Hikma Pharmaceuticals Plc

HQ: London, United Kingdom • Ticker: HIK • Stock exchange: LSE • Nr. of employees: 8,800

COMPANY SUMMARY

Hikma has access to medicine commitments integrated within its business strategy. To expand access to its off-patent and in-licensed products, the company leverages its strong presence and local manufacturing capacity in the Middle East and North Africa (MENA) region. By actively participating in government tenders, the company secures the supply of medicines to the public sector in the countries in which it operates. As a sublicensee, the company has helped lower the price of cancer products, showcasing its ability to utilise its local presence and distribution capabilities to improve product availability and promptly respond to shifts in demand. To ensure a continuous supply of quality-assured products, Hikma implements multiple strategies, including data sharing initiatives and efforts to improve the management of its own supply chain. The company maintains robust quality assurance systems at its own sites and manages quality risks at third-party sites. Hikma reports two examples of adaptive R&D projects, both of which are for antibiotics targeting respiratory infections. The company has also developed formulations with enhanced stability and storage requirements, suitable for use in low- and middle- income countries (LMICs).

Main therapeutic areas
Antidiabetics; anti-infectives; cardiovascular; central nervous system; gastrointestinal; oncology; respiratory.

Business segments
Branded; Generics; Injectables; Other.

Product categories
Active pharmaceutical ingredients (APIs); biosimilars; generic medicines.

Sales presence*
Hikma reports sales in nine countries in scope.

OPPORTUNITIES FOR HIKMA

Expand registration of essential cancer products.
Hikma has registered fluorouracil, a chemotherapy treatment for various cancers, in one country in scope: Egypt, a lower-middle income country. The company has registered gemcitabine, another treatment targeting multiple cancers, in two countries in scope: Algeria, a lower-middle income country, and Sudan, a low-income country. Hikma can consider expanding the registration of these cancer products to other LMICs, particularly those with a high disease burden or those where the company has previously filed other products for registration, such as Morocco and Tunisia.

Strengthen access strategies for oxytocin to ensure availability and affordability for low-income and vulnerable patients
Hikma implements a private sector pricing strategy for oxytocin in Iraq that follows local pricing policies. Oxytocin is crucial for preventing postpartum haemorrhage, a leading cause of maternal mortality in the country. In Iraq, private health insurance is uncommon, and most patients rely on paying out-of-pocket. To expand equitable access and adequate supply for pregnant patients paying out-of-pocket, Hikma can employ access strategies that include elements to address affordability and local barriers to access. Hikma can also engage with public procurement authorities to expand access to oxytocin in the public sector.

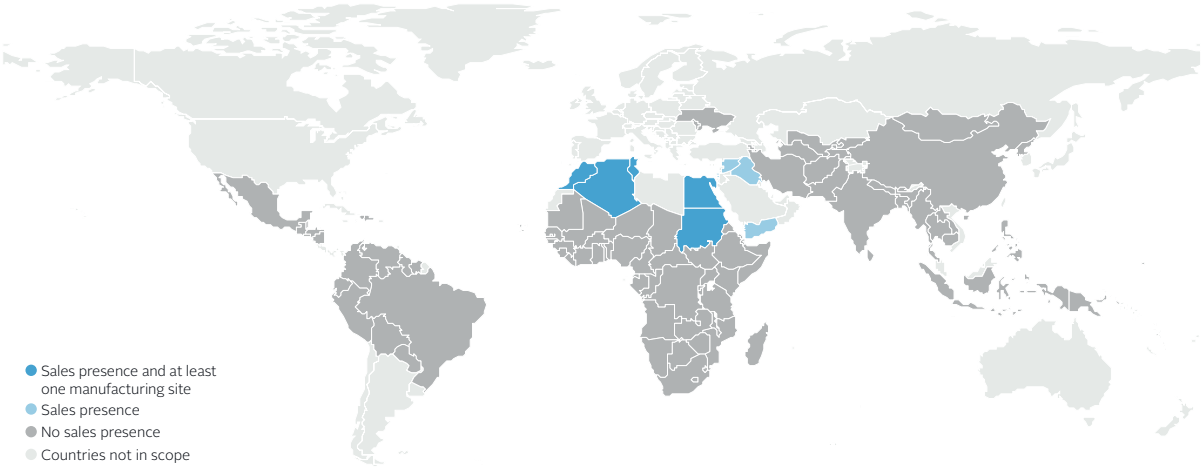
Engage further in adaptive R&D to develop products that address the needs of people in LMICs.
Hikma has demonstrated its capability to develop adaptive R&D projects with favourable storage conditions for people living in LMICs, by developing single-dose sachets of the antibiotics cefaclor and cefalexin - indicated for lower respiratory infections, among other infections. The company can continue leveraging its R&D expertise to adapt products targeting diseases with high burdens in LMICs, where treatment options are ineffective or lacking, such as paediatric formulations.

Expand reach to more LMICs in Africa
Hikma seeks to expand the availability of its generic medicines through harnessing its manufacturing footprint and established local presence across the Middle East and North Africa (MENA) region. Hikma can build on this foundation to expand its operations and reach more LMICs, within the MENA region and beyond, especially in more countries across Africa. The company can leverage its expertise in both direct sales, and distribution and licensing partnerships to address unmet needs in more countries. This is in line with Hikma's corporate strategy, as the company underscored the importance of expanding its reach into new markets in its Sustainability Report 2022.

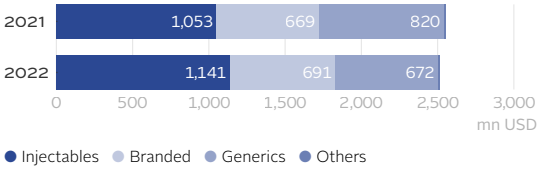
*Refers to countries in which sales are conducted through suppliers, pooled procurement and/or the company sales offices.

COMPANY PRESENCE & REVENUE

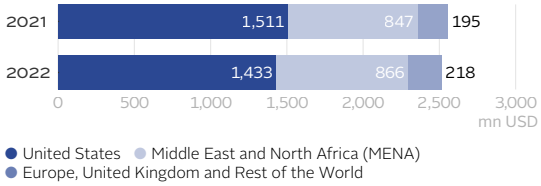
Sales and manufacturing presence in countries in scope



Revenue by business segment*



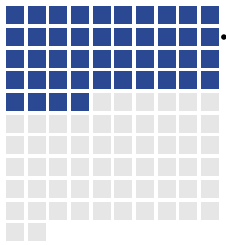
Revenue by region*



PORTFOLIO & PRODUCTS ANALYSED

Products in scope from the company's portfolio

Out of the 102 products in scope of this analysis,** Hikma has 44 products within its portfolio. Hikma's portfolio has a strong focus on non-communicable diseases (NCDs), particularly cancer, with 14 products. Additionally, the company focuses on certain communicable diseases (CDs), including bacterial infections, for which it has ten antibiotics in scope.



44 products
These target NCDs (29); CDs (13); neglected tropical diseases (1); and reproductive, maternal and newborn conditions (2). One product falls into multiple categories.

Product is in Hikma's portfolio
Product is not in Hikma's portfolio

Products selected for assessment

Of the in-scope products that Hikma has in its portfolio, ten off-patent medicines were selected for analysis for the themes EA2 (product registration) and EA3 (expanding access and pricing strategies).

Product	Indication
Amikacin	Bacterial infection
Bisoprolol	Hypertensive heart disease
	Ischaemic heart disease
Fluorouracil	Cancer
Gemcitabine	Cancer
Metformin	Diabetes mellitus
Metronidazole	Bacterial and parasitic infection
Oxytocin	Maternal haemorrhage
Risperidone	Schizophrenia
	Bipolar affective disorder
Salbutamol	Asthma
	Chronic obstructive pulmonary disease (COPD)
Valsartan	Hypertensive heart disease

*Financial year (FY) 2021 covers January - December 2021. FY 2022 covers January - December 2022.

**The Generic & Biosimilar Medicines Programme's product scope includes 102 off-patent medicines, most of which are listed on the 22nd World Health Organization's Model List of Essential Medicines. Essential medicines are those that satisfy the priority health care needs of a population.

EXPANDING ACCESS

EA1. ACCESS-TO-MEDICINE STRATEGY

Hikma integrates its access-to-medicine commitments within its business model and corporate strategy, demonstrating how access is a crucial part of its business operations and long-term growth. The company states a commitment towards improving access to medicine across its geographies, which is supported by its sustainability focus area of "advancing health and wellbeing" and its corporate social responsibility (CSR) activities. These commitments and CSR activities encompass its product donations, market adaptations to address product shortages, collaborations with global health organisations and its initiatives to support education and community outreach. To ensure accountability for its access-to-medicine commitments and activities at the senior level, the company has established an Access to Medicine Committee, which is chaired by two members of its executive committee, one of whom is also a member of the board. The company does not disclose measurable and time-bound objectives for its access commitments, nor does it outline specific goals to extend its patient reach, other than expanding its product donations and growing sales and product volumes across its markets.

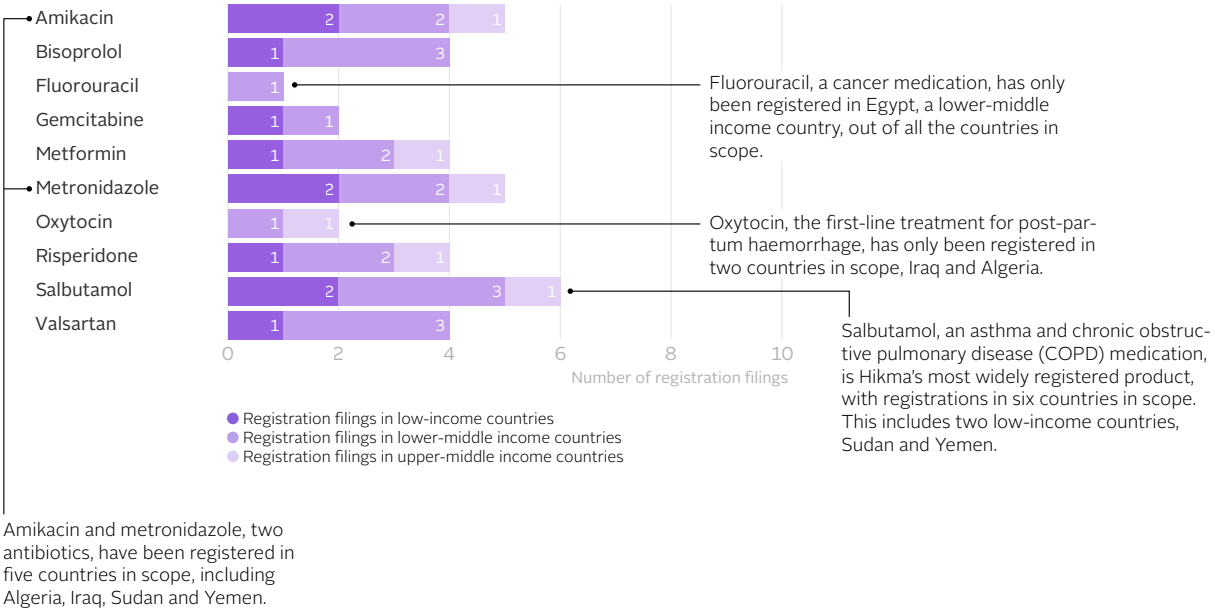
EA2. PRODUCT REGISTRATION

Hikma has filed to register or successfully registered at least one product within its entire portfolio in nine LMICs in scope, specifically, Algeria, Egypt, Iraq, Morocco, Palestine, Sudan, Syria, Tunisia, and Yemen. This demonstrates the company's ability to register products with national regulatory authorities (NRAs) in LMICs in scope.

Of the products within the scope of the Generic & Biosimilar Medicines Programme, ten off-patent medicines were selected for assessment. Hikma has filed at least one of these products for registration in a total of seven out of the nine (78%) LMICs in scope where it has pre-existing regulatory filings*. Moreover, all ten products have been filed in at least one country in scope, with some registered in up to seven countries. The company demonstrates good practice by making efforts to file its products for registration in low-income countries. For example, eight of the ten products are filed for registration in at least one low-income country, with three products registered in two low-income countries (Sudan and Yemen) where the company operates. This is significant, as low commercial potential and limited regulatory capacity in low-income countries pose challenges to registering products and can prevent patients from receiving timely access to effective and quality-assured medicines **.

Hikma does not actively engage in mechanisms to facilitate registration, such as the World Health Organization (WHO) Collaborative Registration Procedure or regional joint assessments. In countries where Hikma has local manufacturing capabilities, including Algeria, Egypt, Morocco, Sudan and Tunisia, it engages with governing bodies to bring products to market.

FIGURE 1 **Registration filings of ten products selected for assessment across income categories**
This figure shows the number of registrations for the ten off-patent products included in this assessment, categorised by whether the filing is in a low-, lower-middle or upper-middle income country.



*Refers to all the countries in scope where the company has previously filed for or successfully registered any of its products. This includes products that fall out side the scope of the Generic & Biosimilar Medicines Programme.

**Based on data analysed in the 2022 Access to Medicine Index and the 2021 Antimicrobial Resistance Benchmark.

EXPANDING ACCESS

EA3. EXPANDING ACCESS AND PRICING STRATEGIES

Hikma demonstrates its commitment to expanding access to the ten products selected for assessment, all of which are covered by at least one access strategy either in the public or private market. Hikma submitted examples of access strategies for one upper-middle, three lower-middle, and one low-income country. Nine products are further complemented by initiatives to build capacity in LMICs, such as educational activities for healthcare professionals and disease awareness programmes. The company provides evidence of the number of patients reached, reported as the number of units sold, for all ten products. It also reports forecasting patient reach to help anticipate future demand.

Of the ten products, the company makes at least one available in the public sector in four out of the nine countries in scope in which it operates, mainly by participating in tenders. During the period of analysis, Hikma was awarded or actively participated in tenders for seven of the ten products. These tenders were awarded based on multiple criteria, such as price, quality, and delivery time, and can be an effective tool for governments to obtain discounts. This includes medicines indicated for CDs, as well as medicines for NCDs including cancer, cardiovascular diseases, asthma and lower respiratory tract infections. Successful tender bids indicate that the company offered favourable terms compared to other suppliers, and that it satisfied requirements set by the public payer, including competitive pricing.

The company supplies its products in the public and/or private markets, while tailoring its approach depending on the country's context. The company supplies gemcitabine and metformin in Sudan, risperidone in Algeria and salbutamol in Morocco through public market tenders. Within these countries, some patients are covered by the national insurance scheme, where the public authority reimburses the products. In Egypt, the company sells three products, namely fluorouracil, bisoprolol and amikacin, in both the public and private markets. The company follows national regulations in Egypt, which involve pricing control measures for pharmaceutical products, which impact the maximum price manufacturers can set for their medicines sold in the private market. To reach different segments of the population, the company sets different prices for the public and private markets, with lower prices offered in public tenders. While such measures can contribute to affordability, it remains unclear whether and how Hikma implements efforts to ensure that those at the bottom of the income pyramid, particular those in the private market without health insurance, can afford its medicines.

For metronidazole, oxytocin and valsartan, the company provides examples of access strategies that exclusively target the private markets in Iraq (for metronidazole and oxytocin) and Sudan (for valsartan). In both countries, the price of generic medicine is regulated within the private market, where the company follows the local price control mechanisms. Moreover, to outperform competitors and offer more affordable prices, the company utilises competitive strategies to price some of the products.

Examples of Hikma's access and pricing strategies

In Sudan,* a low-income country, Hikma supplies gemcitabine, a cancer treatment, in the public sector via government tenders. The tender assessment considers price and lead time as key factors, and the product is fully funded by the government. Additionally, in 2022, the company partnered with the Sadagaat Charity Organization, a non-profit organisation supporting vulnerable populations, to conduct an educational programme in Khartoum, Sudan. The programme seeks to raise awareness about early diagnosis and prevention of breast cancer, targeting 15,000 underserved women and offering free examinations to approximately 5,000 women.

In Egypt, a lower-middle income country, the company supplies fluorouracil, a cancer treatment, and amikacin, an anti-infective, in the public sector via government tenders. For both products, it engages in initiatives to build healthcare capacity locally. For fluorouracil, it implements an annual breast cancer screening programme and, in some cases, follow-up testing to evaluate the medication response. Additionally, for amikacin, the company provides educational materials and access to testing and diagnostics, if not available at hospitals, seeking to ensure the appropriate use of antimicrobials.

FIGURE 2 **How many products are covered by an access strategy?**

For each of the ten products selected for assessment, Hikma was requested to provide one example of a country-specific access strategy covering that product. The company was asked to include examples from a minimum of three low-income countries (LICs) and three lower-middle income countries (LMICs). Further examples could come from upper-middle income countries (UMICs). The types of access strategies the company utilises for each product are outlined in this figure.

International Nonproprietary Name (INN)	Country	Public market access/pricing strategies	Private market access/pricing strategies	Evidence of patient reach	Evidence of forecasting patient reach	Additional initiatives to improve affordability and availability**
Amikacin	Egypt (LMIC)	●	●	●	●	
Bisoprolol	Egypt (LMIC)	●	●	●	●	
Fluorouracil	Egypt (LMIC)	●	●	●	●	
Gemcitabine	Sudan (LIC)*	●		●	●	
Metformin	Sudan (LIC)*	●		●	●	
Metronidazole	Iraq (UMIC)		●	●	●	
Oxytocin	Iraq (UMIC)		●	●	●	
Risperidone	Algeria (LMIC)	●		●	●	
Salbutamol	Morocco (LMIC)	●		●	●	
Valsartan	Sudan (LIC)*		●	●	●	

Hikma provided evidence of implementing initiatives aimed at strengthening healthcare systems in LMICs in scope. While such strategies can improve patient outcomes and help ensure continuity of care, there is currently no evidence suggesting they can improve affordability or availability of the products.

*The supply of this and other products in Sudan may be interrupted due to the ongoing conflict. However, the company's efforts during the period of analysis are captured in the assessment.

**For example: donations, public-private partnerships, or patient assistance programmes.

EXPANDING ACCESS

EA4. ENGAGING IN LICENSING ACTIVITIES

Four in-licensed products were selected for assessment: rituximab, indicated for leukaemia and non-Hodgkin's lymphoma; trastuzumab, indicated for breast and stomach cancer; and molnupiravir and nirmatrelvir, indicated for COVID-19.

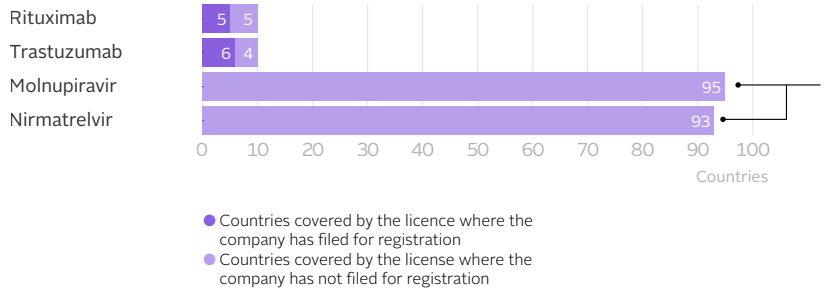
Hikma is currently engaged in two exclusive licensing agreements for trastuzumab and rituximab with Celltrion Healthcare Co., Ltd., who have received WHO prequalification (PQ) for both products. As part of these agreements, Celltrion is responsible for manufacturing the product, while Hikma is responsible for commercialisation across the MENA region.

The company reports that it has helped reduce the price of trastuzumab and rituximab by introducing the first biosimilar versions – the former in Iraq and Morocco, and the latter in Algeria. For both products, the company reports the number of patients reached.

Furthermore, Hikma has set objectives to increase the number of patients receiving trastuzmab in Algeria and rituximab in Iraq and Egypt. While licensing agreements increase availability and potentially reduce the price through biosimilar competition, it is unclear whether Hikma takes the payers' ability to pay into account across different segments of the population when setting the price for these products.

FIGURE 3 **Registration filings of Hikma's in-licensed products***

This figure shows the number of LMICs in scope where Hikma has filed for registration or registered its four in-licensed products selected for assessment, compared to the total number of countries covered by the licensing agreement.



Hikma has entered non-exclusive voluntary licenses for two COVID-19 antivirals – molnupiravir and nirmatrelvir – through the Medicines Patent Pool (MPP). These agreements were made after the COVID-19 vaccines were rolled out, which reduced the demand for these products. Consequently, the company has not filed these products for registration in any LMICs within scope. However, the company retains the right to register and supply these products, should the need arise.

EA5. IMPROVING PRODUCT AVAILABILITY

Hikma's manufacturing network comprises 32 sites globally, with a total of 16 located in Algeria, Egypt, Morocco, Tunisia and Sudan. Overall, the company has 23 sites in the MENA region, which may make it easier for the company to respond to demand fluctuations, prioritise certain products in specific markets, and understand local market needs.

The company implements efforts to scale up and develop its manufacturing presence and capacity in some of the LMICs in scope. For instance, in 2021, Hikma began operating its newly developed oral oncology plant, in Algeria, to supply oncology products within the country. In addition, the company is in the process of constructing two new injectable manufacturing sites in Algeria and Morocco, which will be leveraged to increase the supply of and access to injectable medicines within these two markets. In 2022, Hikma invested USD 72 million in its manufacturing sites across the MENA region to enhance manufacturing capacity, partly covering its injectable sites in Algeria and Morocco; however, the proportion of the investment going towards its sites in LMICs is not reported. In the same year, in response to increased demand, the company scaled up its manufacturing capacity in Algeria by increasing production of the anti-infective amoxicillin/clavulanic acid by adding additional filling lines.

Furthermore, the company reports engaging in technology transfers as part of its toll and contract manufacturing activities in LMICs in scope. This includes engaging in technology transfers to local pharmaceutical manufacturers in Egypt and Tunisia. However, the details and activities of these transfers remain unclear, as the company reports that its extensive market presence across the MENA region reduces the need for them.

*Products may be available through other mechanisms without having been filed for registration by the company.

SUPPLY & QUALITY

SQ1. DEMAND PLANNING AND DATA SHARING

Hikma reports that it has established an internal system for forecasting and demand planning that allows it to effectively manage inventory and identify potential supply constraints. The company undertakes sales and operations planning on a monthly basis, and it evaluates projections for both demand and supply. The company implements forecasting 24 months ahead, on a rolling basis, and creates five-year business plans. Hikma also collaborates with national authorities and procurement agencies to ensure its effective participation in tenders and to respond to specific product needs. For example, by sharing its supply plans and capacity, Hikma contributes to both preventing and fulfilling shortages, thereby ensuring an adequate supply of its products.

Examples of Hikma's data sharing initiatives

In Algeria, Hikma works with the Ministry of Pharmaceutical Industry to prevent product shortages by providing monthly reports with its production plans and current stocks of finished goods and APIs. Additionally, in Egypt, the company collaborates with stakeholders such as the Egyptian Drug Authority, the Unified Procurement Authority and health insurance companies to improve forecasting and demand planning. Through these collaborations, Hikma can promptly address shortages of oncology products in Egypt by scaling up its manufacturing capabilities as needed.

SQ2. DELIVERY PERFORMANCE

Hikma has implemented a system to monitor and track delivery performance within its MENA markets. This includes regular tracking of metrics such as On Time in Full (OTIF), Line-Item Fill Rate (LIFR) and Fill Rate on a quarterly basis. The company has dedicated teams to manage its supply chains at both the regional and site level.

In the event of delivery delays, Hikma's supply chain team maintains regular communication with its internal commercial team and follow-up meetings are held to review products' shipping status and agree on action plans, until the issue is resolved. The company has established a structured process to communicate information on supply constraints and potential delivery delays to external stakeholders, including local buyers', through its in-country key account managers. They work together, as needed, to develop a mitigation plan.

SQ3. STOCKOUTS AND SHORTAGES MITIGATION

Hikma has implemented multiple strategies to promote a continuous supply of its products and mitigate the risk of stockouts and shortages.

The company reports maintaining a safety stock of raw materials, packaging materials and finished goods, and applies a policy of a minimum stock level of finished goods with its wholesalers and agents. To reduce the risk of stockouts, the company employs specific stocking strategies as needed. In 2020, the company conducted a reassessment of its stock levels and, as a result, increased its inventory levels. In addition, the company reports setting inventory targets per site and undertaking audit stocks on a monthly basis. Hikma reports specific steps to decentralise critical component stocks in the LMICs where it operates. For instance, it establishes stock levels and targets for each manufacturing site on a quarterly basis to meet demand.

The company reports taking steps to promote supplier diversity. In 2016, it implemented an enterprise risk management programme to establish alternative sources of active pharmaceutical ingredients (APIs) and improve supply reliability and continuity. Hikma also reports it is actively evaluating opportunities to qualify alternative sources of raw materials and packaging materials. As part of this effort, the company recently extended its assessment to include excipients and glass. Additionally, the company reports that the majority of its secondary packaging materials are sourced locally, which enables better control over product availability.

While the company is primarily involved in the production of finished dosage forms, it also has capabilities to manufacture APIs. One notable example is the company's manufacturing plant in Jordan, which specialises in APIs for oncology medicines. This capability enables the company to vertically integrate its supply chain and to manufacture and supply cancer products throughout the MENA region. The company also utilises manufacturing sites within its network to scale up production and maintain continuity of supply of high-demand products. For instance, it reports having restructured distribution models to adapt to supply needs in countries such as Sudan and Yemen. Furthermore, it has worked to secure capacity with freight forwarders and shipping companies to ensure a reliable supply chain.

Examples of Hikma's strategies to mitigate shortages

In Egypt, Hikma has implemented strategies to ensure a consistent supply of essential medicines. During the COVID-19 pandemic, the company quickly responded to market demands by significantly increasing its production of azithromycin, an anti-infective drug. In 2022, the company reports that it maintained an uninterrupted supply of capecitabine, a cancer medication, despite a tenfold increase in demand due to national import constraints. By leveraging its local presence, the company implemented effective measures to ensure a steady supply and meet patients' needs.

FIGURE 4 **What steps is Hikma taking to mitigate stockouts and shortages?**

This table shows the approaches the company reports taking to ensure the uninterrupted supply of its products.

Approaches to mitigate stockouts and shortages	
Strategies to maintain sufficient stock for critical components, including buffer and safety stocks	●
Conducting regular audits of its stock	●
Disclosure of the frequency of stock auditing	●
Holding regional stocks and/or making efforts to decentralise stocks of critical components	●
Strategies to promote third-party supplier diversity, such as establishing alternative sources of APIs, excipients and packaging materials	●
Implementation of sourcing strategies, such as procuring from local suppliers in LMICs	●
Evidence of a policy or approach for scaling up the production of APIs to quickly adapt to meet surges in demand, when applicable	●
Other initiatives to fulfil emergency orders and/or surges in demand	●

By identifying at-risk API sources, Hikma implements specific stocking strategies to minimise the risk of shortages.

Hikma leverages its API manufacturing capability in Jordan to manufacture and supply cancer products in the MENA region. It also reports having a Standard Operating Procedure (SOP) for scaling up and transferring technology for API processes across Hikma's API plants, should a surge in demand arise.

SUPPLY & QUALITY

SQ4. MANUFACTURING QUALITY ASSURED PRODUCTS

Hikma reports complying with a range of industry and government regulations to ensure the manufacturing of quality-assured products at its sites. This includes current good manufacturing practices (cGMPs) and current good distribution/storage practices set by various regulatory agencies such as the FDA (US), EMA (Europe), and MENA health authorities.

Of the company's 32 manufacturing sites, 15 are inspected by stringent regulatory authorities (SRAs) including US, UK or EU regulators. Of these 15, six are located in the MENA region, but in countries out of scope of this analysis. The remaining sites operate under national/local equivalent authorities. The company has not submitted any products to the WHO PQ programme, which exempts the company from manufacturing site inspections by the WHO. No warning letters from the FDA or non-compliance reports from the EMA were issued at Hikma's sites in countries in scope during the period of analysis.

The company utilises its engineering expertise from its FDA-inspected facilities, for example in Portugal, to standardise quality across other sites, including at its injectable sites in Algeria and Morocco, which are currently under construction. Hikma uses a variety of compliance monitoring and automated quality control systems to ensure quality assurance. The company has a Quality Council, which reports to the Executive Committee, which oversees and shares best practices. To ensure consistent cGMP, the company implements global quality systems across its sites, and the Global Quality team conducts frequent internal audits and implements corrective actions for deviations.

Suppliers and sub-licensors are audited and required to adhere to both company and regulatory standards through Quality Agreements. Before onboarding new API suppliers, a quality audit is conducted as a part of Hikma's supplier qualification system, and scheduled audits are also conducted for key suppliers. Suppliers and third parties must comply with the company's Supplier Code of Conduct, with non-compliance potentially leading to termination, depending on the severity of the breach.

SQ5. SAFEGUARDING QUALITY & SAFETY OF MARKETED PRODUCTS

Hikma implements strategies to maintain the quality and safety of its products. The company's Pharmacovigilance Policy includes strategies to mitigate the circulation of substandard and falsified medicines in LMICs. The policy includes taking immediate action and reporting any quality concerns and/or falsified medicines encounters to the appropriate authorities in accordance with applicable laws and regulations. Hikma also has a recall procedure in place, and in the event of recall, the company informs and works with the relevant regulatory authority to ensure appropriate actions are taken, in a timely and efficient manner.

The company complies with all applicable laws and regulatory requirements pertaining to falsified medicines, including any requirements for serialisation and track and trace. This includes printing a barcode on each package, that contains a product identifier, "Global Trade Item Number® (GTIN®)", as per the current requirements of the markets in scope. Moreover, Hikma is actively working on a project to serialise its finished products, ensuring product tracking in the case of recalls and mitigating the risks of falsified medicines.

In addition to complying with the product labelling instructions established by local regulatory authorities, the company indicates both the source of the finished product on the label and the distributor's details, if separate from the company. Hikma's internal Enterprise Resource Planning (ERP) system traces all produced lots and provides details of the origin, manufacturing sites, and packaging sites for each lot.

FIGURE 5 **Depth and breadth of quality-assurance strategies**

This table shows the types of strategies Hikma implements to maintain the production of quality-assured products and to safeguard the quality and safety of products already in the market.

Quality-assurance strategies		
Manufacturing quality-assured products	Strategies to standardise quality management systems and compliance monitoring tools across all manufacturing sites	●
	Strategies to assesses third party suppliers on GMP compliance	●
	Disclosure of the number of manufacturing sites with approval from a stringent regulatory authority (SRA) or national regulatory authority (NRA) operating at maturity level 3 or 4 (ML3 or ML4)*	●
Safeguarding quality & safety of marketed products	System for recalling products promptly and effectively and alerting the appropriate authorities in a timely and efficent manner	●
	A clear policy to mitigate the circulation of substandard and falsified medicines, including information about which authorities and/or organisations the company reports encounters of substandard or falsified medicines	●
	Evidence of concrete strategies to mitigate the risk of substandard and falsified medicines	●
	Efforts to disclose the source of finished products, including specifying the primary manufacturing plant and disclosure of product components and materials that are third-party sourced	●

To manage third-party risks, the company introduced "RiskRate" in 2021, an automated system that assesses 96% of its suppliers, with high-risk suppliers facing enhanced due diligence measures.

Hikma's Pharmacovigilance Policy (PV) captures how the company mitigates the circulation of substandard and falsified medicines.

Hikma's "Global Trade Item Number® (GTIN®)" allows for the prompt detection of potential encounters of substandard and falsified medicines.

*As benchmarked against WHO Global Benchmarking Tool (GBT)

RESEARCH & DEVELOPMENT

RD1. ADAPTIVE R&D

Hikma has adaptive R&D projects in its pipeline to develop products that are better suited for LMIC settings. During the period of analysis, the company provided two examples of adaptive R&D projects for off-patent medicines in scope: cefalexin and cefaclor. Both products are antibiotics that can be used to treat lower respiratory tract infections, amongst other indications. The company has adapted existing formulations of cefalexin and cefaclor to manufacture single-dose sachets. Cefalexin single-dose sachets received marketing authorisation approval by the National Agency for Pharmaceutical Products in Algeria in August 2022, followed by cefaclor in February 2023. The product adaptation means the antibiotic powder can be reconstituted at the time of administration. As a result, they do not require refrigeration (a requirement for the pre-existing suspension formulation). Eliminating the need for refrigeration allows more storage flexibility – an advantage in many low-resource settings. Additionally, the single dose unit can be reconstituted when needed, helping to reduce waste.

RD2. ACCESS PLANNING

The company does not disclose having an overarching policy or structured framework in place for systematically developing access plans during R&D for their adapted products.

However, for both examples of adaptive R&D provided, the company showed evidence of access planning, specifically plans to register the products in at least one country in scope. The company registered both products in Algeria within the period of analysis. Whilst registration is a necessary first step to ensure availability in country, there is no evidence that the company's access plans for adaptive R&D projects consider other components conducive to access, such as affordability and supply. Additionally, to increase availability beyond Algeria, the company can plan to register the products in more countries in the MENA region.

FIGURE 6 **Examples of adaptive R&D projects in Hikma's pipeline**

International Nonproprietary Name (INN)	Disease in scope	Development stage	Partner(s)	Description of the adaptation	Evidence of an access plan
Cefaclor	Lower respiratory infections	Market approval	N/A	Dry powder sachets	Registration plans in countries in scope; product approved in Algeria
Cefalexin	Lower respiratory infections	Market approval	N/A	Dry powder sachets	Registration plans in countries in scope; product approved in Algeria