalising and modernising production facilities. This should improve the quality of the company's products, while potentially making more markets available for export. As part of this process, the company is aiming to agree to technical and scientific cooperation with universities and research institutes. This will include undertaking bioavailability and bioequivalence studies on company products.

Company Details

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- Website: www.parsdarou.ir

Zahravi Pharmaceutical Company

Strengths

- Product portfolio including both branded and generic medicines.
- Some indigenous R&D.
- One of the leading local producers of pharmaceuticals.
- International quality process certifications.
- Partnerships with several multinational drugmakers.

Weaknesses

- The company's domestic market growth potential is restricted by the low spending capacity of Iran's population.
- Around half of raw materials used in local production have to be imported, which makes domestic manufacture vulnerable to exchange rate fluctuations.
- The company's growth is limited by the basic nature of its output, and it is unable to compete in more hi-tech product markets.

Opportunities

- Domestic market competition is low, with major foreign company representation minimal.
- Government push for self sufficiency in medicine production.
- Potential for increase in exports, given that its manufacturing facilities are compliant with international norms.
- Large population and low drug consumption provides considerable scope for expansion.

Threats

- Unstable trade relationship with the West is potentially having a negative impact on the company's growth potential.
- Rampant inflation and currency fluctuations are hampering the company's ability to make future purchases of raw materials from abroad.

- Underdevelopment of Iran's healthcare system threatens the domestic market potential.
-

Company Overview Zahravi Pharmaceutical Company was established in 1986, foraying into pharmaceutical manufacturing in 1992. Hakin Pharmaceutical Company holds around 22% of shares in Zahravi. Other shareholders include SSO, through the DP Holding Company, and Razak Laboratories, both of which have more than 20% in stakes, as well as staff.

The company is the country's pioneer in producing different soft-gel capsules and immunosuppressive drugs. Its manufacturing facilities conform to international standards. Zahravi employs around 250 staff.

Zahravi is engaged in the manufacturing of a variety of dosage forms, including soft-gel capsules, tablets, ampoules, regular capsules, oral drops and oral solutions. Its annual production capacity includes around 200,000 tablets, 150,000 soft tablets, 135,000 capsules and 2,300 ampoules. The company boasts around 50 products, which are used both in Iran and abroad and has partnerships with several multinational pharmaceutical companies such as Roche and Boehringer Ingelheim.

Strategy The company's key therapeutic areas include anti-infectives, cardiovascular, gastrointestinal and neurological agents, in addition to immunosuppressants and vitamins and minerals. The portfolio expansion was likely to have been carefully tailored to the demands of the local market, with the company's regional exports also expected to benefit from additions to the existing product mix.

Developments 2014

- The company launched a biotechnological medicine production line in May 2014. The first products are filgrastim and pegfilgrastim which are used to reduce the risk of infection during chemotherapy were the first products to be produced. Zahravi has the capacity to produce 500,000 units of filgrastim and 270,000 units of pegfilgrastim annually.

2012

- In early 2012, the company reportedly started producing *Copamer* (glatiramer acetate) locally, which is used to treat multiple sclerosis.

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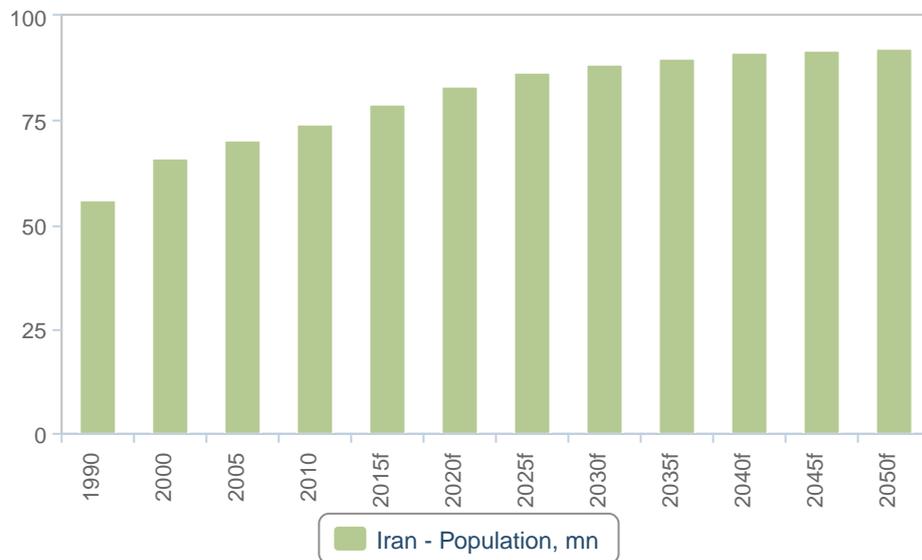
Demographic Forecast

Demographic analysis is a key pillar of **BMI**'s macroeconomic and industry forecasting model. Not only is the total population of a country a key variable in consumer demand, but an understanding of the demographic profile is essential to understanding issues ranging from future population trends to productivity growth and government spending requirements.

The accompanying charts detail the population pyramid for 2015, the change in the structure of the population between 2015 and 2050 and the total population between 1990 and 2050. The tables show indicators from all of these charts, in addition to key metrics such as population ratios, the urban/rural split and life expectancy.

Population

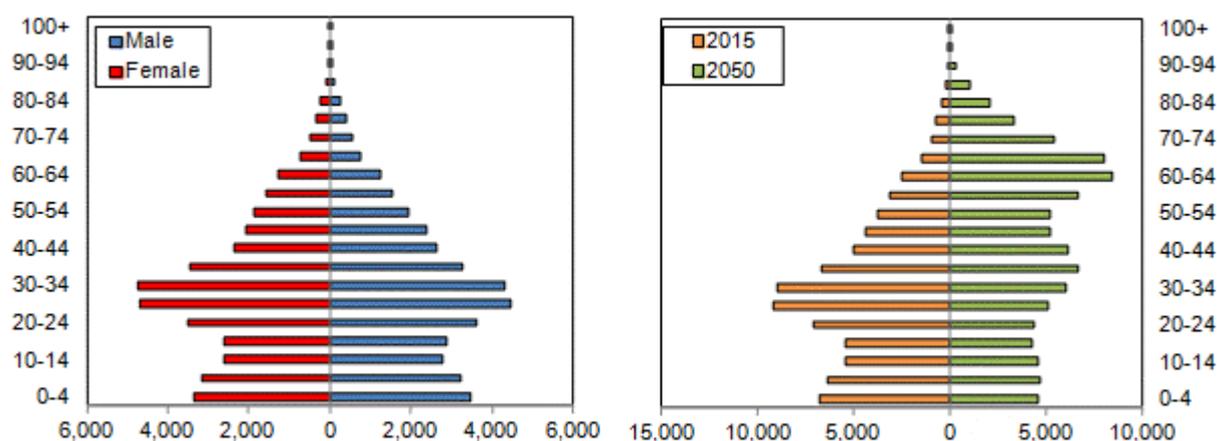
(1990-2050)



f = BMI forecast. Source: World Bank, UN, BMI

Iran Population Pyramid

2015 (LHS) & 2015 Versus 2050 (RHS)



Source: World Bank, UN, BMI

Table: Population Headline Indicators (Iran 1990-2025)

	1990	2000	2005	2010	2015f	2020f	2025f
Population, total, '000	56,169	65,850	70,122	74,253	79,109	83,403	86,496
Population, % y-o-y	na	1.7	1.2	1.2	1.2	0.9	0.6
Population, total, male, '000	28,617	33,372	35,796	37,542	39,835	41,940	43,439
Population, total, female, '000	27,551	32,477	34,325	36,710	39,274	41,463	43,057
Population ratio, male/female	1.04	1.03	1.04	1.02	1.01	1.01	1.01

na = not available; f = BMI forecast. Source: World Bank, UN, BMI

Table: Key Population Ratios (Iran 1990-2025)

	1990	2000	2005	2010	2015f	2020f	2025f
Active population, total, '000	28,800	40,064	48,413	53,171	56,428	58,737	61,495
Active population, % of total population	51.3	60.8	69.0	71.6	71.3	70.4	71.1
Dependent population, total, '000	27,368	25,785	21,709	21,081	22,681	24,665	25,000
Dependent ratio, % of total working age	95.0	64.4	44.8	39.6	40.2	42.0	40.7

Key Population Ratios (Iran 1990-2025) - Continued

	1990	2000	2005	2010	2015f	2020f	2025f
Youth population, total, '000	25,492	23,011	18,251	17,418	18,677	19,449	18,237
Youth population, % of total working age	88.5	57.4	37.7	32.8	33.1	33.1	29.7
Pensionable population, '000	1,876	2,773	3,457	3,662	4,003	5,216	6,763
Pensionable population, % of total working age	6.5	6.9	7.1	6.9	7.1	8.9	11.0

f = BMI forecast. Source: World Bank, UN, BMI

Table: Urban/Rural Population & Life Expectancy (Iran 1990-2025)

	1990	2000	2005	2010	2015f	2020f	2025f
Urban population, '000	31,640.1	42,171.7	47,373.1	52,442.2	58,046.4	63,173.8	67,253.7
Urban population, % of total	56.3	64.0	67.6	70.6	73.4	75.7	77.8
Rural population, '000	24,529.1	23,678.4	22,749.0	21,811.2	21,062.8	20,229.5	19,242.9
Rural population, % of total	43.7	36.0	32.4	29.4	26.6	24.3	22.2
Life expectancy at birth, male, years	61.6	69.2	70.4	72.5	74.5	75.1	75.8
Life expectancy at birth, female, years	66.3	71.1	73.5	75.5	76.7	77.4	78.1
Life expectancy at birth, average, years	63.8	70.1	71.9	74.0	75.6	76.2	76.9

f = BMI forecast. Source: World Bank, UN, BMI

Table: Population By Age Group (Iran 1990-2025)

	1990	2000	2005	2010	2015f	2020f	2025f
Population, 0-4 yrs, total, '000	9,346	6,379	5,494	6,402	6,855	6,228	5,197
Population, 5-9 yrs, total, '000	8,885	7,598	5,556	5,472	6,395	6,836	6,213
Population, 10-14 yrs, total, '000	7,260	9,034	7,200	5,543	5,426	6,384	6,826
Population, 15-19 yrs, total, '000	5,775	8,781	9,299	7,136	5,478	5,407	6,365
Population, 20-24 yrs, total, '000	4,674	6,868	9,123	9,148	7,086	5,434	5,369
Population, 25-29 yrs, total, '000	4,031	5,269	6,796	8,996	9,158	7,026	5,388
Population, 30-34 yrs, total, '000	3,506	4,419	5,156	6,759	9,045	9,096	6,979
Population, 35-39 yrs, total, '000	3,005	3,864	4,670	5,140	6,738	8,988	9,044
Population, 40-44 yrs, total, '000	2,123	3,344	4,091	4,580	5,029	6,688	8,931
Population, 45-49 yrs, total, '000	1,621	2,832	3,393	3,920	4,454	4,979	6,629

Population By Age Group (Iran 1990-2025) - Continued

	1990	2000	2005	2010	2015f	2020f	2025f
Population, 50-54 yrs, total, '000	1,527	1,930	2,776	3,227	3,813	4,384	4,906
Population, 55-59 yrs, total, '000	1,393	1,431	1,767	2,631	3,124	3,723	4,286
Population, 60-64 yrs, total, '000	1,140	1,322	1,336	1,629	2,497	3,009	3,594
Population, 65-69 yrs, total, '000	899	1,145	1,258	1,193	1,475	2,338	2,828
Population, 70-74 yrs, total, '000	508	826	1,055	1,054	1,009	1,299	2,075
Population, 75-79 yrs, total, '000	269	509	654	780	785	776	1,015
Population, 80-84 yrs, total, '000	136	203	347	413	477	494	502
Population, 85-89 yrs, total, '000	49	67	113	174	194	232	249
Population, 90-94 yrs, total, '000	11	18	22	40	54	63	79
Population, 95-99 yrs, total, '000	1	2	3	5	7	10	12
Population, 100+ yrs, total, '000	0	0	0	0	0	0	1

f = BMI forecast. Source: World Bank, UN, BMI

Table: Population By Age Group % (Iran 1990-2025)

	1990	2000	2005	2010	2015f	2020f	2025f
Population, 0-4 yrs, % total	16.64	9.69	7.84	8.62	8.67	7.47	6.01
Population, 5-9 yrs, % total	15.82	11.54	7.92	7.37	8.08	8.20	7.18
Population, 10-14 yrs, % total	12.93	13.72	10.27	7.47	6.86	7.66	7.89
Population, 15-19 yrs, % total	10.28	13.34	13.26	9.61	6.93	6.48	7.36
Population, 20-24 yrs, % total	8.32	10.43	13.01	12.32	8.96	6.52	6.21
Population, 25-29 yrs, % total	7.18	8.00	9.69	12.12	11.58	8.42	6.23
Population, 30-34 yrs, % total	6.24	6.71	7.35	9.10	11.43	10.91	8.07
Population, 35-39 yrs, % total	5.35	5.87	6.66	6.92	8.52	10.78	10.46
Population, 40-44 yrs, % total	3.78	5.08	5.84	6.17	6.36	8.02	10.33
Population, 45-49 yrs, % total	2.89	4.30	4.84	5.28	5.63	5.97	7.66
Population, 50-54 yrs, % total	2.72	2.93	3.96	4.35	4.82	5.26	5.67
Population, 55-59 yrs, % total	2.48	2.17	2.52	3.54	3.95	4.46	4.96
Population, 60-64 yrs, % total	2.03	2.01	1.91	2.19	3.16	3.61	4.16
Population, 65-69 yrs, % total	1.60	1.74	1.79	1.61	1.87	2.80	3.27
Population, 70-74 yrs, % total	0.90	1.25	1.51	1.42	1.28	1.56	2.40
Population, 75-79 yrs, % total	0.48	0.77	0.93	1.05	0.99	0.93	1.17
Population, 80-84 yrs, % total	0.24	0.31	0.50	0.56	0.60	0.59	0.58

Population By Age Group % (Iran 1990-2025) - Continued

	1990	2000	2005	2010	2015f	2020f	2025f
Population, 85-89 yrs, % total	0.09	0.10	0.16	0.23	0.25	0.28	0.29
Population, 90-94 yrs, % total	0.02	0.03	0.03	0.05	0.07	0.08	0.09
Population, 95-99 yrs, % total	0.00	0.00	0.01	0.01	0.01	0.01	0.01
Population, 100+ yrs, % total	0.00	0.00	0.00	0.00	0.00	0.00	0.00

f = BMI forecast. Source: World Bank, UN, BMI

Glossary

- **Pharmaceuticals, medicines, drugs:** synonym terms used interchangeably.
- **Pharmaceutical market/sales:** the sum of revenues generated by generic, patented, and over-the-counter (OTC) drugs through hospitals, retail pharmacies and other channels. Unless otherwise stated, market value is reported at final consumer price including mark-ups, taxes, etc.
- **Prescription drugs:** patented and generic drugs regulated by legislation that requires a physician's prescription before they can be sold to a patient.
- **Patented drug:** an innovative medicine granted intellectual property protection by the patent and trademark office. The patent may encompass a wide range of claims, such as active ingredient, formulation, mode of action, etc, giving the patent holder the sole right to sell the drug while the patent is in effect.
- **Generic drug:** a bioequivalent medicine that contains the same active ingredient as an originator drug. The originator drug is an innovative medicine that no longer has intellectual property protection due to patent expiry.
- **OTC drug:** a medicine that does not require a prescription to be sold to patients. Also known as non-prescription medicines.
- **Counterfeit drugs:** unregistered and illegal medicines which have not been subject to regulatory assessments to ensure quality, safety, efficacy and manufacturing standards.
- **Similares:** non-bioequivalent alternatives to either an originator patented drug or a generic drug. While *similares* and the originator/generic drug have a common indication, *similares* do not always contain the same active ingredient as an originator and invariably have a different pharmacokinetic and pharmacodynamic profile. Prevalent in select South American countries, *similares* are legal. **BMI** does not include their sales in total pharmaceutical market values.
- **Health expenditure:** the sum of the funds mobilised by government and private systems for the operation of a healthcare system, according to the WHO. It includes the purchase of healthcare services and goods by public entities such as ministries and social security institutions; or by private entities such as non-profit institutions, commercial insurances and households acting as complementary funders to the previously cited institutions or unilaterally disbursing health commodities. The revenue base of these entities varies by country and comprises multiple sources. The inclusion of this in **BMI's** forecasts necessitates taking into account the essential attributes of country-specific health accounting such as comprehensiveness, consistency, standardisation and timeliness.
- **Government health expenditure:** the sum of outlays for health maintenance, restoration or enhancement paid by government entities such as a ministry of health, other ministries, parastatal organisations and social security agencies, including transfer payments to households to offset medical care costs and extra-budgetary funds to finance healthcare provision.
- **Private health expenditure:** the sum of outlays for health by private entities such as commercial or mutual health insurance, households, non-profit institutions serving households, resident corporations and quasi-corporations not controlled by governments, according to the WHO.
- **Medical devices:** products used for diagnosis or therapy in patients. Whereas pharmaceuticals achieve their principal action by pharmacological, metabolic or immunological means, medical devices act by physical or mechanical means. Medical devices include a wide range of products, including syringes, thermometers, blood-sugar tests, prosthetic limbs, ultrasound scans and X-ray machines.

- **Burden of Disease Database (BoDD):** BMI's disease database incorporates WHO, World Bank, IMF and BMI's own data to create a proprietary dataset. BoDD data are quantified as the sum of disability-adjusted life years lost to a disease in a particular country.
- **Disability-adjusted life years (DALYs):** the sum of the years of life lost (YLL) due to premature mortality in a population and the years lost due to disability (YLD) for incident cases of the health condition. The DALY is a health gap measure that extends the concept of potential years of life lost due to premature death (PYLL) to include equivalent years of 'healthy' life lost in states of less than full health (broadly termed 'disability'). One DALY represents the loss of one year of equivalent full health.

Methodology

Pharmaceutical Expenditure Forecast Model

Historic pharmaceutical market data is collected from a range of sources, including:

- regulatory agencies;
- pharmaceutical trade associations;
- company press releases and annual reports;
- subscription information providers;
- local news sources;
- information from market research firms that is in the public domain.

Currently available data varies in confidence levels, so it is calibrated by **BMI**'s Pharmaceuticals & Healthcare analysts. In the absence of a complete time series of numbers, intermediate years are calculated from secondary sources. This 'composite' approach is used to ensure the accuracy and consistency of historic data, which is crucial for reliable forecasts.

To remove the effect of inflation, real pharmaceutical expenditure figures are then calculated by removing the annual average consumer price index (CPI).

Real per-capita pharmaceutical expenditure numbers are calculated by dividing by population figures.

A linear regression (*see Note 1 for explanation*) is then performed on five years of real per-capita pharmaceutical expenditure against real per-capita final consumption (*see Note 2*). From analysis of the top 130 economies, **BMI** has established a strong statistical relationship between pharmaceutical expenditure and final consumption expenditure ($r = 0.985$).

Healthcare Expenditure Forecast Model

Historic public and private healthcare expenditure data is sourced from the World Health Organization (WHO)'s Global Health Expenditure Database, which contains the National Health Accounts (*see Note 1 for methodology*).

Data is provided in nominal local currency terms.

To remove the effect of inflation, real healthcare expenditure figures are then calculated by removing the annual average CPI.

Real per-capita healthcare expenditure numbers are calculated by dividing by population figures.

A linear regression is then performed (*see Note 2 for explanation*). This is first on five years of real per-capita public healthcare expenditure against real per-capita government final consumption expenditure (*see Note 3 for definition*). This generates a 10-year forecast of future of real per-capita public healthcare expenditure figures from 'known' projected real per-capita government final consumption expenditure figures. Another linear regression is simultaneously performed on real per-capita private healthcare expenditure against real per-capita private final consumption expenditure (*see Note 4 for definition*).

To generate the nominal public healthcare spending forecast, population and CPI numbers are returned to both real per-capita public healthcare expenditure figures and real per-capita private healthcare expenditure figures.

The overall healthcare expenditure forecast is then calculated by combining public and private healthcare expenditure.

Notes On Methodology

Note 1: National Health Accounts methodology. The global health expenditure database that the WHO has maintained for the past 10 years provides internationally comparable numbers on national health expenditures. The WHO updates the data annually, taking, adjusting and estimating the numbers based on publicly available reports (national health account reports, reports from ministries of finance, central banks, national statistics offices, public expenditure information and reports from the World Bank, the IMF, etc). The estimates are sent out to the ministries of health for validation prior to publication, but users are advised that country data may still differ in terms of definitions, data collection methods, population coverage and estimation methods used. This database is the source of the health expenditure tables in the World Health Statistics Report and the WHO Global Health Observatory.

Note 2: Linear regression equation.

$$y = mx + b$$

Where y = unknown variable, m = slope of gradient, x = known variable, and b = where the line crosses the y -axis.

Note 3: Final consumption is the sum of government final consumption expenditure and private final consumption expenditure. Government final consumption expenditure is the sum of expenditure on final goods and services by the government. Included in this are public sector salaries, but it does not include transfer payments such as unemployment benefits or pensions. Private final consumption expenditure is the sum of all private consumption of goods and services within the economy, including both durable and non-durable goods. Housing purchases, however, are excluded. Government final consumption expenditure and private final consumption expenditure are the 'G' and 'C' in this equation:

$$GDP = C + I + G + (X - M)$$

Where GDP = gross domestic product, C = private final consumption expenditure, I = gross investment, G = government final consumption, X = exports, and M = imports.

Risk/Reward Index Methodology

Geographic diversification may be a favourable strategy for any multinational pharmaceutical company but it is vital that a company recognises both the rewards and the risks present in a market, in both developed and emerging pharmaceutical markets. **BMI's** index, which provides a globally comparative and numerically based assessment of a market's attractiveness, was established to address this.

BMI's Pharmaceutical Risk/Reward Index (RRI) analyses and assesses a market's attractiveness to multinational drugmakers looking to launch innovative medicines in the country. Our approach in assessing the risk/reward balance incorporates our industry-leading Country Risk Index (CRI), drawing on our 25-year expertise in assessing political, economic and business operational risk, as well as our in-depth knowledge of the global pharmaceutical industry.

It should be emphasised that the Pharmaceutical RRIs broadly assess the rewards and the risks that a company will face when looking to launch an innovative drug in a market. For example, we do not differentiate between drugs that are a part of different therapeutic groups or whether the drug being

launched is the first to be launched in the market or will be one of the many different drugs of the same therapeutic class that has been launched in the market.

Index Overview

With regards to assessing rewards, we identify industry specific factors (such as the size of the pharmaceutical market) and country specific factors (such as the size of the pensionable population) that represent opportunities to would-be investors.

With regards to assessing risks, we identify industry specific dangers (such as approvals expediency) and those emanating from the state's political/economic profile (such as bureaucracy) that call into question the likelihood of anticipated returns being realised over the assessed time period. With regard to the economic and political assessment, only aspects most relevant to the pharmaceutical industry are incorporated in the assessment.

Table: Pharmaceutical Risk/Reward Index Indicators

	Rationale
Rewards	
Industry Rewards	
Market expenditure, USDbn	Denotes breadth of pharmaceutical market. Large markets score higher than smaller ones
Market expenditure per capita, USD	Denotes depth of pharmaceutical market. High value markets score better than low value ones
Sector value growth, % y-o-y	Denotes sector dynamism. Scores based on annual average growth over five-year forecast period
Country Rewards	
Urban-rural split	Urbanisation is used as a proxy for development of medical facilities. Predominantly rural states score lower
Pensionable population, % of total	Proportion of the population over 65 years of age. States with ageing populations tend to have higher per-capita expenditure
Population growth, 2003-2015	Fast-growing states suggest better long-term trend growth for all industries
Risks	
Industry Risks	
Patent respect	Markets with fair and enforced IP regulations score higher than those with endemic counterfeiting
Policy reinforcement	Markets with full and equitable access to modern medicines score higher than those with minimal state support
Approvals expediency	High scores awarded to markets with a swift appraisal system. Those that are weighted in favour of local industry or are corrupt score lower

Pharmaceutical Risk/Reward Index Indicators - Continued

Rationale

Country Risks

Economic diligence	Evaluates the structural balance of the economy, noting issues such as reliance on single sectors for exports/growth, and past economic volatility
Policy continuity	Evaluates the risk of a sharp change in the broad direction of government policy
Lack of bureaucracy	Denotes ease of conducting business in the state
Legal diligence	Denotes the strength of legal institutions in each state. Security of investment can be a key risk in some emerging markets
Business Transparency	Denotes the risk of additional illegal costs/possibility of opacity in tendering/business operations affecting companies' ability to compete

Source: BMI

Indicator Weightings

	Market Expenditure	Spending Per Capita	Sector Value Growth	Industry Rewards	Urban/Rural Split	Pensionable Population	Population Growth	Country Rewards	Rewards	Patent Respect	Policy Enforcement	Approvals Expediency	Industry Risks	Economic Diligence	Policy continuity	Lack of Bureaucracy	Legal Diligence	Business transparency	Country Risks	Risks	RRR
Weighting	20	12	12	44	8	8	5	21	65	7	7	7	21	3	3	3	3	2	14	35	100

Source: BMI

The weighting of each indicator reflects its relative importance to the pharmaceutical industry and the relative reward or risk that each factor poses to drug companies. The score assigned to each sub-sector (ie Industry Rewards) indicates the weighting of the sub-sector segment in the final RRI, and the score assigned to each indicator shows each indicator's influence within the sub-sector and the final RRI. All the indicators and their weightings are visible, improving the transparency of the index, allowing for the identification of regional (or group) outperformers across one indicator.

Uses For BMI's Pharmaceutical RRIs

- Strategic decision making and country/market comparisons, providing quantifiable reasons as to why one market is more attractive than another.
- Assessing the viability of new markets.
- A benchmark for internal rating systems.
- Assessing frontier markets or markets in which data collection is difficult.
- Internal presentations.

Principals Likely To Derive Benefit

- Disease manager
- Country manager
- Regional manager
- CEO and other senior executives involved in high level strategic decisions
- Business development team
- Credit risk team

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