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Q1 2015

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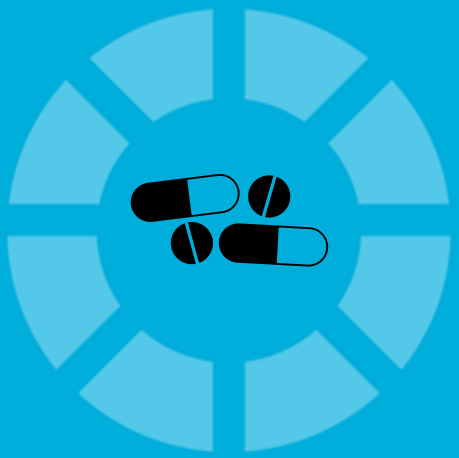
IRAN

PHARMACEUTICALS & HEALTHCARE REPORT

INCLUDES 10-YEAR FORECASTS TO 2023



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Iran Pharmaceuticals & Healthcare Report Q1 2015

INCLUDES 10-YEAR FORECASTS TO 2023

Part of BMI's Industry Report & Forecasts Series

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BMI Industry View

BMI View: BMI *continues to adjust its forecasts for Iran's pharmaceutical market to account for the sanction-induced currency crisis and high rates of inflation. The rapid depreciation of the rial means that we expect the value of the market to contract sharply in US dollar terms. While improved international relations have reduced the regulatory risk associated with operating in the market for multinational drugmakers, the recent proclamation of the Islamic State (IS) in neighbouring Iraq and Syria increases the threat of political instability.*

Headline Expenditure Projections

- **Pharmaceuticals:** IRR44,216bn (USD2.46bn) in 2013 to IRR51,684bn (USD1.63bn) in 2014; +16.9% in local currency terms and -33.9% in US dollar terms.
- **Healthcare:** IRR548,672bn (USD16.63bn) in 2013 to IRR617,190bn (USD19.41bn) in 2014; +12.5% in local currency terms and +16.7% in US dollar terms.

Risk/Reward Index

BMI considers Iran's business environment to be slightly less appealing than the previous quarter, with a score of 41.5 out of 100 in Q115, unchanged from the previous quarter. Due to reappraisals of the scores of other countries, Iran's position in the regional rankings improved three places in the regional rankings to 14th out of 30 countries in the Middle East and Africa in Q115. Its overall score is below the regional average of 42.3. Generally speaking, Iran benefits from a large and growing population and relatively widespread access to healthcare services. However, its regulatory regime - including intellectual property (IP) rights, political and economic situation - is highly questionable. Consequently, the country performs above the regional average for potential rewards and below the regional average in terms of risk.

Key Trends And Developments

- 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.
- Iran's pharmaceutical supply crisis is over according to Deputy Minister of Health and Chairman of the Food and Drug Administration Rasul Dinarvand. After having faced challenges from price volatility and drug shortages in 2013, the Islamic Republic News Agency reports that drug prices are now under control and customs clearance on imported medicine has resulted in an adequate supply of drugs.

BMI Economic View: The Iranian economy will expand modestly over the coming years, and we project real GDP growth of 2.8% and 2.9% in 2014 and 2015, respectively. This compares with our estimate of a

2.9% contraction in 2013. Foreign direct investment by Western companies will remain minimal next year owing to the failure to reach a breakthrough in talks on the nuclear programme.

BMI Political View: We believe that talks between Iran and the P5+1 countries (the US, Russia, China, France, Britain and Germany) on the Islamic Republic's nuclear programme will continue through 2015 and 2016. We see minimal scope for reaching a 'permanent' agreement - which would ensure Iran cannot use its enrichment activities to produce a nuclear weapon before the West can intervene - before the expiry of a deadline set for November 24 2014. Risks of reaching a final deal over the coming decade are tilted slightly to the downside owing to significant political obstacles.

SWOT

SWOT Analysis	
Strengths	▪ Large pharmaceutical market in regional terms, supported by large population. ▪ 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. ▪ Antiretrovirals are distributed free of charge.
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. ▪ 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 in regards to pharmaceutical needs.
Opportunities	▪ Low taxes on foreign-made drugs that are not manufactured locally. ▪ Expanding public health insurance coverage. ▪ Improved intellectual property and regulatory conditions to attract some investment in local facilities.

SWOT Analysis - Continued

- 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.

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.
- Questionable progress on WTO membership given further controversies over patents.
- Regional instability linked to the proclamation of the Islamic State (IS) creating political and economic instability.

Political

Political SWOT Analysis

Strengths

- Since the overthrow of the Pahlavi family in 1979, there has been some reduction in the level of political corruption, while wealth distribution has improved marginally.
- The Revolutionary Guard and Basij militia are fiercely loyal to the supreme leader, helping to maintain social stability.

Weaknesses

- The country has one of the poorest human rights records in the region, and authorities do not hesitate to quell dissidents. A number of journalists and anti-government protesters are being held in custody.
- While decision-making ultimately rests with the supreme leader, the regime is heavily fragmented, and consensus is hard to reach.
- Widespread perceptions of electoral fraud during the course of June 2009's presidential elections have damaged the regime's legitimacy in the eyes of many Iranians.

Opportunities

- The Majlis (parliament) is more than just a rubber stamp; the move by 150 parliamentarians (out of 290) to hold former president Mahmoud Ahmadinejad accountable for his handling of the economy in March 2012 is a positive indication that checks exist.
- The victory of moderate cleric Hassan Rouhani in Presidential elections in June 2013 is leading to a significant improvement in relations with the West.

Threats

- Despite progress in nuclear talks, the prospect of further US and EU sanctions and the possibility of a military strike by the US or Israel cannot be dismissed.
- Youth unemployment is high.
- The strong influence of the Revolutionary Guards within the political and economic arena may present a challenge to reform over the long term.

Economic

Economic SWOT Analysis

Strengths	▪ Iran has the world's second largest proven oil reserves after Saudi Arabia, and the world's second largest proven gas reserves after Russia. ▪ Oil and gas aside, Iran is rich in other resources and has a strong agricultural sector.
Weaknesses	▪ Local consumption of hydrocarbons is rising rapidly; this, coupled with ageing technology in the sector, will have a negative impact on its oil and gas exporting capacity. ▪ International sanctions discourage foreign oil companies from bringing much-needed technical knowledge and equipment to maintain oil output levels.
Opportunities	▪ The gas sector remains underdeveloped, and there is considerable room to maximise this source of revenue. ▪ A growing population, combined with a shortage of housing, provides opportunities for investment in residential construction.
Threats	▪ A decline in global oil prices would have a marked impact on the economy. Although an Oil Stabilisation Fund exists to protect the economy at times of weaker oil prices, it has increasingly been used to fund government overspending and could be close to empty. ▪ Capital flight could continue, particularly should negotiations on the nuclear programme fail.

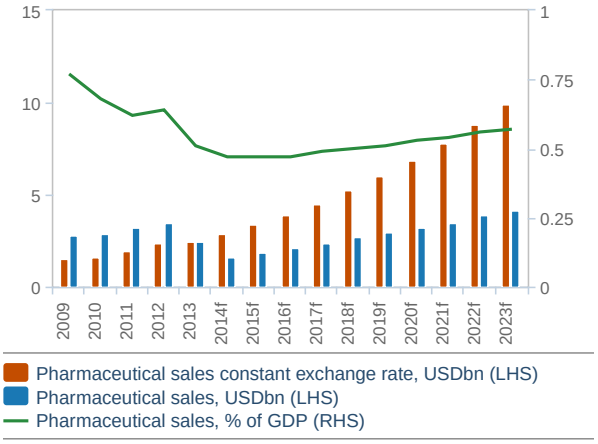
Industry Forecast

Pharmaceutical Market Forecast

BMI continues to adjust its forecasts for Iran's pharmaceutical market to account for the sanction-induced currency crisis. The rapid depreciation of the rial means that we expect the value of the market in US dollar terms to fall by a third in 2014. The forecast has been downgrade in USD terms is as a result of new expectations that the rial will weaken further against the US dollar. It is important to note that these monetary calculations are based on extreme currency distortions. Volume sales of pharmaceuticals are significantly down in the embattled country, with imports also severely affected.

Pharmaceutical Market Forecast

2009-2023



Local news sources, domestic companies, BMI. f = BMI forecast.

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.

Iran's pharmaceutical market will become increasingly reliant on pharmaceutical imports over the next decade. Due to ongoing trade sanctions, increasing import reliance puts Iran at significant risk of long-term medicine shortages. Uptake of medicines in the short-term is further risked by currency depreciation and hyperinflation of local medicine prices. We believe the medicines market will contract sharply in US dollar value in 2014.

Hospitals in Iran are facing severe drug shortages due to a series of unilateral financial and trade sanctions imposed by the US, the EU and their allies. These sanctions are indirectly affecting Iran's supply of medicines. Although countries, including the US, have not banned imports of medicines to Iran, they now require exporters to apply for a special licence. Other sanctions have made it impossible to transfer money through banks, indirectly impacting on the health care sector. The sanctions were imposed as the EU, the US and other allies alleged Iran is pursuing non-civilian objectives in its nuclear energy programme.

Indeed, our forecasts for the Iranian pharmaceutical market remain at risk due to the sanctions on the country, with the US dollar forecasts potentially being misleading due to the rise in black market transactions, which are seen as necessary to circumvent financial sanctions. The sanctions are severely inhibiting the country's ability to pay for essential humanitarian goods, including medicines. The sanctions have barred multinational banks from any interaction with the central bank or 23 'designated' (i.e. blacklisted) financial institutions. Any bank found to be cooperating with a blacklisted bank will be cut out of the US financial system, a penalty so serious that no large bank will be willing to take the risk of interacting with the Iranian financial sector.

Financial sanctions have led the country to become a part-barter economy for foreign transactions, with people first looking for smaller banks to handle their payments, but also trading gold, cattle, hard currency and any other relatively valuable goods in lieu of electronic transactions to pay for medicines. This presents enormous problems for companies looking to trade with the country.

To make matters worse, in March 2012 the Society for Worldwide Interbank Financial Telecommunication (SWIFT) expelled Iranian banks from its system to help enforce sanctions. SWIFT's decision came at the same time as EU sanctions against Iran over its nuclear programme. The end of SWIFT services will make it almost impossible for Iran to make international transactions via legitimate banking channels.

Sanctions on transport links and the increased price of supply chain activities due to the weakened rial will continue to severely hinder access to medicines in Iran. We, nevertheless, believe that essential medicines will continue to reach patients due to unmet demands, opportunity-seeking by companies from lower-cost manufacturing locations and loopholes in the financial transfer system. We also believe that the uptake of locally produced cheaper generic drugs and OTCs has strengthened, despite being hindered by hyperinflation.

However, should the Iranian pharmaceutical supply be on the verge of depletion, there is the possibility that the government will make concessions to its nuclear programme in response to the country's desperate demand for medication for chronic conditions. Consequently, financial and trade commodity sanctions would be relaxed, Iran's oil revenues would be restarted, the local currency would strengthen and economic growth would slowly resume. **BMI** believes that the country could be forced to adopt this strategy when various markets are on the verge of collapse and can no longer be further squeezed by the US-imposed sanctions.

Our core view remains that the accountability of Iran's regime continues to deteriorate, with the institution of the presidency set to weaken while the power of unelected bodies increases. However, as the worsening

economic situation triggers popular discontent, spontaneous protests will increase in the future. As a result, we expect political instability to rise in the coming years.

These issues notwithstanding, key drivers of growth will be volume-based, given improvements in healthcare provision and rising population numbers, as downward pressure on prices remains in place over the longer term. As their purchasing power is lower than that of their regional peers, Iranian patients are likely to opt for generic medicines where possible, especially given the current levels of inflation. Moreover, the population are aware of what a generic drugs is, further driving demand for medicines in this segment.

Although we caution that long-term forecasts are at high risk owing to the current situation, we expect steady growth of the market. Nevertheless, we expect that Iran is still likely to remain a challenging and a relatively unattractive proposition for multinationals, despite the clear demand for chronic disease drugs.

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 GMP standards and, therefore, boost export potential.

Table: Pharmaceutical Sales, Historical Data And Forecasts (Iran 2010-2018)

	2010	2011	2012	2013	2014f	2015f	2016f	2017f	2018f
Pharmaceutical sales, USDbn	2.905	3.260	3.516	2.459	1.625	1.886	2.129	2.395	2.686
Pharmaceutical sales, USDbn, % y-o-y	3.73	12.24	7.85	-30.06	-33.91	16.02	12.88	12.53	12.14
Pharmaceutical sales, IRRbn	29,589.57	34,610.63	42,885.06	44,215.74	51,683.89	60,343.07	70,243.06	81,438.34	94,009.04
Pharmaceutical sales, IRRbn, % y-o-y	6.73	16.97	23.91	3.10	16.89	16.75	16.41	15.94	15.44
Pharmaceutical sales constant exchange rate, USDbn	1.646	1.925	2.385	2.459	2.874	3.356	3.907	4.529	5.228
Pharmaceutical sales, USD per capita	39.0	43.2	46.0	31.8	20.7	23.7	26.5	29.4	32.6
Pharmaceutical sales, % of GDP	0.68	0.62	0.64	0.51	0.47	0.47	0.47	0.49	0.50
Pharmaceutical sales, % of health expenditure	9.4	9.0	9.5	14.8	8.4	8.2	8.4	9.0	9.5

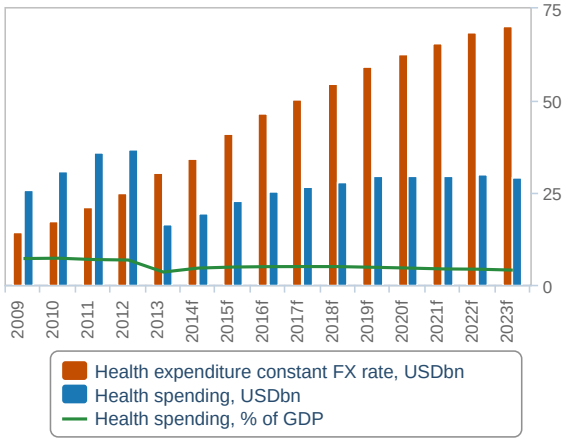
f = BMI forecast. Source: National Sources/BMI

Healthcare Market Forecast

Government involvement in healthcare is below that seen in developed countries, although we expect fiscal spending to increase over the medium term, providing some upsides for pharmaceutical companies operating in Iran. The government currently meets less than half of the total healthcare spend in the country, with a third of pharmaceuticals' costs under health insurance continuing to be met out-of-pocket, despite substantial increases in the government healthcare budget in recent years on the back of growing oil revenues.

Healthcare Expenditure Forecast

2009-2023



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

We estimate healthcare expenditure reached IRR548,672bn (USD16.63bn) in 2013. Over the longer term, healthcare spending is forecast to grow broadly in line with GDP growth, although our forecasts will remain at risk for as long as the political and economic uncertainty lasts. Following a sharp contraction of the market in US dollar value-terms in 2013, we expect the rate of growth of healthcare spending to stabilise over the forecast period as inflationary pressures are stabilised. At the same time, its share of GDP will fall, partly due to the growing importance of the oil sector to the country's output.

In the shorter term, however, the removal of energy and food subsidies by the government has reportedly resulted in a 20-40% spike in healthcare costs. According to Shahabeddin Sadr, the head of the Medical Council of Iran, the move has impacted hospitals, as well as manufacturers of pharmaceuticals and medical supplies. Health minister Marzieh Vahid Dastjerdi in November 2011 urged the government to increase its budget for the MOHME, which has reportedly stagnated for the past five years. While the authorities stipulate that co-payment for medical services should stand at 30%, in reality this figure is reportedly as high as 54%.

More recently, Western sanctions imposed on Iran over its nuclear programme have indirectly driven up the cost of drugs and treatment in the country. The sanctions have limited regular supplies to hospitals and pharmacies, which in turn has helped black market pharmaceutical peddlers to flourish across the country.

In Iran's slumping economy, the cost of certain imported medicines and supplies has almost doubled. Although the sanctions do not block medicine and humanitarian supplies, damage from the sanctions will continue to be felt in almost every level of Iranian healthcare.

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 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.

Table: Healthcare Expenditure Trends, Historical Data And Forecasts (Iran 2010-2018)

	2010	2011	2012	2013	2014f	2015f	2016f	2017f	2018f
Health spending, USDbn	30.976	36.097	36.996	16.626	19.409	22.978	25.378	26.734	28.176
Health spending, USDbn, % y-o-y	19.03	16.53	2.49	-55.06	16.73	18.39	10.44	5.34	5.39
Health spending, IRRbn	315,569.0	383,232.0	451,268.0	548,671.9	617,189.6	735,288.6	837,461.2	908,955.4	986,152.9
Health spending, IRRbn, % y-o-y	22.46	21.44	17.75	21.58	12.49	19.14	13.90	8.54	8.49
Health expenditure constant FX rate, USDbn	17.550	21.313	25.097	30.514	34.325	40.893	46.575	50.551	54.844
Health spending, USD per capita	416.0	478.6	484.1	214.7	247.3	289.1	315.4	328.3	342.1
Health spending, % of GDP	7.21	6.85	6.72	3.45	4.53	4.81	4.92	4.94	4.93

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

Table: Government Healthcare Expenditure Trends, Historical Data And Forecasts (Iran 2010-2018)

	2010	2011	2012	2013	2014f	2015f	2016f	2017f	2018f
Govt. health spend, USDbn	12.098	15.565	14.937	6.760	8.070	9.735	10.970	11.926	13.027
Govt. health spend, USDbn, % y-o-y	11.09	28.66	-4.04	-54.75	19.38	20.63	12.69	8.72	9.23
Govt. health spend, IRRbn	123,253.00	165,254.00	182,198.00	223,066.17	256,608.76	311,506.59	361,997.26	405,478.97	455,933.02
Govt. health spend, IRRbn, % y-o-y	14.30	34.08	10.25	22.43	15.04	21.39	16.21	12.01	12.44
Govt. health spend, % total health spend	39.06	43.12	40.37	40.66	41.58	42.37	43.23	44.61	46.23

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

Table: Private Healthcare Expenditure Trends, Historical Data And Forecasts (Iran 2010-2018)

	2010	2011	2012	2013	2014f	2015f	2016f	2017f	2018f
Private health spend, USDbn	18.878	20.532	22.059	9.867	11.339	13.243	14.408	14.808	15.149
Private health spend, USDbn, % y-o-y	24.74	8.76	7.44	-55.27	14.92	16.79	8.80	2.78	2.30
Private health spend, IRRbn	192,316.0	217,978.0	269,070.0	325,605.7	360,580.8	423,782.0	475,463.9	503,476.4	530,219.9
Private health spend, IRRbn, % y-o-y	28.34	13.34	23.44	21.01	10.74	17.53	12.20	5.89	5.31
Private health spend, % total health expenditure	60.94	56.88	59.63	59.34	58.42	57.63	56.77	55.39	53.77

f = BMI forcecast. Source: World Health Organization (WHO)/ BMI

Prescription Drug Market Forecast

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 OTC medicines is unclear, making the differentiation between sectors even more difficult. Indeed, a significant number of prescription drugs are still available without a prescription, with this issue 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 IP 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.

Nevertheless, 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.

However, Iran is facing a shortage of cancer and multiple sclerosis (MS) drugs due to sanctions imposed by the EU and US, the head of the Charity Foundation for Special Diseases, Fatemeh Hashemi, stated in October 2012. According to the statements made by a member of the Iranian parliament, Rasoul Khezri, around the same time, pharmaceutical supplies in Iran were expected to run out within two months.

Patients suffering from thalassemia and dialysis are also facing problems, Hashemi told Tabnak news agency, adding that sanctions against Iran's banking sector and difficulties transferring foreign currency have resulted in deep-rooted problems. Pharmaceutical companies are finding it hard to export medicines to Iran due to the banking sanctions, according to UN secretary general Ban Ki-moon.

However, the Iranian government has shunned these sanctions, instead insisting that its nuclear programme should continue. At the same time, local companies are reportedly starting to produce treatments such as MS medication, which is also to be exported to markets including Russia and Syria.

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, the rising resistance to such medicines may prompt the government to introduce some restrictions on the use of antibiotics in public institutions, especially as the

SSO 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

We estimate that patented medicines account for around one-third of the overall market's value. As the purchasing power for medicines is low, both in the public and private sphere, we expect that the development of the generic drug market will outpace that of its patented counterpart. Additionally, although we note that the longer term market development will be predicated on the resolution of the current crisis, we expect that patent expirations will further negatively impact the value of the patented drug segment. In the shorter term, the inability of domestic stakeholders to pay for the imported high-value medicines will also curtail the sales of patented drugs.

Clearly, growth will be difficult to assess accurately, also given the high volume of counterfeit trade 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 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 of the total.

Iran is also keen to develop its own drug development industry and is actively seeking out capital investment and technology transfer from foreign firms. This could result in the country eventually beginning to market its own innovative products. However, much improvement to the intellectual property regime is needed first, while the country's relative international isolation remains a further limiting factor, despite considerable potential returns.

Generic Drug Market Forecast

The outlook for generic drug sales in Iran is favourable. With generic drugs habitually prescribed and a reasonable level of public awareness, we believe that 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.

Changes to the drug registration law suggest that the government is taking a more open approach to branded drugs, although a number of such products are actually branded generic drugs. Previously, all drugs had to be registered under their generic name, but now it is mandatory to register them under a brand name.

Additionally, the proposed four-track registration system can potentially boost the use of foreign-made patented drugs by significantly reducing their approval times, to the detriment of the copy products.

OTC Medicine Market Forecast

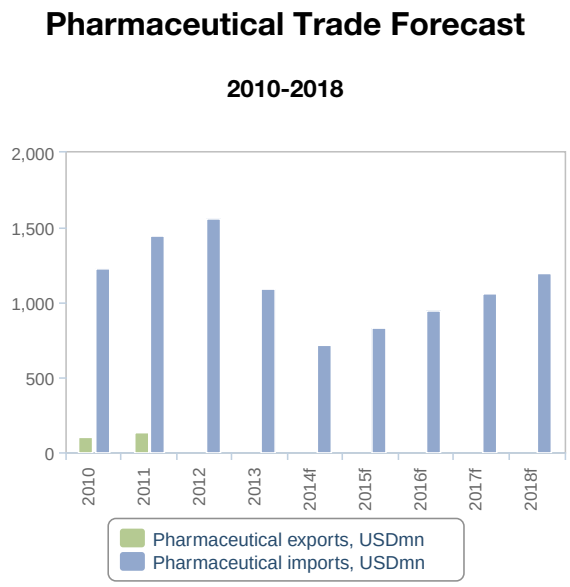
Given that most products are still reimbursed, the legitimate OTC drug market in Iran is estimated to account for no more than 10-15% of the pharmaceutical market's total value. However, the distinction between OTC and prescription is still unclear - even at the point of sale at the pharmacy. OTC medicines 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 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 is likely to impact the market value of consumer health products as patients are forced to pay for the products out of their own pockets. The low-income and rural populations will therefore be disadvantaged if the move goes ahead, especially as slow GDP growth forecast over the coming years will also have a negative impact on consumer confidence and ability to pay for non-essential goods.

Currently, analgesics form the key sector of the OTC segment, accounting for more than half of the total value of the OTC market. Driven by demand, analgesics will remain the leading component of the 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, although 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.

Pharmaceutical Trade Forecast

Iran's efforts to reduce its trade deficit for pharmaceuticals by ignoring the majority of international patent laws limit its export capabilities in terms of its geographical reach. Furthermore, while the industry lacks the expertise to make the most technologically challenging drugs, imports from Europe (led by Switzerland, France and Germany) will continue to make up a large part of the total legitimate market in value terms.



United Nations Comtrade Database DESA/UNSD, BMI. f = BMI forecast.

The Iranian Ministry of Health and Medical Education (MOHME) believes the country's import reliance in 2010 was around 4% in volume terms and 35% in value terms. **BMI** estimated that Iran's actual pharmaceutical import reliance in value terms is 40-50%, although we stress that this is a market from which it is difficult to obtain reliable information. We also note that available historical import data is patchy, which makes it difficult to predict an accurate forward-looking value trajectory. Additionally, political issues and the rampant inflation levels only serve to increase risks to our forecasts.

BMI believes that the trend within the country is that it has become more, not less, import dependent in value terms. Indeed, drugs imports in Iran increased by 40% month-on-month (m-o-m) to 1,540 tonnes, valued at USD119mn, in the eighth Iranian calendar month ended November 22 2013 according to Nasser Riahi, chairman of the Syndicate of Iranian Pharmaceutical Importers.

Data from the Iranian DARU Journal of Pharmaceutical Sciences confirm **BMI**'s view that pharmaceutical imports as a proportion of total pharmaceutical sales have been increasing over the last decade. According to the publication, total finished pharmaceutical imports increased by 42% between 1997 and 2010, from USD15mn to USD828mn. The proportion of total pharmaceutical sales increased from 10% to 33%. While local production, forming the bulk of total pharmaceutical sales by value, increased less quickly, by 9.3% over the period from USD139mn to USD1,639mn, reducing its share of total sales from 90% to 66%. **BMI**'s 2010 total pharmaceutical sales estimate of USD2.90bn is slightly above the Journal of Pharmaceutical Sciences' reported value of USD2.47bn.

We expect that this trend will continue over the next decade - although at a much slower pace. In addition to becoming less self sufficient, increasing import reliance puts Iran at high risk of long-term medicine shortages due to ongoing trade sanctions. In addition to the sanctions restricting access to imported medicines, diminishing foreign currency reserves and continued depreciation of the Iranian rial will see a reduction in total pharmaceuticals consumption in US dollar terms in 2013. Even when sanctions are lifted, we believe that the importation of pharmaceuticals will be limited by the Iranian government, which will seek to meet local demand with cheap, locally produced products.

A report by US-based Woodrow Wilson International Center for Scholars has suggested a decline in US pharmaceutical exports to Iran during 2012, despite of a 9% increase in total exports. While overall exports rose from USD229.3mn in 2011 to USD250.2mn in 2012, exports of pharmaceutical products dwindled to USD14.8mn during 2012 from USD31.1mn in 2011. Exports of surgical appliances and supplies and those of vitamins, medicinal and botanical drugs also fell from USD3.7mn in 2011 to USD2.4mn in 2012 and from USD10.8mn in the previous year to USD4.9mn during 2012 respectively.

The decrease in US drug exports to Iran has been attributed to financial sanctions against the latter's nuclear programme and the Iranian government's pharmaceutical import administration. The statistics appear to support the claims that financial sanctions are making it difficult for Iranians to obtain medicines, despite loopholes in the sanctions designed to permit such trade to continue. Moreover, the Iranian government has also probably chosen to divert its spending to other areas, including the Assad regime in Syria and its nuclear programme, rather than increasing healthcare provision and medicines access and providing foreign exchange to the Health Ministry.

In fact, pharmaceutical exporters to Iran were hit the hardest when **Tejaret,** the third-largest bank in Iran, was blacklisted, given that it was the last legal route for financial transactions in the country. Since then, drugmakers have been able to trade with Iran under humanitarian licences but they have been unable to receive payments or repatriate their earnings. Representatives from **Merck & Co** and **Pfizer** have reported problems extracting money from the country but have reiterated their commitment to supplying drugs. Nevertheless, **BMI**'s data indicate that the US exposure to the Iranian pharmaceutical market is relatively small in comparison to the exposure by Western European countries.

Generally speaking, we believe that exports from western trade partners increasingly dried up in 2012 as monetary transactions were not carried out. We also believe that the actual value of medicines consumption in 2012 was lower than the import figures due to sanction-induced hyperinflation and severe currency

weakness which will have caused reduced supply chain activities and low consumer purchasing power once the medicines had reached local retailers.

In November 2012, the US government eased sanctions on the sale of medicines and medical supplies to Iran. The government took the decision amid fears that it might lose global support for an international campaign to impose sanctions on Iran for its disputed nuclear programme. 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, thereby directly affecting the lives of millions of patients, 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 was projected to export pharmaceutical products worth about USD400mn during FY12/13, according to IRNA News Agency, citing the country's health minister, Marzieh Vahid-Dastjerdi. While the Iranian pharmaceutical industry exported products amounting to about USD114mn in FY11/12, drugs worth about USD1bn were reportedly imported during the same period. A plan proposed to the government of Iran also projected annual exports of about USD70bn if each of the 140 drug manufacturing units in the country exports products costing USD500mn.

Export growth should eventually come from domestic firms expanding their foreign markets to countries such as the Ukraine, Iraq, Vietnam, Russia and the Philippines. With trade embargos remaining in place for the foreseeable future, Iran's drugmakers are restricted to exporting to markets where regulatory standards and purchasing power are relatively low. Iran is expected to continue relying on its close allies to buy its drug exports in return for much-needed foreign currency.

Data has been made available by the WHO on the import dependence and average pharmaceutical mark-ups within Iran. According to a report by Dr Akbar Abdollahiasl from the MOHME for the WHO, the average mark-up for locally manufactured generic drugs is between 29% and 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.

BMI provides its market size at consumer prices, so mark-ups from manufacturers to retail are an important component of total value. In light of the new data, we have ascribed an average mark-up of 31% to locally produced drugs and 75% to imported pharmaceutical products.

Regardless, most of Iran's basic pharmaceutical needs in volume terms are manufactured locally, so the majority of the population is unlikely to be affected by the inability to buy foreign-made pharmaceuticals. The people who will be badly affected are patients in need of difficult-to-manufacture drugs that are unavailable from local companies. **BMI** believes that the inability to get these drugs into the country will result in an increase in medical tourism out of Iran, with those who can afford it likely to travel to facilities in Lebanon. It will also lead to an increase in black market parallel trading.

Iran's growing population and increased demands for healthcare have led to growing investment in drug manufacturing plants, which will also contribute to the rise in exports. As foreign investment is limited by government rules, **BMI** believes the development of local production facilities will eventually reduce Iran's reliance on imported patented products. Indeed, local companies are reportedly starting to produce medicines such as MS drugs, with **Zahravi** launching *Copamer* (glatiramer acetate) in early 2012.

While privatisation of import companies in Iran has led to more international trade, the government still has a strict stance on drug imports. The MOHME said in early 2010 that it aimed for Iran to become fully self-sufficient within four years. As Iran finds itself increasingly isolated and financially wounded by sanctions, the government is pushing for some of the more expensive Western drugs to be produced in Iran, although this may sometimes contravene international intellectual property laws. Additionally, a difficult reimbursement regime will continue to discourage the population from purchasing imported products, which carry considerable levels of co-payment.

Table: Pharmaceutical Trade Data And Forecasts (Iran 2012-2018)

	2012	2013	2014f	2015f	2016f	2017f	2018f
Pharmaceutical imports, USDmn	1,562.20	1,092.62	722.16	837.89	945.79	1,064.28	1,193.46
Pharmaceutical imports, USDmn, % y-o-y	7.85	-30.06	-33.91	16.02	12.88	12.53	12.14

f = BMI forecast. Source: National Sources/BMI

Table: Pharmaceutical Trade Data And Forecasts local currency (Iran 2012-2018)

	2012	2013	2014f	2015f	2016f	2017f	2018f
Pharmaceutical imports, IRRmn	19,055,194.4	19,646,456.9	18,415,163.6	22,622,911.7	27,428,041.1	32,992,786.2	39,384,273.1
Pharmaceutical imports, IRRmn, % y-o-y	23.91	3.10	-6.27	22.85	21.24	20.29	19.37

f = BMI forecast. Source: National Sources/BMI

Other Healthcare Data

Iran has a large but predominantly young population. The median age in the country is 23 and there are an estimated, 18mn children of school age. The fact that approximately 27.1% of the population falls in the 0-14 age bracket and as much as 45% was below the age of 25 in 2010, according to the UN (even though the figure is much lower than the 59% estimated in 2000), is set to put great pressure on the health system in the coming years. The country's population has doubled over the past two decades, while drug consumption has also grown rapidly.

Considering the high rates of inflation and unemployment in the country, the authorities are struggling to cope with the expense of healthcare, which will have an effect on the future of the healthcare policy. However, Iran's total fertility rate (the average number of children a woman will have in her lifetime) has been falling sharply, from above 6.0 in the early 1980s to below 2.1 (the replacement level) by the early 2000s. It stood at 1.77 in 2010. This is likely to gradually reduce population pressure in Iran.

We estimate that Iran has only around one doctor per thousand population. The government is attempting to improve the situation through the funding of various educational schemes, although the wider economic situation will have a bearing on the outcome. The government has attempted to redress the shortage of rural

doctors and rural health care in general through investment in rural health centres and by offering incentives for doctors who practice in deprived regions for more than five years.

Key Risks To BMI's Forecast Scenario

Iran's pharmaceutical market continues to be influenced by the country's more general economic, political and social issues. We expect that Iranian economic expansion over the coming years will be weighed down in part by the effect of subsidy phase-outs and international sanctions over the country's political stance. While latest developments point to a notable improvement in relations between Iran and the West, a major breakthrough in negotiations on the Islamic Republic's nuclear programme appears off the cards for the time being. Furthermore, the declaration of the Islamic State (IS) in neighbouring Iraq and Syria threatens to heighten regional instability.

The Iranian economy is characterised by inefficiency, with private enterprise largely confined to small trading and service businesses. Iran's economic development remains closely linked to the oil sector, despite efforts to expand other industries. Indeed, the reliance on oil and gas revenues for healthcare finances makes the budget vulnerable to any major downturns in the price of those natural resources, especially in the face of a strained political situation in the country.

In the meantime, our forecasts for the Iranian pharmaceutical market are at risk due to the economic situation and financial sanctions. Specifically, new sanctions on Iran's banks are severely inhibiting the country's ability to pay for essential humanitarian goods, including medicines. These difficulties have already resulted in certain medicines not being imported to Iran, posing risks to the forecast values of the overall market (given that the market is reliant on imports of patented medicines) and pharmaceutical imports. At the same time, rampant inflation will make imports of APIs more expensive, potentially pricing domestically-made drugs out of reach for the majority of the population.

Currency fluctuations make our forecasted growth rates subject to change as import prices tend to rely on the US dollar rate. The Central Bank of Iran undertook a de facto devaluation of the rial in the official market in July 2013. The value of the unit will probably drop in unregulated market transactions as a result, while prices are likely to spike, ensuring that consumer price inflation remains elevated in 2013. In a sign of ongoing economic stress, the Central Bank of Iran (CBI) listed the price of the rial to IRR24,779/USD on its website on July 6 2013, compared to the previous official rate of IRR12,260/USD. The central bank did not issue any statement explaining the change. Iranian Mehr and ISNA news agencies said that the rate would replace the previous official rate.

The government's desire to diversify the economy away from the oil sector has resulted in another privatisation drive. Currently, around 80% of the economy is owned by the state, but the authorities are looking to sell off up to 80% of government-run companies, although this will require a constitutional amendment. Pharmaceutical companies - especially in the drug import sector - are expected to be included in this initiative, although **BMI** cautions that previous attempts to sell state assets have met with little interest, due to the country's poor business environment.

Iran's attempts to join the WTO will hinge on the country's willingness to accept international obligations with regards to IP rights. That local companies are to begin production of products patented by multinationals will further dent Iran's chances of succeeding in joining the organisation, although they may serve to improve trade outflows beyond the forecasts. Delays will have a negative effect on foreign investment in the country, with companies (as a longer-term scenario) also potentially withdrawing their products from the local market, or deciding to boycott the country in terms of new launches.

Macroeconomic Forecasts

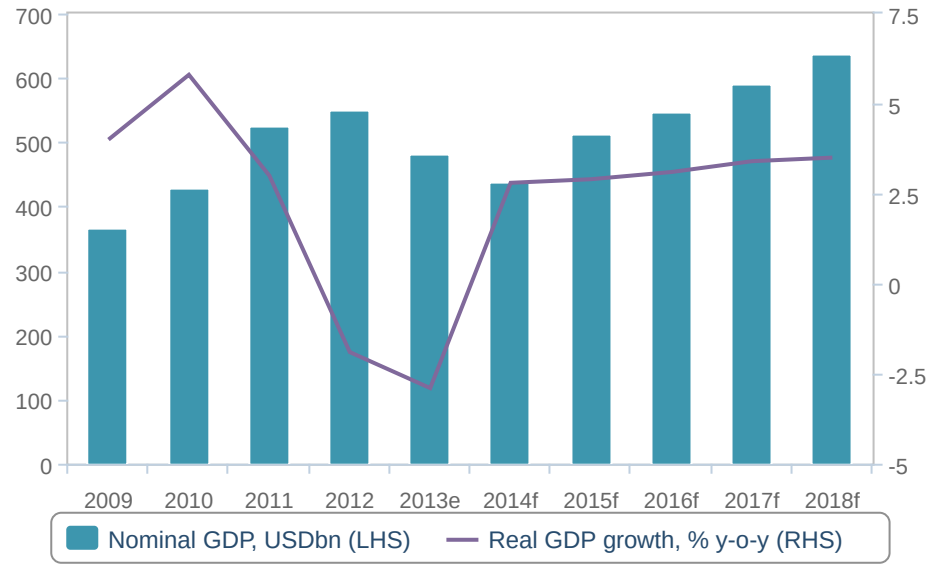
Economic Analysis

BMI View: *The Iranian economy will expand modestly over the coming years, and we project real GDP growth of 2.8% and 2.9% in 2014 and 2015, respectively. Foreign direct investment by Western companies will remain minimal next year owing to the failure to reach a breakthrough in talks on the nuclear programme.*

The Iranian economy will expand slowly in 2015 as talks on the nuclear programme continue without reaching a breakthrough, and project real GDP growth of 2.8% and 2.9% in 2014 and 2015 respectively, from our estimate of a 2.9% contraction in 2013.

Sanctions Remaining Key Constraint To Growth

Iran - GDP



e/f = BMI estimate/forecast. Source: BMI, UN

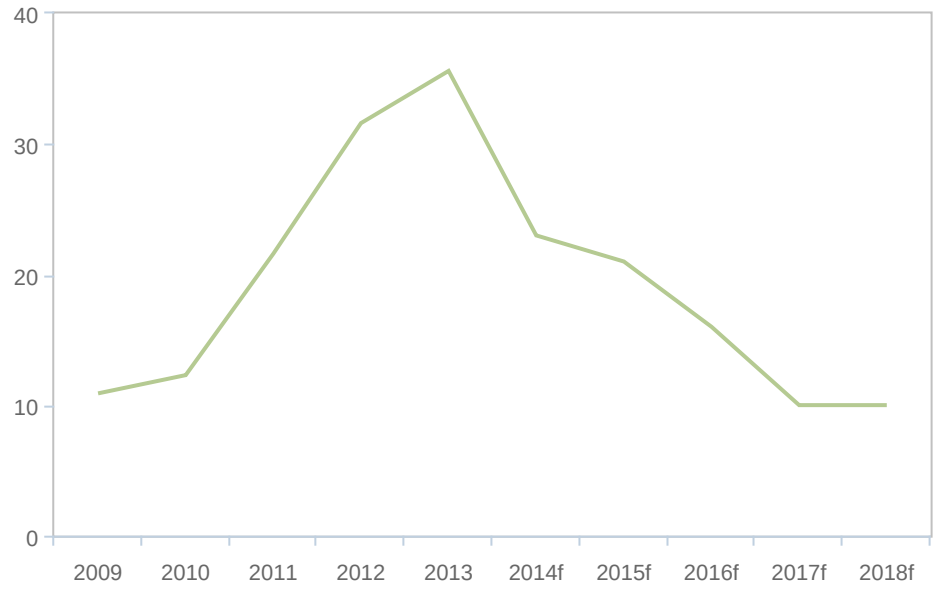
International sanctions on the Islamic Republic's nuclear programme will continue to damage the country's economic outlook over the next quarters. We do not foresee a breakthrough in talks between the P5+1 countries (United States, Russia, China, United Kingdom, France and Germany) and Iran in 2015 following

an interim agreement signed in November 2013, and oil and banking sanctions will be only marginally eased. Moreover, while we expect President Hassan Rouhani's administration to undertake significant efforts to reform to the economy, the effects will be limited by a persistently opaque business environment, domestic resistance to opening up the economy and the slow political process. We project real GDP growth to average 3.1% over the 2014-18 period, compared to 1.6% over 2009-13.

Private Consumption Outlook: Consumer spending will remain modest over the coming quarters, and we expect expansion of 3.5% and 4.0% in 2014 and 2015 respectively. The inflationary environment will improve, but persistently elevated price pressures will continue to hit purchasing power. We project consumer price index (CPI) inflation to average 23.0% in FY2014/15 (fiscal year running from March 21 2014 to March 20 2015) and 21.0% in FY2015/16, compared with 35.6% in FY2013/14. Moreover, the government will be unable to increase current spending significantly in 2015, as it seeks to improve its fragile fiscal position by cutting subsidies and limiting previously universal cash subsidies to only low-income families (*see 'Inflationary Environment Improving In 2015', September 18*). The failure to reach a breakthrough in nuclear talks will also somewhat temper confidence in the economy among domestic and international investors.

Decline Not Enough To Stimulate Consumption

Iran - Consumer Price Index Inflation, % chg, ave

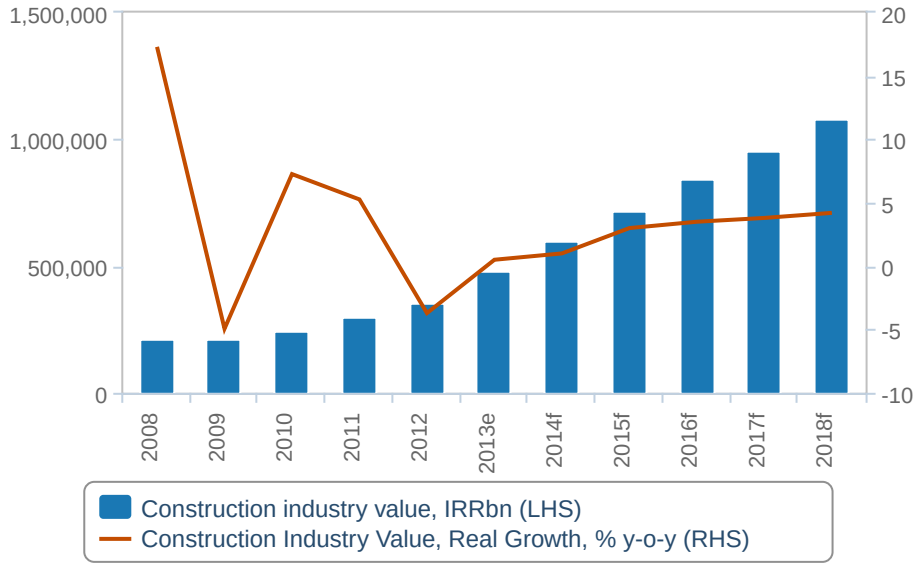


f= BMI forecast. Source: BMI, Central Bank of Iran, Bloomberg

Government Spending Outlook: Spending on the healthcare, education and services sectors will be subdued over the coming quarters owing to the executive's efforts to tighten fiscal spending. This is not to say that the government will cut on spending on public services, as it seeks to maintain popular support to its rule. As an illustration, the Iranian Ministry of Energy signed an agreement with local water and sewage utility **ABFA** at the beginning of September to develop seven water and wastewater management projects for the value of IRR9.5trn (USD310mn). We project government consumption increasing by 0.5% in 2014 and 1.5% in 2015.

High Demand Triggering Expansion

Iran - Construction Industry

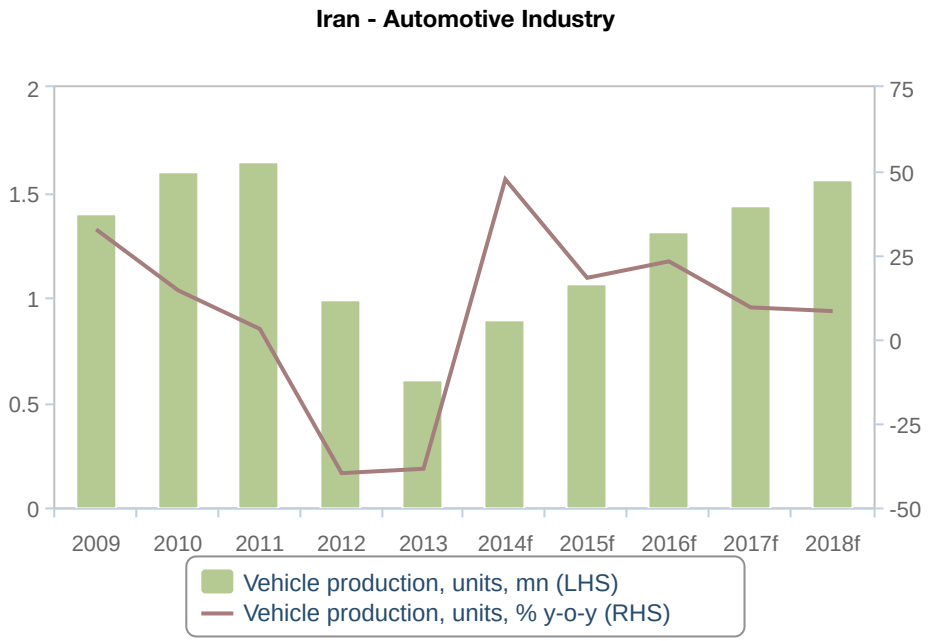


e/f = BMI estmate/forecast. Source: BMI, National sources

Fixed Investment Outlook: Capital formation growth will gradually accelerate over the next quarters, which we project to expand by 3.5% in 2014 and 5.0% in 2015. **BMI**'s Infrastructure research team holds a relatively positive outlook for the construction sector, which we project to expand by an average of 4.7% over the next five years, from 0.9% growth in 2014. The gradual increase in the expansion of the segment will result from a partial easing of economic sanctions, low base effects, increasing interest from foreign players and a high demand for infrastructure projects.

The automotive sector will remain a key beneficiary of the interim agreement reached in November 2013 between Tehran and the P5+1, when sanctions for the imports of auto parts were eased. Total production by local car manufacturers reached 399,846 units during the first five months of the current calendar year, a 72% y-o-y increase, and our Autos research team expects robust expansion in the industry over the coming quarters.

Benefitting From Interim Nuclear Agreement

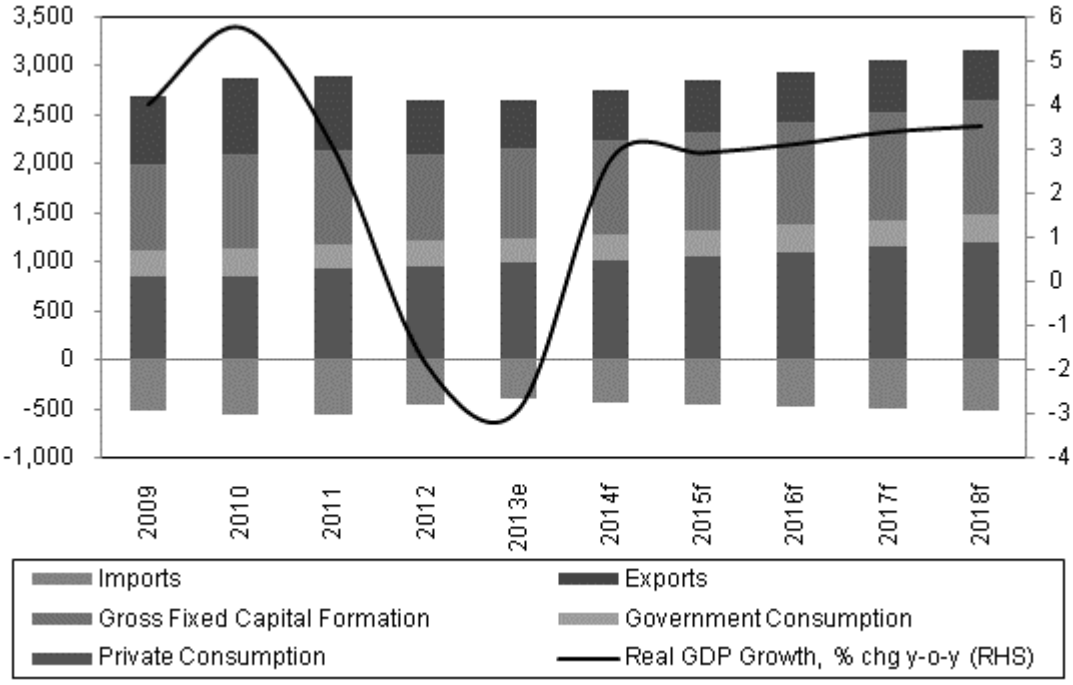


f = BMI forecast. Souce: IVMA, BMI

A host of factors will hinder a more rapid expansion of fixed investment. Foreign companies in nearly every sector have recently expressed interest in returning to the Iranian market, but we believe that Western companies will be unable to undertake major investment in the country due to the sanctions regime. Another key impediment will be Iran's difficult operational environment, with high levels of bureaucracy providing a significant barrier to trade and the utilities infrastructure struggling to meet demand. Iran scores poorly overall in the **BMI** Operational Risks Index, with 41.5 out of 100 ranking the country 13th out of 18 states in the MENA region.

Slow Growth In The Coming Five Years

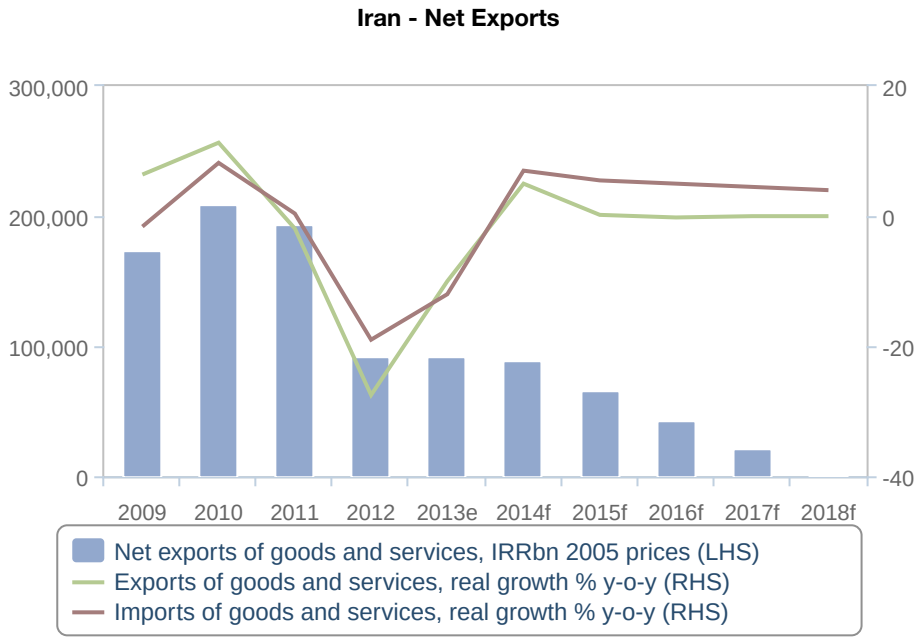
Iran - Components Of GDP (IRRtrn) & Real GDP Growth



e/f = BMI estimate/forecast. Source: United Nations, BMI

Chinese and Russian firms will remain the main contributors to foreign direct investment in 2015. In particular, Russian firms have recently expressed strong interest in the Iranian market, reflecting improving relations between Tehran and Moscow. Russia will become an increasingly important economic partner over the coming years, even as the majority of projects will not come to completion due to technical and logistical challenges. On September 9, Iran and Russia entered an agreement to collaborate in the oil sector; according to Russian Energy Minister Alexander Novak, Moscow is ready to carry out USD90.0bn worth of projects in Iran. In the same month, a memorandum was signed between unspecified Russian and Iranian firms for the construction of a pipeline stretching from Iranshahr to Chabahar in south eastern Iran, for an investment of approximately USD0.7bn.

Surplus Narrowing Steadily

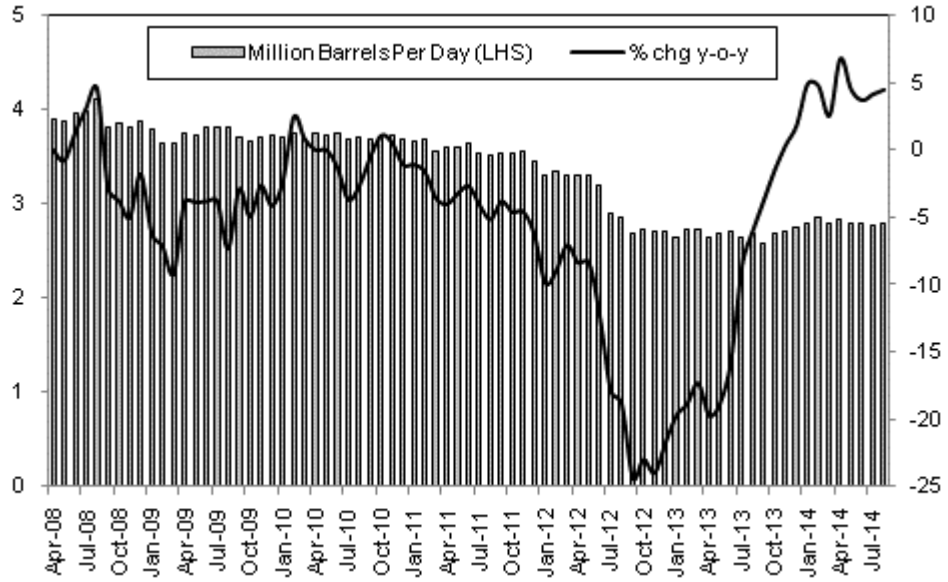


e/f = BMI estimate/forecast. Source: BMI, UN

Net Exports: We project the net exports surplus to narrow significantly over the next five years. Export growth will slow in 2015 owing to a deceleration in energy production - oil exports accounted for 70.0% of total exports in 2012 - and we project total export growth of 5.0% in 2014 and 0.2% in 2015. According to the International Energy Agency, total oil production expanded by 4.5% y-o-y in August, compared with a 10.6% decline in 2013. Low base effects and an uptick in condensates exports - which are not subject to international sanctions - will lead to an acceleration of energy export growth this year. We are pessimistic that large-scale projects which could boost oil and gas supply will come online in 2015, and the sanctions regime will continue to hinder the hydrocarbons industry.

Production On The Mend...

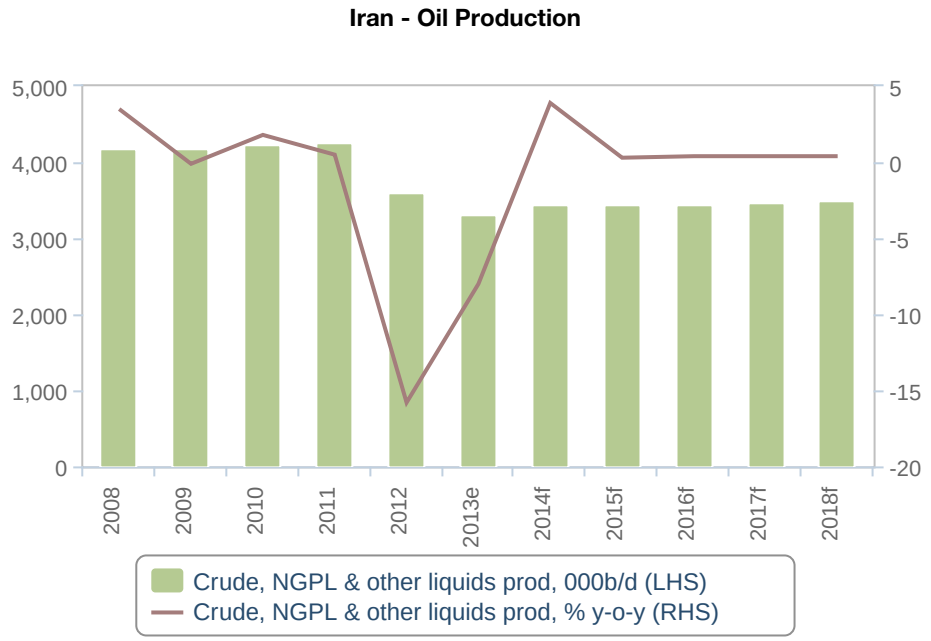
Iran - Oil Production



e/f = BMI estimate/forecast. Source: EIA, BMI

The medium-term outlook for exports is also uninspiring. We project total exports to remain virtually flat over the 2014-2018 period, as rapidly increasing energy consumption will result in a decline of hydrocarbons export growth.

...But Five-Year Outlook Uninspiring



e/f = BMI estimate/forecast. Source: EIA, BMI

A weak rial will lead to subdued import growth in 2015. Moreover, the country's dependence on imported fuels has decreased over the past few quarters owing to refining capacity expansions and fuel subsidy cuts implemented in April, and our Oil & Gas research team expects a slight decrease or stagnation in fuel demand over Q414 and early 2015 (*see 'On The Cusp Of Refined Fuels Independence' September 11*). We forecast total import growth of 7.0% and 5.5% in 2014 and 2015, respectively.

Table: Economic Activity (Iran 2009-2018)

	2009	2010	2011e	2012e	2013e	2014f	2015f	2016f	2017f	2018f
Nominal GDP, USDbn	365.7	429.4	527.3	550.6	481.6	428.7	477.4	515.7	541.0	571.0
Real GDP growth, % y-o-y	4.0	5.8	3.0	-1.9	-2.9	2.8	2.9	3.1	3.4	3.5
GDP per capita, USD	4,972	5,766	6,991	7,204	6,217	5,462	6,006	6,409	6,644	6,933
Population, mn	73.5	74.5	75.4	76.4	77.4	78.5	79.5	80.5	81.4	82.4
Unemployment, % of labour force, eop	12.0	13.5	13.3	13.1	13.0	11.0	10.0	10.0	10.0	10.0

e/f = BMI estimate/forecast. Source: UN, BMI

Industry Risk Reward Ratings

Middle East & Africa Risk/Reward Index

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 Q115 RRIs, the Middle East and Africa scores 42 out of 100, comparing poorly against Western Europe (68), Asia Pacific (53), Central and Eastern Europe (51) and the Americas (50).

The indicators used to assess the attractiveness of a pharmaceutical market are now visible, improving the transparency of the rating 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%.

Q115 Middle East And Africa Pharmaceutical Risk/Reward Index

Rewards And Risks Scores

	Industry Rewards	Country Rewards	Rewards	Industry Risks	Country Risks	Risks	RRR	Ranking
Weighting	44	21	65	21	14	35	100	
Saudi Arabia	29.6	12.8	42.4	7.7	9.7	17.4	59.8	1
UAE	23.2	11.0	34.2	14.7	9.7	24.4	58.6	2
Kuwait	21.6	14.6	36.2	14.0	8.3	22.3	58.5	3
South Africa	25.2	10.5	35.7	11.2	9.3	20.5	56.2	4
Israel	22.0	15.8	37.8	9.5	8.5	18.0	55.8	5
Qatar	19.6	13.8	33.4	11.9	10.2	22.1	55.5	6
Lebanon	21.2	16.2	37.4	9.5	7.9	17.3	54.7	7
Bahrain	16.4	11.3	27.7	13.3	10.3	23.6	51.3	8
Algeria	24.0	12.8	36.8	5.6	6.9	12.5	49.3	9
Oman	17.2	13.0	30.2	10.5	8.6	19.1	49.3	10
Jordan	14.8	13.8	28.6	9.8	7.8	17.6	46.2	11
Mauritius	15.2	9.0	24.2	11.2	10.2	21.4	45.6	12
Egypt	18.4	9.9	28.3	6.3	7.3	13.6	41.9	13
Iran	18.8	11.0	29.8	5.6	6.1	11.7	41.5	14
Morocco	12.0	10.7	22.7	10.5	7.9	18.4	41.1	15
Namibia	15.2	9.6	24.8	7.7	8.3	16.0	40.8	16
Iraq	18.8	12.2	31.0	5.6	3.9	9.5	40.5	17
Kenya	16.0	9.0	25.0	7.7	6.8	14.5	39.5	18
Gabon	11.6	14.1	25.7	6.3	7.0	13.3	39.0	19
Botswana	12.8	9.7	22.5	7.7	8.1	15.8	38.3	20
Nigeria	15.6	11.4	27.0	4.2	5.9	10.1	37.1	21
Angola	12.8	12.2	25.0	4.2	4.1	8.3	33.3	22
Uganda	11.6	8.2	19.8	6.3	7.0	13.3	33.1	23
Tanzania	10.4	9.0	19.4	6.3	7.2	13.5	32.9	24
Cameroon	11.6	10.9	22.5	4.9	5.2	10.1	32.6	25
Zambia	9.2	10.6	19.8	6.3	6.2	12.5	32.3	26
Ghana	4.4	10.4	14.8	7.0	8.9	15.9	30.7	27
Mozambique	9.2	9.3	18.5	4.9	6.1	11.0	29.5	28
Zimbabwe	11.6	10.6	22.2	2.8	4.0	6.8	29.0	29
Sudan	11.6	8.8	20.4	4.2	4.1	8.3	28.7	30
Cote d'Ivoire	9.2	10.9	20.1	2.8	5.2	8.0	28.1	31
Regional Average	15.8	11.4	27.2	7.7	7.3	15.1	42.3	

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 Q115, Saudi Arabia is ranked as the most attractive market in the Middle East and Africa region (scoring 59.8 out of 100), followed by the UAE (58.6) and Kuwait (58.5). In the same quarter, Cote d'Ivoire is ranked as the least attractive market in the Middle East and Africa (scoring 28.1 out of 100), followed by Sudan (28.7) and Zimbabwe (29.0).

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 rating system, Saudi Arabia scores a total of 42.4 out of 65, the highest score in subsector. Saudi Arabia's score is boosted by the country's large drug market (market expenditure score of 14.0 out of 20) and 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, Mozambique scores a total of 18.5 out of 65, the lowest score in the subsector.

Q115 Middle East And Africa Pharmaceutical Rewards

Industry Rewards And 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
Saudi Arabia	14.0	6.0	9.6	29.6	7.2	1.6	4.0	12.8	42.4
UAE	10.0	6.0	7.2	23.2	7.2	0.8	3.0	11.0	34.2
Kuwait	6.0	7.2	8.4	21.6	8.0	1.6	5.0	14.6	36.2
South Africa	12.0	3.6	9.6	25.2	5.6	2.4	2.5	10.5	35.7
Israel	10.0	6.0	6.0	22.0	8.0	4.8	3.0	15.8	37.8
Qatar	4.0	6.0	9.6	19.6	8.0	0.8	5.0	13.8	33.4
Lebanon	8.0	7.2	6.0	21.2	7.2	4.0	5.0	16.2	37.4
Bahrain	2.0	6.0	8.4	16.4	7.2	1.6	2.5	11.3	27.7
Algeria	12.0	3.6	8.4	24.0	6.4	2.4	4.0	12.8	36.8
Oman	4.0	4.8	8.4	17.2	6.4	1.6	5.0	13.0	30.2
Jordan	4.0	4.8	6.0	14.8	7.2	1.6	5.0	13.8	28.6
Mauritius	2.0	4.8	8.4	15.2	4.0	4.0	1.0	9.0	24.2
Egypt	10.0	2.4	6.0	18.4	4.0	2.4	3.5	9.9	28.3
Iran	8.0	1.2	9.6	18.8	5.6	2.4	3.0	11.0	29.8
Morocco	6.0	2.4	3.6	12.0	4.8	2.4	3.5	10.7	22.7
Namibia	2.0	4.8	8.4	15.2	4.0	1.6	4.0	9.6	24.8
Iraq	8.0	2.4	8.4	18.8	5.6	1.6	5.0	12.2	31.0
Kenya	4.0	1.2	10.8	16.0	2.4	1.6	5.0	9.0	25.0
Gabon	2.0	3.6	6.0	11.6	7.2	2.4	4.5	14.1	25.7
Botswana	2.0	3.6	7.2	12.8	5.6	1.6	2.5	9.7	22.5
Nigeria	6.0	1.2	8.4	15.6	4.8	1.6	5.0	11.4	27.0
Angola	2.0	1.2	9.6	12.8	5.6	1.6	5.0	12.2	25.0
Uganda	2.0	1.2	8.4	11.6	1.6	1.6	5.0	8.2	19.8
Tanzania	2.0	1.2	7.2	10.4	2.4	1.6	5.0	9.0	19.4
Cameroon	2.0	1.2	8.4	11.6	4.8	1.6	4.5	10.9	22.5
Zambia	2.0	1.2	6.0	9.2	4.0	1.6	5.0	10.6	19.8
Ghana	2.0	1.2	1.2	4.4	4.8	1.6	4.0	10.4	14.8
Mozambique	2.0	1.2	6.0	9.2	3.2	1.6	4.5	9.3	18.5
Zimbabwe	2.0	1.2	8.4	11.6	4.0	1.6	5.0	10.6	22.2
Sudan	2.0	1.2	8.4	11.6	3.2	1.6	4.0	8.8	20.4
Cote d'Ivoire	2.0	1.2	6.0	9.2	4.8	1.6	4.5	10.9	20.1
Regional Average	5.0	3.3	7.5	15.8	5.3	2.0	4.1	11.4	27.2

Scores out of 100, with 100 highest. Source: BMI

With regard 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 rating system, Zimbabwe scores a total of 6.8 out of 35, the lowest score in 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 24.4 out of 35, the highest score in the subsector, making it the least risky proposition for pharmaceutical product launch.

Q115 Middle East And Africa Pharmaceutical Risks

Industry Risks And 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
Saudi Arabia	2.1	2.8	2.8	7.7	2.1	2.4	2.7	1.8	0.7	9.7	17.4
UAE	5.6	3.5	5.6	14.7	2.2	2.7	1.8	1.7	1.3	9.7	24.4
Kuwait	4.2	4.2	5.6	14.0	1.8	2.1	1.5	1.7	1.3	8.3	22.3
South Africa	3.5	4.2	3.5	11.2	2.4	1.8	1.8	1.8	1.5	9.3	20.5
Israel	2.1	3.9	3.5	9.5	2.4	2.1	1.3	1.8	0.9	8.5	18.0
Qatar	4.9	3.5	3.5	11.9	1.6	2.7	2.6	2.0	1.3	10.2	22.1
Lebanon	3.2	2.8	3.5	9.5	2.1	2.1	1.5	1.3	0.9	7.9	17.3
Bahrain	4.9	3.5	4.9	13.3	2.3	2.7	2.3	2.0	1.1	10.3	23.6
Algeria	2.1	1.4	2.1	5.6	1.9	1.8	1.7	1.0	0.5	6.9	12.5
Oman	4.2	3.5	2.8	10.5	1.9	2.4	1.5	1.7	1.2	8.6	19.1
Jordan	3.5	2.8	3.5	9.8	2.0	2.4	1.0	1.4	1.1	7.8	17.6
Mauritius	3.5	4.2	3.5	11.2	2.0	2.7	2.0	1.9	1.5	10.2	21.4
Egypt	2.8	2.1	1.4	6.3	2.0	1.8	1.7	1.3	0.5	7.3	13.6
Iran	0.7	2.8	2.1	5.6	1.9	2.1	1.1	1.0	0.0	6.1	11.7
Morocco	4.9	2.1	3.5	10.5	1.9	2.1	1.8	1.3	0.7	7.9	18.4
Namibia	2.1	2.8	2.8	7.7	1.8	2.1	1.3	1.7	1.5	8.3	16.0
Iraq	2.1	1.4	2.1	5.6	1.6	0.9	0.5	0.7	0.2	3.9	9.5
Kenya	2.1	2.8	2.8	7.7	1.9	2.1	1.2	1.1	0.6	6.8	14.5
Gabon	2.1	2.8	1.4	6.3	1.9	2.7	1.0	0.8	0.6	7.0	13.3
Botswana	2.8	2.8	2.1	7.7	1.2	2.7	1.4	1.5	1.4	8.1	15.8
Nigeria	0.7	2.1	1.4	4.2	1.6	1.8	1.0	1.1	0.4	5.9	10.1
Angola	1.4	1.4	1.4	4.2	1.6	1.2	0.3	0.6	0.4	4.1	8.3
Uganda	2.1	2.1	2.1	6.3	2.0	1.8	1.5	1.0	0.7	7.0	13.3
Tanzania	2.1	2.1	2.1	6.3	1.9	2.1	1.1	1.2	0.9	7.2	13.5
Cameroon	2.1	1.4	1.4	4.9	1.6	1.8	0.6	0.7	0.5	5.2	10.1
Zambia	1.4	2.8	2.1	6.3	1.4	1.5	1.2	1.2	0.9	6.2	12.5
Ghana	2.8	2.1	2.1	7.0	2.0	2.4	1.5	1.6	1.5	8.9	15.9
Mozambique	2.1	1.4	1.4	4.9	1.4	2.4	0.7	0.8	0.8	6.1	11.0
Zimbabwe	0.7	1.4	0.7	2.8	1.0	0.9	0.9	0.8	0.4	4.0	6.8
Sudan	0.7	1.4	2.1	4.2	0.9	0.9	1.3	0.8	0.1	4.1	8.3
Cote d'Ivoire	0.7	1.4	0.7	2.8	1.4	1.5	1.0	0.6	0.6	5.2	8.0
Regional Average	2.6	2.6	2.6	7.7	1.8	2.0	1.4	1.3	0.8	7.3	15.1

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.

Q115 Middle East And Africa Pharmaceutical Risk/Reward Index

Rewards And Risks Scores As A Percentage Of The Maximum Score

	Industry Rewards	Country Rewards	Rewards	Industry Risks	Country Risks	Risks	RRR	Ranking
Saudi Arabia	67	61	65	37	69	50	60	1
UAE	53	52	53	70	69	70	59	2
Kuwait	49	70	56	67	59	64	59	3
South Africa	57	50	55	53	66	58	56	4
Israel	50	75	58	45	61	51	56	5
Qatar	45	66	51	57	73	63	56	6
Lebanon	48	77	58	45	56	49	55	7
Bahrain	37	54	43	63	74	67	51	8
Algeria	55	61	57	27	49	36	49	9
Oman	39	62	46	50	61	55	49	10
Jordan	34	66	44	47	56	50	46	11
Mauritius	35	43	37	53	73	61	46	12
Egypt	42	47	44	30	52	39	42	13
Iran	43	52	46	27	44	33	42	14
Morocco	27	51	35	50	56	52	41	15
Namibia	35	46	38	37	59	46	41	16
Iraq	43	58	48	27	28	27	40	17
Kenya	36	43	38	37	49	41	40	18
Gabon	26	67	40	30	50	38	39	19
Botswana	29	46	35	37	58	45	38	20
Nigeria	29	58	38	20	29	24	33	21
Angola	26	39	30	30	50	38	33	22
Uganda	24	43	30	30	52	39	33	23
Tanzania	26	52	35	23	37	29	33	24
Cameroon	21	50	30	30	44	36	32	25
Zambia	10	50	23	33	64	46	31	26
Ghana	26	50	34	13	29	20	29	27
Mozambique	26	42	31	20	29	24	29	28
Zimbabwe	21	52	31	13	37	23	28	29
Sudan	35	54	42	20	42	29	37	30
Cote d'Ivoire	21	44	28	23	43	31	29	31
Regional Average	36	54	42	37	52	43	42	

Scores out of 100, with 100 highest. Source: BMI

Iran Risk/Reward Ratings

BMI considers Iran's business environment to be slightly less appealing than the previous quarter, with a score of 41.5 out of 100 in Q115, unchanged from the previous quarter. Due to reappraisals of the scores of other countries, Iran's position in the regional rankings improved three places in the regional rankings to 14th out of 30 countries in the Middle East and Africa in Q115. Its overall score is below the regional average of 42.3. Generally speaking, Iran benefits from a large and growing population and relatively widespread access to healthcare services. However, its regulatory regime - including intellectual property (IP) rights, political and economic situation - is highly questionable. Consequently, the country performs above the regional average for potential rewards and below the regional average in terms of risk.

Rewards

Industry and Country Reward scores are weighted and combined to form the Rewards indicator. Iran's score of 29.8 remains more favourable than the regional average.

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 MEA peers.

Risks

Industry and Country Risks are weighted and combined to form the score for the Risks indicator. Iran's score is among the lowest in the table (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.

Industry Risks: Industry Risk refers to a subjective assessment of the country's IP 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.

Market Overview

Iran's pharmaceutical market is developing. Access to basic healthcare is widespread, reaching about 90% of the rural population and almost the entire urban population. The use of locally produced generic drugs is widespread, especially in the government healthcare sector. Furthermore, self-medication is common among the population, creating a strong (if not always legitimate) over-the-counter (OTC) drug market. **BMI** estimates that the total market was worth IRR44,216bn (USD2.5bn) in 2013, with OTC medicines accounting for around 10-15% of the market by value.

Data from the Iranian DARU Journal of Pharmaceutical Sciences confirm **BMI**'s view that pharmaceutical imports as a proportion of total pharmaceutical sales have been increasing over the last decade. According to the publication, total finished pharmaceutical imports increased by 42% between 1997 and 2010, from USD15mn to USD1,226mn. The proportion of total pharmaceutical sales increased from 10% to 33%, while local production, forming the bulk of total pharmaceutical sales by value, increased less quickly, by 9.3% over the period from USD139mn to USD1,639mn, reducing its share of total sales from 90% to 66%.

The Iranian Ministry of Health and Medical Education (MOHME) believes the country's import reliance in 2010 was around 4% in volume terms and 35% in value terms. **BMI** believes that the trend within the country is that it has become more, not less, import dependent in value terms. Indeed, drugs imports in Iran increased by 40% month-on-month (m-o-m) to 1,540 tonnes, valued at USD119mn, in the eighth Iranian calendar month ended November 22 2013 according to Nasser Riahi, chairman of the Syndicate of Iranian Pharmaceutical Importers.

BMI believes Iran's actual pharmaceutical import reliance is 40-50%, although we stress that this is a market from which it is difficult to obtain reliable information. Nevertheless, if import dependence is high, average mark-up value will compensate for lower domestic manufacturing value. We are, therefore, confident that our values for Iran best reflect its market size and growth trajectory.

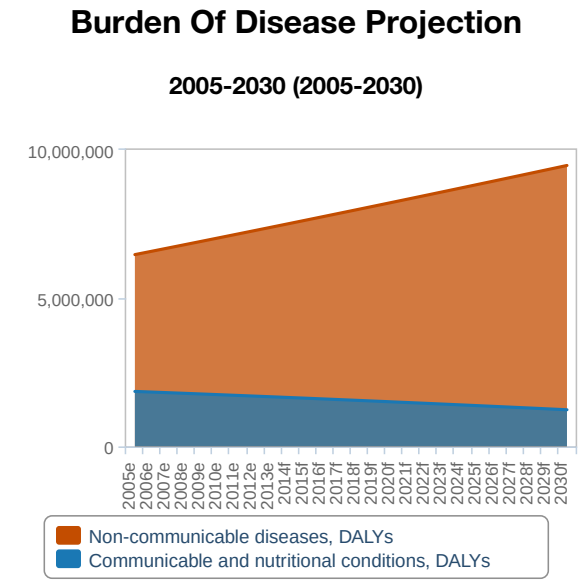
The Iranian pharmaceutical sector is made up of 89 local drugmakers and 93 pharmaceutical importers. Given the large number of local drugmakers, with the top 10 accounting for approximately 45% of the total consumption of locally produced medicines, the domestic industry is in need of consolidation. 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 that Cobel, Akbarieh and Behestan Darou stand to benefit the most from increased import reliance and that they will eliminate smaller players from the market.

Iran's business environment remains unattractive to overseas investors, hampering inflows of foreign direct investment (FDI). Particular issues that resonate strongly in the pharmaceutical industry include a lack of intellectual property protection and strict government price controls. Additionally, Iran's law does not allow any FDI unless it enters the country through a joint venture (JV) 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, according to a stock market disclosure.

Industry Trends And Developments

Epidemiology

According to **BMI**'s *Burden of Disease Database* (BoDD), the number of disability-adjusted life years (DALYs) lost to disease or injury in Iran is expected to increase from around 8.7mn in 2010 to over 10.7mn 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% year-on-year (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.



e/f = BMI estimate/forecast. Source: National Sources/BMI

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 of asthma and other respiratory illnesses rises, 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

According to health ministry figures cited by news agency ILNA in November 2009, at least 3,409 people in Iran died as a result of AIDS, while another 2,097 people had been diagnosed with the disease since the start of the year. The ministry stated that the most common way for HIV to be transmitted in the country was through the shared use of syringes to inject intravenous drugs. ILNA reported that nearly 20,130 people tested positive for HIV in Iran.

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 are an estimated 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 ARVs 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.

Table: HIV/AIDS Prevalence In Iran

	Estimated number of HIV cases
Adults (15-49)	66,000
Women (15-49)	11,000
Estimated number of deaths due to AIDS	1,600

Source: UNAIDS Global AIDS Report 2006

In December 2008, Iran Daily reported that Iran's Drugs Campaign Headquarters had spent USD20mn on HIV prevention over the previous five years. Some of this money was spent on Drugs Information Centres (DIC) and Methadone Maintenance Therapy (MMT) centres, which reportedly succeeded in containing the spread of HIV among drug users. Around the same time, a Unicef representative was reported as stating that AIDS in Iran is limited to high-risk groups, and confirmed that the authorities are addressing key sectors of society. The government ran a two-year National AIDS Programme (2008-2009), which received USD6.4mn in support from the UN in order to raise awareness of the disease.

These activities appear to be having an effect, and HIV/AIDS rates among drug addicts in the country have fallen by more than 50% in a year, according to local press reports in 2009. The reasons for this reduction remain unclear, with some observers claiming that it is primarily due to greater attempts to control the amount of addicts. More recent strategies have included the expansion of disease reduction centres, increased medical and treatment services for patients and their families and greater social protection for the infected population.

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. Since 2005, a rural insurance scheme has been 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 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 Zanjan 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.

Medical researchers and public-health officials have warned that tightening of already-strict international economic sanctions against Iran is resulting in the shortage of certain medicines, vaccines and other key medical supplies in the country. There is a severe shortage of many medicines, including antibiotics, drugs for leukaemia and thalassaemia, which has resulted in deaths of several children and adults in early November 2013, according to Ali Gorji, a neuroscientist at the University of Münster, Germany. The shortage has particularly affected drugs and vaccines used for treating and protecting infants, as well as supplies for diagnostic equipment, due to which lives are being put at risk, Gorji added.

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 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, to insure five million 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.

Private Iranian companies previously announced the construction of three healthcare clinics in Dushanbe in Tajikistan in February 2011, pending approval from the Tajik health ministry. The clinics will focus on eye disorders, plastic and reconstructive surgery, and kidney and urologic diseases. Iranian companies are looking to expand into neighbouring markets.

In January 2012, local press reported that a MoU was signed between the Iraqi government and an unnamed Iranian company. The deal covers the construction of a power station and a housing complex, as well as a 400-bed hospital in the Iraqi province of Wassit. The understanding should also lead to the employment of Iranian doctors to treat Iraqi patients in the new hospital.

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 Jazzayeri. 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

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 Iranian Deputy Health Minister for Research and Technology Mostafa 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 restricts 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.

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 limits the number of global markets to which the country's biotech firms can 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, a leading biotechnology company in Iran and the Middle East, 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 2007, Iran and Syria agreed to promote bilateral knowledge transfer in the biotechnology sector, which we believe initiated the evident rapid development of the MOHME. Local demand for speciality medicines, hormone-based treatments and vaccines has driven growth in the biotechnology sector, though it has come

at a cost, with the ministry also stating that purchasing foreign currency in order to import medicines was a significant expense.

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 entered 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 (JV) firm **Noavaran Tec Kish** with the Pasteur Institute. The JV 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.

Regulatory Development

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 pharmacoeconomics. 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.

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 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.

Generic Registration

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 NDL 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.

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.

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 And Reimbursement

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. 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.

Competitive Landscape

Pharmaceutical Sector

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 Mfg**.

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.

Local production satisfies more than 90% of the local demand in volume terms, but 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. 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 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.

As relations with the West improve, the willingness of multinational drugmakers to invest in Iran is likely to increase. Indeed, in December 2013 the Tehran Times reported that several multinational drugmakers were considering investments in Iran following a thaw in relations over the country's nuclear program. German pharmaceutical major **Merck** is considering partnering an Iranian drugmaker to manufacture drugs in the country. French drugmaker **Sanofi**, and German technology and service giant **Bosch** are also assessing whether to tap into pharmaceutical production opportunities in Iran according to the report. However, we stress that the political situation remains challenging and until issues are resolved, multinationals will largely remain wary of Iran.

Nevertheless, more sophisticated medicines remain sourced from abroad. The presence of multinationals is minimal, although **GlaxoSmithKline** (GSK), **Roche** and **Novo Nordisk** have been reported to be in the process of establishing manufacturing units in the country over the past few years. However, no concrete developments in this area have been reported for months, which is unsurprising given the international stances against the country's political agenda. Although US companies are officially boycotting trade with Iran, industry sources claim that they are increasing their presence and marketing activities in the country through their European subsidiaries.

The Iranian pharmaceutical market clearly presents 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.

Domestic Pharmaceutical Sector

Table: Leading Drug Manufacturers, Iranian Year To March 20, 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	Jaber 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 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.

Fifty-five 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.

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.

It was reported that between April and August 2013, Iranian pharmaceutical companies did not manufacture Thalassemia medicines citing Iranian Thalassaemia Society Head Mohammad Reza Mashhadi. Domestic pharmaceutical companies are meeting only 20-30% of their obligations, according to Mashhadi.

In recent years, Iranian pharmaceutical companies have produced versions of well known drugs domestically. In 2012, it was reported that domestic production of paciltaxel, a mitotic inhibitor used as drug for chemotherapy, had begun. This development is expected to save more than IRR140bn (USD11.5mn) a year for the country.

In March 2010, Iranian drug manufacturer **Soha Pharmaceuticals** reported that it had mass-produced generic copies of venflaxine and the antibiotic clindamycin. Whether these are approved generic versions is unclear. The new domestically produced drugs are also said to be cheaper than the imported ones, which in turn presents further opportunities for exports.

Similarly glatiramer acetate, an immunomodulator drug used for the treatment multiple sclerosis (MS) has been produced locally since 2012. In January 2013, the Fars News Agency, citing Haleh Hamedifar, manager of an Iranian drug manufacturing company, reported that Iran will 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. The Iranian authorities are registering the domestically produced MS drug in several other countries.

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 multiple sclerosis (MS). According to Osvah, the Iranian Health Ministry has issued the necessary licence for the production of fingolimod in the country. The drug is a

copy of Gilenya, produced by Novartis, which reached blockbuster status in 2012, when its global sales reached USD1.2bn.

At the same time, local players appear to be targeting foreign markets. Iran will set up a pharmaceutical plant in Indonesia in the near future, IRNA reported in September 2012. According to the Indonesian chairman of Iran-Indonesia Parliamentary Friendship Group, Ahmad Shahab, the Ministry of Health had requested the plant. He was speaking at a meeting with several officials from the Iranian health ministry. Shahad also highlighted the need to work on the MoU signed between the countries five years previously

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 Wholesale

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 are facing severe drug shortages due to a series of unilateral sanctions imposed by the US, the EU and their allies. These sanctions are indirectly affecting Iran's supply of medicines. Although countries, including the US, have not banned imports of medicines to Iran, they now require exporters to apply for a special licence. Other sanctions have made it impossible to transfer money through banks, indirectly jeopardising the health and lives of several Iranians. The sanctions were imposed as the EU, the US and other allies alleged Iran is pursuing non-civilian objectives in its nuclear energy programme.

The final straw for pharmaceutical importers, it seems, was the blacklisting of the Tejarat, the third-largest bank in Iran, in January 2012. This was the last remaining legal route for financial transactions with the country. This means drugmakers have been able to trade with Iranian companies under a humanitarian licence but they have been unable to receive payments or repatriate their earnings. 'Everything from aspirin to multivitamins, you name it, it's all jammed up,' said Cari Stinebower, an international trade lawyer with Crowell & Moring, in an interview with Reuters.

The Financial Times reported that the US Treasury's Office of Foreign Assets Control (OFAC) has made the commercial exporting or re-exporting of medicine to Iran subject to licensing requirements. However, even companies with a licence have reported problems. Importers said that, despite resorting to various, more expensive financial channels, such as changing from one European bank to another or using middlemen and unofficial transactions, medicines do not arrive on time or in sufficient quantities.

In fact, one importer said that, despite having a licence from OFAC, imports have dropped by more than half and it pays much more than before. Another importer said that the exemption of medicines from sanctions happens only in theory as international banks do not accept Iran's money for fear of facing US punishment, even though importing essential medicines was exempt from the financial sanctions in June 2012.

Representatives from US drugmakers Merck & Co and Pfizer have spoken to Reuters and reported problems in getting paid. Both companies have reiterated their commitment to continue to supply goods in the difficult economic climate. However, compared with European drugmakers, US drugmakers' exposure to Iran's pharmaceutical market is relatively small. The US was the 10th largest exporter of drugs to Iran and only accounted for 2.2% of total pharmaceutical imports in 2010.

European drugmakers, on the other hand, are likely to need to deal in larger sums and will, therefore, find it even harder to extract money from the country. The companies that will suffer most are the SMEs that do not have the capital to absorb the cash flow problems.

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, the number of pharmacies is currently in the region of 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.

More recently, Western sanctions imposed on Iran's nuclear programme have indirectly driven up the cost of drugs and treatment in the country. The sanctions have limited regular supplies to hospitals and pharmacies, which in turn has 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 has almost doubled. Although the sanctions do not block medicine and humanitarian supplies, damage from the sanctions is felt at almost every level of Iranian healthcare.

Company Profile
Amin Pharmaceutical Company

Strengths	▪ Product portfolio including both branded and generic medicines. ▪ Some indigenous R&D. ▪ One of the leading local producers of pharmaceuticals.
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. ▪ The company's growth is limited by the basic nature of its output, with it 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 for exports within the region.
Threats	▪ Unstable trade relationship with the West will potentially have a negative impact on the company's growth potential. ▪ Rampant inflation is hampering the company's ability to make future purchases of raw materials from abroad. ▪ Underdevelopment of the country's healthcare system is continuing to threaten domestic market potential.

Company Overview

Established in 1984 and producing medicines since 1990, Amin is a publicly listed manufacturer of around 90 ethical drugs, of both branded and generic varieties, as well as some nutritional supplements, such as B-complex and glucosamine sulphate. The major shareholders in the company are Kowsar Pharmaceutical Company and Pars Darou.

Currently, the company employs some 260 staff in discovery, development and marketing. Its key area of expertise is drug and supplement formulation. Of 88 pharmaceutical companies operating in Iran, Amin reports that it is the 21st largest in terms of revenue and 17th in terms of production.

Strategy

The company produces a variety of its own pharmaceuticals, while also working under licence for other players. The company has an in-house R&D team, working mostly on new formulations and dosages of existing medicines and bioavailability. Amin has the capacity to produce various formulations of medicines, including syrups, capsules and tablets. Its products belong to a number of therapeutic categories, from cardiovascular and CNS to herbal agents.

Recent Developments

Amin Pharma has been listed on the Tehran Stock Exchange (TSE) since 1996. In more recent years, the company achieved ISO 9001 standard (in 2008) and the OHSAS (Occupational Health and Safety Advisory Services) certification in safety and professional health (in 2007).

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Caspian Tamin Pharmaceutical Company

Strengths

- One of the leading local drug companies.
- Some indigenous R&D.
- Strong export portfolio.

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.

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 (IPDIC), 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 SSO (74.5%) and the Iran Social Security Investment Company (ISSIC) (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 the Tamin Pharmaceutical Investment Co. (TPICO), the country's leading pharmaceutical holding company.

The company's portfolio comprises 89 products, most of which are exported. 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.

Recent Developments

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

In February 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* (calcionin), *Pamidat* (pamidronate) and *Andron* (testosterone) to its portfolio.

At the start of 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.

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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 (JV) 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.
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 TSE, but the SSO 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 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.

Recent Developments

Darou Pakhsh has been developing the capabilities to supply blood plasma, and holds an Iranian plasmapheresis licence from the MHME. In 2004 the company formed the joint-venture Biodarou, with German pharmaceutical and diagnostics company Biotest holding a 49% share of the new group. The contract included the establishment of an initial total of three plasmapheresis stations and test laboratories in Iran.

In September 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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Exir Pharmaceuticals

Strengths	▪ One of the largest domestic drug manufacturers. ▪ Ability to innovate. ▪ Product portfolio includes OTCs.
Weaknesses	▪ Reliance on imported APIs. ▪ 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.
Threats	▪ Iran's political situation limiting FDI. ▪ 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 CEE markets including Armenia, Turkmenistan, Azerbaijan, Yemen, Afghanistan, Russia, Belarus and the Ukraine.

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

The company is listed on the TSE. The SSO, which controls 20 pharmaceutical companies in Iran, is a major stakeholder in Exir, through the DP Holding Company.

Strategy

In May 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, parts of Latin America and a number of African countries.

Recent Developments

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 2010, 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.

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GlaxoSmithKline

Strengths	▪ One of the largest global drug manufacturers. ▪ Ability to expand through acquisition as well as organically. ▪ Diverse product portfolio, including OTCs.
Weaknesses	▪ No local manufacturing presence. ▪ Iran's underdeveloped healthcare system. ▪ Counterfeiting remaining a major threat to innovative pharmaceuticals.
Opportunities	▪ Rising demand for innovative drugs, albeit in the longer term. ▪ Strong competition from other global players. ▪ Demographic profile prioritising chronic disease treatments.
Threats	▪ Rampant inflation in Iran is limiting revenue opportunities expressed in foreign currency. ▪ Iran's political situation limiting FDI, as well as financial transactions, with pharmaceutical importers largely unable to be compensated for deliveries. ▪ Difficulties securing adequate healthcare and pharmaceutical funding.

Company Overview	UK major GlaxoSmithKline (GSK) 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. GSK does not have an office in Iran.
Strategy	GSK is reportedly planning to set up a manufacturing unit (for the production of bronchodilator sprays and vaccines) near the city of Shiraz after receiving permission from the Ministry of Health and Medical Education. This would represent a strong signal

by the company, in terms of its longer-term commitment to the local and regional market. The company strengthened its vaccines unit through an asset swap with Novartis in April 2014. GSK will acquire Novartis' vaccines business in exchange for its oncology business.

Company Details

- www.gsk.com

Merck & Co

Strengths	▪ One of the largest global drug manufacturers. ▪ Ability to innovate. ▪ Diverse product portfolio, including OTCs.
Weaknesses	▪ No local manufacturing presence. ▪ Iran's underdeveloped healthcare system. ▪ Counterfeiting remaining a major threat to innovative pharmaceuticals.
Opportunities	▪ Rising demand for innovative drugs, albeit in the longer term. ▪ Strong competition from other global players. ▪ Demographic profile prioritising chronic disease treatments.
Threats	▪ Pending patent expirations. ▪ Country's focus on the development of pharmaceutical self-sufficiency. ▪ Iran's political situation limiting FDI, as well as financial transactions, with pharmaceutical importers largely unable to be compensated for deliveries. ▪ Rampant inflation in Iran is limiting revenue opportunities expressed in foreign currency. ▪ Difficulties securing adequate healthcare and pharmaceutical funding.

Company Overview	US-based Merck & Co is one of the leading global pharmaceutical companies. 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.

Strategy	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.
Company Details	▪ www.merck.ae

Novartis

Strengths	▪ One of the largest global drug manufacturers. ▪ Ability to innovate. ▪ Diverse product portfolio, including OTC and generic medicines.
Weaknesses	▪ No local manufacturing presence. ▪ Iran's underdeveloped healthcare system. ▪ Counterfeiting remaining a major threat to innovative pharmaceuticals.
Opportunities	▪ Rising demand for innovative drugs, albeit in the longer term. ▪ Strong competition from other global players. ▪ Demographic profile prioritising chronic disease treatments.
Threats	▪ Pending patent expirations. ▪ Iran's political situation limiting FDI, as well as financial transactions. ▪ Difficulties securing adequate healthcare and pharmaceutical funding.

Company Overview	Novartis is the leading Swiss manufacturer of prescription and consumer pharmaceuticals. The company offers generic drugs through its Sandoz subsidiary. 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).
Strategy	The company's iconoclastic approach to the industry has seen it expand into generic drugs. The progressive ageing of the population is increasing the need for medicines as well as the need to restrain healthcare costs, which supports demand for generic drugs. Novartis also recently engaged in an asset swap with GlaxoSmithKline (GSK), which saw Novartis acquire GSK's oncology business in exchange for its own vaccines unit.

Novartis is likely to remain wary of the political and economic situation in Iran, although it is likely to continue offering prescription medicines in key therapeutic areas, such as oncology.

Recent Developments

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 multiple sclerosis (MS). According to Osvah, the Iranian Health Ministry has issued the necessary licence for the production of fingolimod in the country.

Novartis has marketed the branded drug, *Gilenya* (fingolimod) since approval by the US FDA in September 2010. Subsequently, in early 2011, the innovative drug was approved in Europe, the UK and Canada. Gilenya's global sales reached USD1.2bn in 2012.

Company Details

- www.novartis.com

Pars Darou

Strengths

- One of the leading local drug companies.
- Some indigenous R&D.
- Antibiotics remain widely demanded in Iran.

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.
- 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 API 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 TSE, 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.

Recent Developments

The company's R&D department is currently working on between 35 and 40 new dosage forms. Pars Darou is also planning to expand capacity and production volume in order to meet domestic demand. Meanwhile, the firm is conducting partnerships with research institutes and universities in order to improve production techniques.

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Pfizer

Strengths	▪ The largest global drug manufacturer.
	▪ Ability to expand through acquisition.
	▪ Diverse product portfolio, including OTCs.
Weaknesses	▪ No local manufacturing presence.
	▪ Iran's underdeveloped healthcare system.
	▪ Counterfeiting remaining a major threat to innovative pharmaceuticals.
Opportunities	▪ Demographic profile prioritising chronic disease treatments.
	▪ Rising demand for innovative drugs, albeit in the longer term.
	▪ Strong competition from other global players.
Threats	▪ Iran's political situation is limiting FDI, as well as financial transactions, with pharmaceutical importers largely unable to be compensated for deliveries
	▪ Pending patent expirations.
	▪ Iran's focus on self-sufficiency in pharmaceutical supply.
	▪ Rampant inflation in Iran limiting revenue opportunities expressed in foreign currency.
	▪ Difficulties securing adequate healthcare and pharmaceutical funding.

Company Overview	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 GCC region.

Strategy	Iran is likely to remain of marginal interest to Pfizer, given the prevailing operating and political conditions. Some of Pfizer's medicines, such as *Viagra* (sildenafil) remain among the most commonly illegally copied and traded pharmaceuticals worldwide.
Company Details	▪ www.pfizer.com

Pharmieco

Strengths

- One of the leading exporters.
- Improvement in links between regional markets.
- Portfolio includes raw materials and finished products as well as pharmaceutical packaging materials.

Weaknesses

- 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.
- Around half of raw materials used in local production have to be imported, which makes local production vulnerable to exchange rate fluctuations.
- Limited reimbursement coverage.
- High inflation rates are raising the price of medicines out of reach for some consumers.
- Limited ability to innovate.

Opportunities

- Rising demand for generic medicines in the region.
- The company's portfolio is well-suited to prevailing epidemiological profile.
- Government support for the development of the local pharmaceutical industry.

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

Iran Pharmaceutical Industries Export Company (Pharmieco) was established through the co-operation of 17 large pharmaceutical manufacturers along with NIIO, an organisation with more than 400 affiliated manufacturers, in order to facilitate and promote the export of Iranian pharmaceutical products.

Strategy

The combined companies produce almost 700 pharmaceutical products. Pharmieco has registrations for these products and exports more than 500 of them to about 20 countries. Therapeutic areas include anti-infective agents, central nervous system (CNS) treatments, cardiovascular drugs, gastrointestinal drugs and respiratory tract medication. The company also manufactures more than 35 different APIs, with its product portfolio thus well suited to meet local demand. However, competition from larger players will continue to intensify, requiring further investment into manufacturing capacities and product mix. Nevertheless, Pharmieco may choose to concentrate on exports, which already account for a sizeable part of its activities.

Recent Developments

Since the establishment of Pharmieco, the Iranian industry has increased the supply of pharmaceuticals to the domestic market from 20% to 95%. Pharmaceutical plants have increased from 30 to 56 units and are expected to reach 86 units.

Financial Data

Pharmieco does not feature in the top-10 pharmaceutical players in the country. We estimate that its annual revenues in the country are in the region of USD30mn, with around twice as much achieved from exports.

Company Details

- Pharmieco
- No. 11 2nd St, Qasir Ave
  POB 11365-4478

  Tehran

  Iran
- Tel: +98 21 873 63 35
- Website: www.pharmieco.org

Sanofi

Strengths	▪ One of the largest global drug manufacturers.
	▪ Ability to expand through acquisition as well as organically.
	▪ Diverse product portfolio, including generic medicines and vaccines.
Weaknesses	▪ Iran's underdeveloped healthcare system.
	▪ Counterfeiting remaining a major threat to innovative pharmaceuticals.
Opportunities	▪ Rising demand for innovative drugs, albeit in the longer term.
	▪ Strong competition from other global players.
	▪ Demographic profile prioritising chronic disease treatments.
Threats	▪ Rampant inflation in Iran is limiting revenue opportunities expressed in foreign currency.
	▪ Iran's political situation is limiting FDI, as well as financial transactions, with pharmaceutical importers largely unable to be compensated for deliveries.
	▪ Difficulties securing adequate healthcare and pharmaceutical funding.

Company Overview	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.
Strategy	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.

Recent Developments

One of Sanofi's leading products, oncology drug *Taxotere* (docetaxel), is also one of the bestsellers on the Iranian market, in terms of value.

Company Details

- Sanofi Groupe Iran
- 18, 35th Str, Alvand Ave
  Argentine Sq

  Tehran

  15166-83511

  Iran
- Tel: +98 21 88 64 97 00
- Website: www.sanofi.com

Sina Darou Pharmaceutical Company

Strengths	▪ Leading local manufacturer of ophthalmic, nasal and topical preparations in Iran. ▪ International-standard production facilities. ▪ In-house R&D programme. ▪ Diversified production line including pharmaceuticals, OTCs, consumer health products and plastics.
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. ▪ 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 minimal, with major foreign company representation virtually non-existent. ▪ Government's focus on the development of local drug production. ▪ Large population and low drug consumption is providing considerable scope for expansion.
Threats	▪ Unstable trade relationship with the West will potentially have a negative impact on the company's growth potential. ▪ Rampant inflation is hampering the company's ability to make future purchases of raw materials from abroad. ▪ Underdevelopment of the country's healthcare system is continuing to threaten domestic market potential.

Company Overview

Sina Darou Pharmaceutical Company is one of the smaller local producers in Iran, employing 350 staff. It was established in 1962 under the name of Dopar Pharmaceutical Company. Since 2001, the company has been ISO 9001-certified - operating an 18,000m^2 facility in Tehran.

Sina Darou Pharmaceutical Company is the main manufacturer of ophthalmic, nasal and topical preparations in Iran, and it is a leader in the field of ophthalmic preparations. It has products registered in Afghanistan, Sri Lanka, Azerbaijan and Oman, and is in the process of gaining regulatory approval for exports to Iraq, Libya and Pakistan.

Sina Darou has collaborated with Italian drug manufacturer Chiesi Farmaceutici SpA (manufacturing its products under licence), a number of other European pharmaceutical producers, and with national universities and medical academies.

Strategy

As part of an expansion process, the company has renovated its production facilities. In terms of therapeutic areas, the company deals in antibiotics, corticosteroids, anaesthetics, anti-glaucomas, miotics, muscle relaxants, bronchodilators, anti-tussives, analgesics and anti-histaminic preparations. The company is preparing products containing latanoprost, an eye medication for glaucoma, and buserelin, a hormone. It also produces a consumer health range including shampoos and plastic packaging items.

Company Details

- Sina-Darou
- Makhsoos Karaj Rd
  15th km Iran Ave

  Tehran

  Iran
- Tel: +98 21 4419 45213
- Website: www.sina-darou.com

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.
- 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.

Recent Developments

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

Company Details

- Zahravi Pharmaceutical Co
- 8 Hoveyzeh Gharbi St

Shahid Abdolhamid

Saboonchi Ave, Shahid Dr Beheshti Ave

Tehran

15336

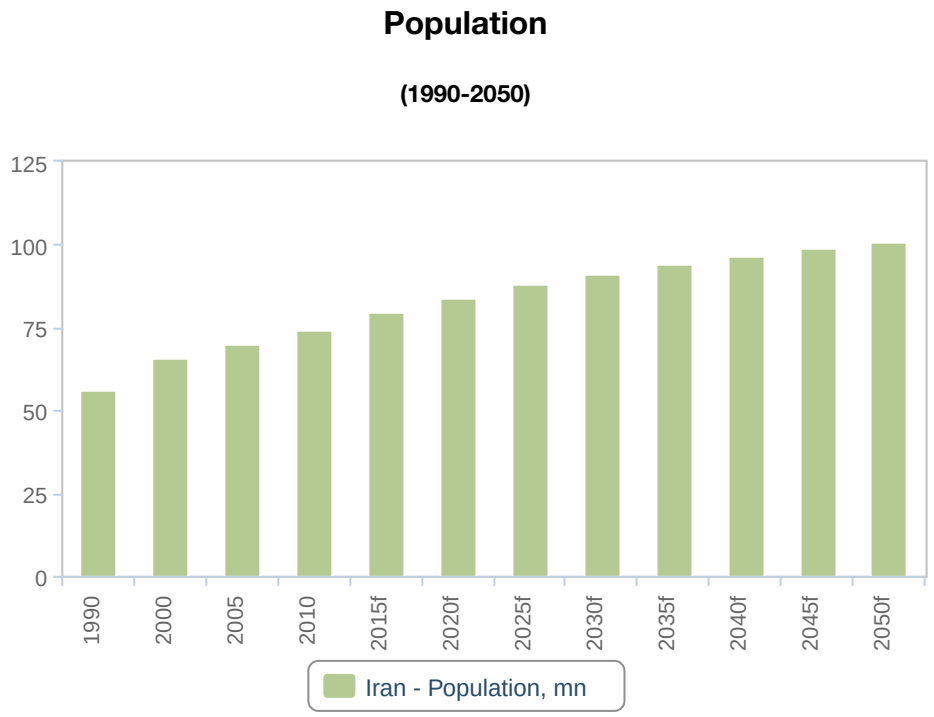
Iran

- Tel: +98 21 88756039
- Website: www.zahravipharma.com

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.

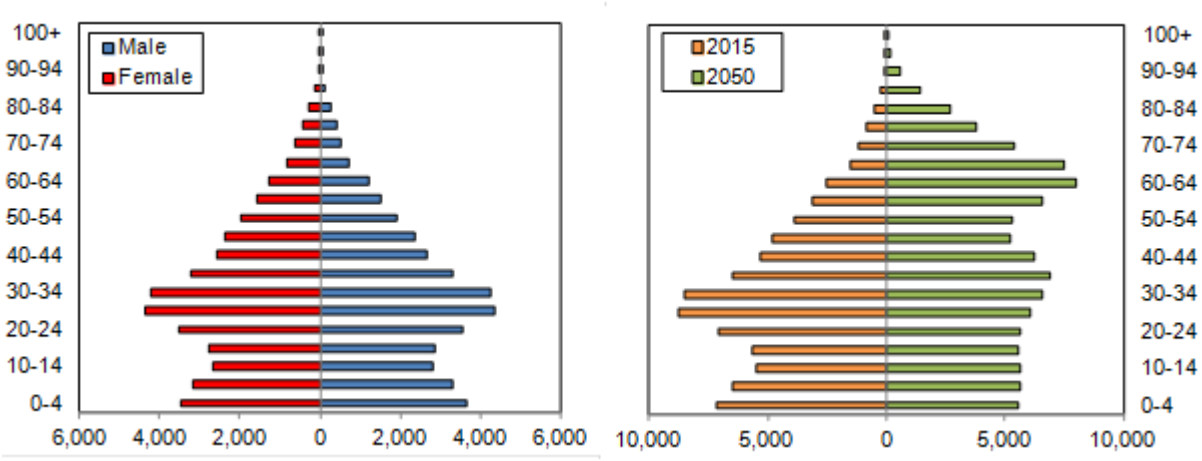
The accompanying charts detail the population pyramid for 2015, the change in the structure of the population between 2015 and 2050 and the total population between 1990 and 2050. The tables show indicators from all of these charts, in addition to key metrics such as population ratios, the urban/rural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



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	56,361	65,911	70,152	74,462	79,476	84,148	88,064
Population, % change y-o-y	na	1.6	1.2	1.3	1.3	1.1	0.8
Population, total, male, '000	28,807	33,504	35,917	37,656	39,915	42,307	44,213
Population, total, female, '000	27,554	32,406	34,235	36,805	39,560	41,840	43,850
Population ratio, male/female	1.05	1.03	1.05	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	28,945	40,290	48,583	53,034	55,945	58,184	60,945
Active population, % of total population	51.4	61.1	69.3	71.2	70.4	69.1	69.2
Dependent population, total, '000	27,415	25,620	21,569	21,427	23,530	25,964	27,118
Dependent ratio, % of total working age	94.7	63.6	44.4	40.4	42.1	44.6	44.5

Key Population Ratios (Iran 1990-2025) - Continued

	1990	2000	2005	2010	2015f	2020f	2025f
Youth population, total, '000	25,543	22,850	18,115	17,585	19,140	20,362	19,984
Youth population, % of total working age	88.2	56.7	37.3	33.2	34.2	35.0	32.8
Pensionable population, '000	1,872	2,770	3,453	3,841	4,389	5,601	7,134
Pensionable population, % of total working age	6.5	6.9	7.1	7.2	7.8	9.6	11.7

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

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

	1990	2000	2005	2010e	2015f	2020f	2025f
Urban population, '000	31,748.6	42,210.8	47,393.5	51,332.8	55,362.4	59,374.4	63,078.7
Urban population, % of total	56.3	64.0	67.6	68.9	69.7	70.6	71.6
Rural population, '000	24,613.2	23,700.3	22,758.8	23,129.5	24,113.9	24,774.2	24,985.6
Rural population, % of total	43.7	36.0	32.4	31.1	30.3	29.4	28.4
Life expectancy at birth, male, years	61.2	68.7	70.0	71.3	72.8	74.2	75.5
Life expectancy at birth, female, years	65.8	70.6	73.1	75.1	76.6	78.0	79.2
Life expectancy at birth, average, years	63.4	69.6	71.5	73.1	74.6	76.0	77.3

e/f = BMI estimate/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	9,312	6,316	5,483	6,555	7,146	6,751	6,148
Population, 5-9 yrs, total, '000	8,905	7,552	5,476	5,416	6,507	7,116	6,729
Population, 10-14 yrs, total, '000	7,324	8,981	7,154	5,613	5,487	6,494	7,105
Population, 15-19 yrs, total, '000	5,822	8,800	9,247	7,215	5,643	5,466	6,474
Population, 20-24 yrs, total, '000	4,697	6,932	9,143	8,993	7,067	5,595	5,424
Population, 25-29 yrs, total, '000	4,054	5,315	6,859	8,704	8,726	6,997	5,541
Population, 30-34 yrs, total, '000	3,535	4,442	5,202	6,521	8,484	8,649	6,937
Population, 35-39 yrs, total, '000	3,030	3,886	4,693	5,210	6,497	8,410	8,579
Population, 40-44 yrs, total, '000	2,123	3,372	4,112	4,833	5,262	6,431	8,333
Population, 45-49 yrs, total, '000	1,620	2,857	3,421	4,032	4,757	5,193	6,353

Population By Age Group (Iran 1990-2025) - Continued							
	1990	2000	2005	2010	2015f	2020f	2025f
Population, 50-54 yrs, total, '000	1,526	1,929	2,800	3,244	3,895	4,665	5,101
Population, 55-59 yrs, total, '000	1,393	1,431	1,766	2,637	3,109	3,788	4,548
Population, 60-64 yrs, total, '000	1,140	1,322	1,336	1,639	2,500	2,985	3,652
Population, 65-69 yrs, total, '000	898	1,145	1,257	1,279	1,550	2,340	2,813
Population, 70-74 yrs, total, '000	507	825	1,055	1,129	1,143	1,369	2,090
Population, 75-79 yrs, total, '000	269	508	654	802	876	902	1,105
Population, 80-84 yrs, total, '000	135	203	347	413	528	598	637
Population, 85-89 yrs, total, '000	48	66	112	172	216	290	343
Population, 90-94 yrs, total, '000	10	17	21	38	63	84	119
Population, 95-99 yrs, total, '000	1	2	3	4	8	15	22
Population, 100+ yrs, total, '000	0	0	0	0	0	1	2

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	16.52	9.58	7.82	8.80	8.99	8.02	6.98
Population, 5-9 yrs, % total	15.80	11.46	7.81	7.27	8.19	8.46	7.64
Population, 10-14 yrs, % total	13.00	13.63	10.20	7.54	6.90	7.72	8.07
Population, 15-19 yrs, % total	10.33	13.35	13.18	9.69	7.10	6.50	7.35
Population, 20-24 yrs, % total	8.34	10.52	13.03	12.08	8.89	6.65	6.16
Population, 25-29 yrs, % total	7.19	8.06	9.78	11.69	10.98	8.32	6.29
Population, 30-34 yrs, % total	6.27	6.74	7.42	8.76	10.68	10.28	7.88
Population, 35-39 yrs, % total	5.38	5.90	6.69	7.00	8.18	9.99	9.74
Population, 40-44 yrs, % total	3.77	5.12	5.86	6.49	6.62	7.64	9.46
Population, 45-49 yrs, % total	2.88	4.33	4.88	5.42	5.99	6.17	7.22
Population, 50-54 yrs, % total	2.71	2.93	3.99	4.36	4.90	5.54	5.79
Population, 55-59 yrs, % total	2.47	2.17	2.52	3.54	3.91	4.50	5.17
Population, 60-64 yrs, % total	2.02	2.01	1.90	2.20	3.15	3.55	4.15
Population, 65-69 yrs, % total	1.59	1.74	1.79	1.72	1.95	2.78	3.19
Population, 70-74 yrs, % total	0.90	1.25	1.50	1.52	1.44	1.63	2.37
Population, 75-79 yrs, % total	0.48	0.77	0.93	1.08	1.10	1.07	1.26
Population, 80-84 yrs, % total	0.24	0.31	0.50	0.55	0.66	0.71	0.72

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	0.27	0.34	0.39
Population, 90-94 yrs, % total	0.02	0.03	0.03	0.05	0.08	0.10	0.14
Population, 95-99 yrs, % total	0.00	0.00	0.00	0.01	0.01	0.02	0.03
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 s*imilares* 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 World Health Organization (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 consumer price index (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 I = 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 (RRIs) 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