

IQVIA™ MARKET PROGNOSIS 2017-2021

Asia/Australia – Vietnam

A special edition in conjunction with:

 **CPhI** south east asia



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FOREWORD

IQVIA and CPhI are pleased to bring you our co-branded special Market Prognosis report sharing our view of the future of the Vietnam pharma market. Both CPhI and IQVIA consider that such information is key for the growth and development of the pharma industry and believe that this report will provide valuable insight as you look to develop your business in Vietnam.

The report provides an evidence-based outlook for Vietnam based on the knowledge of our country experts who carry out extensive research into key business and healthcare events and apply this to a gold standard historical view of the market.

We are excited to share this valuable country information with you and look forward to welcoming you to CPhI SouthEast Asia in Jakarta.

CPhI and IQVIA team

MARKET OVERVIEW AND FORECASTS

Market Synopsis

- The Vietnamese pharmaceutical market is forecast to grow at a CAGR of 8.0% ($\pm 2.5\%$) between 2016 and 2021, reaching VND123,631 billion by 2021.

Business Environment

- GDP is forecast to grow by 6.3% in 2017, up slightly from 6.2% in 2016, and growth will remain stable at an average of 6.3% during 2018-2021, making Vietnam one of the fastest growing emerging markets in the region. Growth will be underpinned by healthy growth in private consumption. Government spending will slow, while private investment activity will be spurred by policies to liberalize business regulations and deepen global integration. Inflation will accelerate compared to 2016, on the back of marginally stronger economic activity, a rebound in global commodity prices in 2017 and a weakening currency, particularly in 2018-2019. The dong will depreciate against the US dollar throughout the forecast period, to be valued at VND25,757:US\$1 in 2021.
- The reappointment of conservative Nguyen Phu Trong as the Communist Party of Vietnam's (CPV) general secretary in January 2016 reaffirmed the country's status quo as a stable one-party socialist state. Together with the prime minister, Nguyen Xuan Phuc, Mr Trong will oversee a period of continued gradual economic liberalization, driven by international trade deals. More state-owned enterprises will be partially privatized to improve efficiency and aid fiscal consolidation, and restructuring the banking sector remains a priority. Ties with China will be prone to setbacks, but the government will remain keen to strengthen ties with the US.

Healthcare Provision

- Government policy will seek to broaden access to healthcare and improve the quality of provision. This will involve further investment in expansion and restructuring of the public hospital sector and efforts to strengthen primary care provision - both are sorely required, as major city hospitals continue to battle chronic overcrowding. Effective implementation of healthcare reforms will be hampered by funding issues, staff and equipment shortages, and poor management.
- Pressure on the healthcare system will intensify as social health insurance (SHI) coverage increases. Almost 82% of the population is now covered by the SHI system, and the target for coverage in 2020 has been raised to 90%. Most uninsured patients are poor, and funding coverage for this segment of the population will drive up public health expenditure.
- Total healthcare expenditure has been growing rapidly and had reached around 7% of GDP in 2014, according to the latest World Health Organization (WHO) estimates. The share of private healthcare spend has been declining, but out-of-pocket payments continue to dominate private spending. New revenue sources will be pursued in a bid to bankroll increased government healthcare spending.

- The public hospital sector will remain the dominant provider of services. Bed capacity will be increased and investment in provincial and district level hospitals will continue in order to increase capacity and alleviate the burden on the major, high-level facilities. Expansion of the private hospital sector will be encouraged.
- Primary care provision will be strengthened and more funds will be channeled into the sector in a bid to lighten the load on public hospitals and improve the management of chronic, non-communicable diseases. A family doctor system is being piloted, but progress will be slow.
- The SHI scheme is reporting a growing deficit. With budgets under growing pressure, the establishment of more robust cost-containment measures will be required, and pharmaceutical spending will be a major target. Circulars issued in 2016 set out new tendering rules which will impose further downward pressure on institutional procurement prices by seeking greater centralization of tenders at national and provincial level, as well as national-level price negotiations.
- Greater attention will be paid to the use of original brands. The quotas for the purchase of branded products by hospitals may be reduced from 2018. Changes could also be introduced for selected off-patent brands on the innovator list, which may be required to undergo price negotiations, potentially involving significant price cuts, although no final decision had been taken as of mid-2017.

Prescribing and Dispensing

- Capped budgets, quotas for the use of individual drugs, prescription monitoring and new tendering procedures will all affect prescribing trends in the public hospital sector. These factors will also have a growing impact on prescribing in private hospitals as more SHI patients are treated in private facilities.
- Inclusion on the National List of Essential Drugs (NLED) and the health insurance Reimbursement Drug List (RDL) will become increasingly important as insurance coverage rates continue to rise. Both lists were scheduled for review in 2017, with updated formularies expected to take effect in 2018, but no official announcements of their updates had been made as of mid-2017. For originators, moves towards the inclusion of basic cost-effectiveness reviews in listing decisions will represent a welcome development.
- Formularies in provincial and district hospitals will be expanded as the range of services provided by these facilities increases. This will affect prescribing trends in the public hospital sector, encouraging originators to broaden their focus.
- There will be few constraints on prescribing choice in the private sector, where original brands and high-quality generics will remain the products of choice for most physicians and patients who can afford to purchase them.
- The prevalence of dispensing without a prescription will begin to decline as good pharmacy practice standards are adopted more widely. The government aims to strengthen controls over the sale of prescription drugs and a prescription-only policy will be enforced for antibiotics by

2020. This will be a gradual process, however. Pharmacy substitution of prescribed drugs – usually with cheaper alternatives – will remain a feature of the retail market.

Pricing

- The 2016 Law on Pharmacy lays the foundations for the negotiation of prices for some drugs procured for use in the public sector. It also calls for an increase in levels of price transparency, and hands the MOH broad powers to ‘stabilize’ drug prices where appropriate.
- Decree 54, detailing implementation regulations for the Law on Pharmacy, outlines measures aimed at tightening price management. These include requirements for price declaration and re-declaration, regulations for reviewing and publishing drug prices on the MOH website, rules to determine the ‘rationality’ of prices, criteria for the posting of prices and price increases, as well as maximum retail margins.
- Eight drugs have been identified as initial subjects for price negotiations, which will be carried out at national level. First negotiations are unlikely to commence until late in 2017, but the number of drugs subject to negotiated pricing procedures is expected to rise once regulators gain experience with the approach.
- Pressure on prices will intensify during the early part of the forecast period as negotiated pricing procedures and national-level consolidated tenders become a reality. The proportion of drugs purchased through provincial level consolidated tenders will increase. Competitive pressure, the Drug Administration of Vietnam’s (DAV) reluctance to sanction significant hikes in the price of established products, and moves to increase levels of price transparency will all act as constraints on retail market price growth.
- Regulators will monitor mark-ups more closely, while caps on margins generated by providers will be applied more widely. Moves to restructure the distribution market could have a significant impact on margins in the retail distribution chain.

Regulatory Environment

- The 2016 Law on Pharmacy will trigger significant changes to the regulatory framework governing pharmaceuticals, affecting wholesalers, retailers and providers, as well as manufacturers. Decree 54, or ‘Pharmacy Decree’, which was published in May 2017 and took effect on 1 July, details implementation regulations for certain provisions under the Law on Pharmacy, including for price management and import and distribution rights.
- Efforts to improve the efficiency and transparency of the drug approval process will be pursued. Originators will benefit from the widespread waiver of local clinical trial requirements under the 2016 Law on Pharmacy. Regulators will prioritize the review of the registration requests for new generics and biosimilars, but orphan drugs will also be granted priority status.
- The DAV has stepped up inspection and quality testing activity, while the new Law on Pharmacy will trigger the introduction of tighter standards governing the manufacture, distribution and sale of medicines.

- A review of the 2005 Intellectual Property Law is anticipated at an early stage in the forecast period. Originators will lobby for more timely patent approvals, improved dispute resolution procedures and the introduction of effective regulatory data protection provisions. The free trade agreement (FTA) negotiated by Vietnam and the EU will be the most likely driver of improvements to the existing intellectual property framework.

Pharmaceutical Business Environment

- Demand for medicines will continue to rise, but pressure on prices will intensify. Shifts in the structure of the market will be witnessed, reflecting the impact of further increases in health insurance coverage and policies designed to restructure the supply of public healthcare services.
- Local manufacturers will benefit from preferential treatment where public sector purchasing is concerned, but pressure on margins and the imposition of tighter quality standards will trigger a degree of restructuring in the domestic industry. The government's ambitious import substitution goals are unlikely to be met.
- SHI reimbursement policies, public hospital procurement mechanisms and hospital formulary listings will all continue to favor the use of generics. Pressure on generic prices will intensify, however, as consolidated tenders account for a growing share of institutional drug purchases.
- Decree 54 allows foreign-invested enterprises (FIEs) to obtain the necessary license to import drugs into Vietnam, and to sell drugs on to wholesalers registered with the MOH. The decree continues to explicitly prohibit FIEs with import rights from engaging in drug distribution, however. The government may eventually be forced to relax existing prohibitions under the terms of the FTA it has negotiated with the EU.
- Retail market dynamics will mitigate against the emergence of pharmacy chains as a major force in the sector. Pharmacies may begin to encounter competition from supermarkets for sales of some OTC medicines. Strict implementation of good pharmacy practice standards, which has the potential to drive more significant restructuring in the sector, appears unlikely in the near future.
- Interest in the OTC market will increase as prescription drug prices and margins in the hospital sector are squeezed. Increasing health awareness, rising incomes and patients accustomed to self-medicate with medicines obtained directly from pharmacies will drive demand. Heavier investment by manufacturers and the involvement of supermarkets in the sale of some OTCs will act as drivers of growth in the sector.
- Flexible, multi-faceted promotional strategies will be required to succeed in a market where reimbursement and formulary listings are increasingly important, and where the range of stakeholders with the power to influence prescribing and dispensing trends is growing. As provincial and central tender administrators assume greater decision-making power in the evolving tender system, companies will need to develop relationships with key decision-makers in the new system.

TOTAL MARKET FORECASTS 2017-2021

Summary of the Prognosis

All values shown are in local currency. Sales are reported at the ex-manufacturer price level based on invoice pricing that does not capture discounts and rebates.

IQVIA captures 86% of the total pharmaceutical market. The prognosis incorporates an estimate of the value of the unaudited sector and, for the purpose of this forecast, assumes that this will grow in line with the rest of the market and hold a market share of 14% throughout the forecast period.

The total pharmaceutical market is forecast to grow at a CAGR of 8.0% ($\pm 2.5\%$) over the period 2016-2021.

Key Issues Affecting Market Growth

- Recent and new product launches will contribute to market growth. Cancer and cardiovascular treatments, as well as new generation hepatitis C antivirals, feature among the leading new product launches expected to contribute to market growth over the forecast period. Provisions in the 2016 Law on Pharmacy have the potential to reduce lengthy registration times. Under the new law, local clinical trial requirements will be waived for all new drugs except vaccines, under conditions.
- Changes to the public hospital sector drug procurement system will be implemented, which aim to consolidate drug procurement for certain drugs at national and provincial level, and to introduce national price negotiations for certain drugs. While progress will be gradual, greater centralization is expected to trigger significant reductions in the prices of affected products due to the high volumes at stake.
- Social health insurance (SHI) coverage will continue to expand. The government aims to have 90% of the population covered by 2020, having adjusted upwards its previous target of 80%. An update of the health insurance Reimbursement Drug List (RDL) is expected in the short-medium term.
- Further improvements will be made to public hospital infrastructure, especially at provincial and district level. Greater participation of the private hospital sector in healthcare provision, boosted by increasing investment and government support, will also improve access to care.
- Interest in the OTC market is growing, with both local manufacturers and foreign companies devoting more resources to OTC portfolios in a bid to mitigate the impact of pricing pressures on their prescription product businesses. Increasing health awareness, rising incomes, and patients being accustomed to self-medicate with medicines obtained directly from pharmacies will continue to act as drivers of demand for OTC medicines.
- Cost containment in the public hospital sector will increase. Greater attention will be paid to the use of original brands. The quotas for the purchase of branded products by hospitals may be

reduced, while pressure on the budget of groups 1 and 2 for generics is also increasing. Selected off-patent brands on the innovator list may be required to undergo price negotiations and suffer price cuts, although no final decision had been taken as of mid-2017.

Change in the Prognosis

The five-year outlook for Vietnam has been revised downwards in the short and medium term, compared to the previous forecast published in March 2017. The following changes have been made to the forecast:

Baseline Changes

- **Retail Sector:** Continuing negative volume growth in the first half of 2017 led to a downward adjustment of the volume baseline forecast.
- **Hospital sector:** While volume growth remained in double digits in the first half of 2017, it was lower than expected in the previous forecast, leading to a downward correction of the volume baseline in the short-medium term.

Event Changes

- **The probability of the event ‘Greater attention to cost containment’ has been raised, a negative impact on volume added, and the negative impact on price increased.** The health insurance fund's deficit is reported to be growing and measures to contain costs are expected to be implemented. Greater attention will be paid to the use of original brands, which may see their quota reduced, and there is a possibility of price negotiations and price cuts for off-patent brands on the innovator list.