

Unlocking opportunity

Baker & McKenzie paves the way to success
in pharmerging markets



The go-to firm for pharmerging markets

Baker & McKenzie has been helping pioneering companies establish operations overseas since our inception in 1949. Our first cross-border client — who we serve to this day — is one of the world's leading pharmaceutical and medical products brands. And we continue to be deeply involved in the pharmaceutical industry the world over.

Our team of more than 400 pharmaceutical lawyers, engineers and other industry specialists operate from 39 offices across the globe, and we regularly advise the world's major industry players on the most complex cross-border matters. With an established pharmaceutical and healthcare practice in 16 of 21 pharmerging markets — developing jurisdictions where industry growth is expected to be significantly higher than in mature markets — we are uniquely positioned to help you capture emerging opportunities.

As an integrated and multidisciplinary firm, we can provide a full range of locally relevant advice and innovative strategies. From pipeline and geographic development to cross-border mergers, acquisitions and reorganizations, we can help you achieve your business goals in pharmerging markets and the rest of the globe.

We are the only law firm with experienced pharmaceutical lawyers in all key pharmerging markets.

- Greater China
- Southeast Asia
- Brazil
- Pacific Alliance
- Russia
- Middle East, Turkey and Africa



Expand

Our strong multinational capabilities help companies realize full deal values during mergers, acquisitions and joint ventures. We manage strategic partnering in the commercialization of products, along with distribution and supply chain matters, including financing.



Develop

Our deep local knowledge in markets that matter enables us to help you swiftly establish and operate R&D facilities or collaborative development deals, including through joint ventures.



Access

Familiar with local nuances, we are up-to-date with legal and market issues. Our lawyers are active in most pharmerging markets — we create and implement strategy for market access, regulatory approval, and reimbursement issues. If a need for product recall arises, our team is prepared to help.



Enforce

An essential consideration before market entry is intellectual property enforcement. Our local experience can guide thinking on this issue, and our lawyers regularly conduct due diligence and prepare freedom-to-operate reports.



Comply

New pharmerging markets have increasingly dynamic laws, regulations and industry codes of conduct. With skilled lawyers on the ground, we can assist in ensuring compliance, with respect to promotional activity matters, as well help you effectively respond to regulatory actions and proceedings.



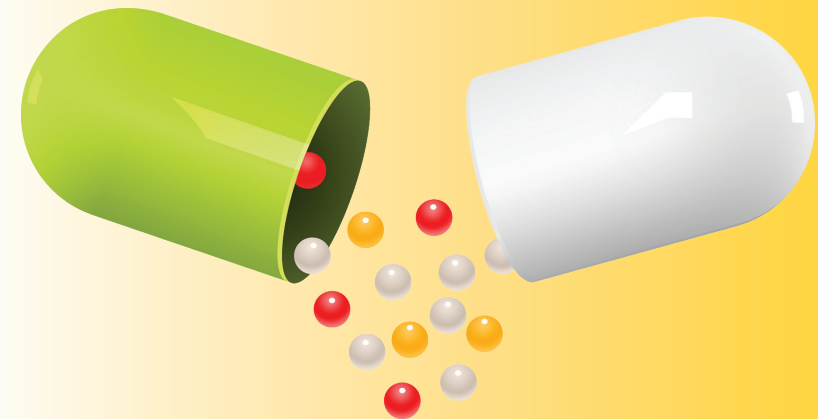
Look ahead

We help multinational pharmaceutical companies lobby for regulatory and legislative changes and advise on market strategies to optimize local market exclusivity protocols.

Pharmaceutical & Medical Technology: Our capabilities

The pharmaceutical and medical technology industry has long operated across borders, but the growing importance of emerging markets creates new geographic complexities.

Advisers seasoned in industry nuances, as well as emerging markets, are key to maximizing rising opportunities and neutralizing cross-border risk.



Greater China

+14.7%

PHARMACEUTICAL
MARKET GROWTH, 2013-14
(projected value: USD99.7 billion)

*source: BMI China Pharmaceuticals & Healthcare Report Q2 2014

+13.5%

HEALTHCARE
MARKET GROWTH, 2013-14
(projected value: USD587.8 billion)

OPPORTUNITY

**5 YEAR
GOV'T
PLAN**

FOCUSES ON
HEALTHCARE REFORM,
R&D, BETTER
PRODUCTION AND
QUALITY STANDARDS,
AND RESTRUCTURING



OUR LOCAL PHARMACEUTICAL &
HEALTHCARE PRACTICE



Baker & McKenzie's unique position in the People's Republic of China was built on more than 40 years of experience navigating the jurisdictions' continuously evolving legal systems. We have considerable experience helping Western companies with FDI, mergers and acquisitions, joint ventures and other partnering strategies. Our regulatory and intellectual property teams are familiar with the industry and provide clients with valuable insight into the country's complex legal environment.

MATTERS TO CONSIDER



Licensing and regulatory approvals
at provincial and central levels



Strategizing local IP protection



Geographic and economic diversity
means markets within markets

Greater China

OUR EXPERIENCE

Advised Medtronic, Inc. on its USD816 million acquisition of China Kanghui Holdings, a leading provider of orthopaedic devices in China. This was one of the largest acquisitions in the industry last year in a BRIC country.

Advised Cardinal Health on its USD470 million acquisition of leading local healthcare distributor Zuellig Pharma China, known locally as Yong Yu, which is the country's largest pharmaceutical importer.

Acted as US legal advisor to Hanmax Investment Limited, Fosun Industrial Co. Ltd and Tonsun International Company Limited, in connection with their USD117 million acquisition by way of merger of Tongjitang Chinese Medicines Company, a leading specialty pharmaceutical company in China.

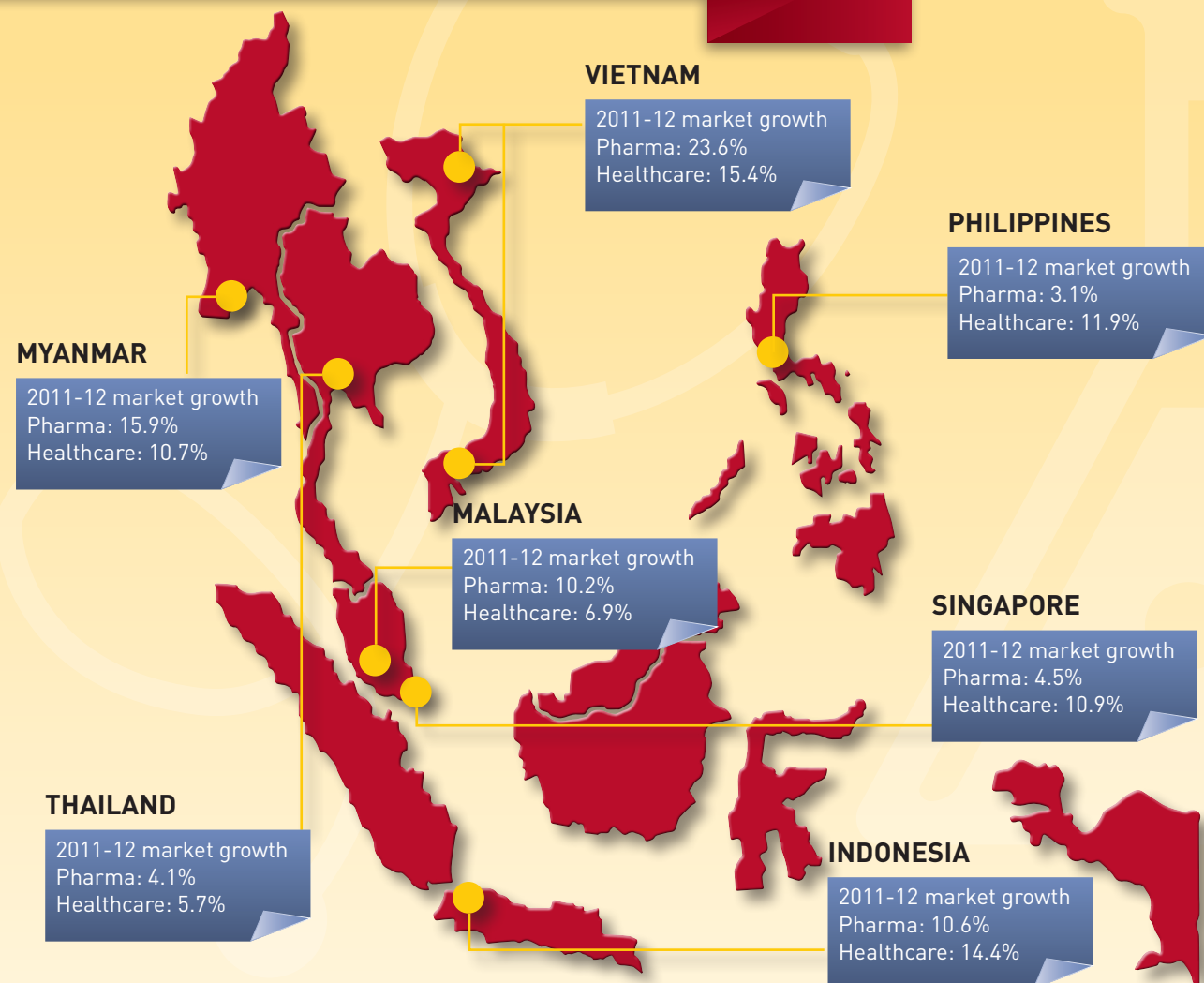
Advised Alliance Boots plc, a leading pharmacy-led health and beauty group on its agreement to form a 50:50 joint venture with the then-controlling shareholder of Guangzhou Pharmaceuticals Corporation, the third-largest pharmaceutical wholesaler in China.

Advised Nycomed in its USD214 million acquisition of a majority stake in Guangdong Techpool Bio-Pharma Co., Ltd., a fast-growing Chinese bio-pharmaceutical company based in Guangdong.

Represented Smiths Medical Group Limited in the USD46 million acquisition of a 100% equity interest of a domestic company in Hangzhou, Zhejiang engaged in the manufacture and sale of syringe pumps and nutrition pumps.

Southeast Asia

Source: BMI Q2 2014 country reports, Pharmaceuticals & Healthcare



OPPORTUNITY

**ASEAN
Economic Community (AEC)**
INTEGRATION IN 2015 MEANS

A SINGLE MARKET
FAIR COMPETITION
A SINGLE PRODUCTION BASE

MATTERS TO CONSIDER



Slow evolution — mutual recognition arrangements, not directives, to harmonize laws



Application forms for regulatory approval have been developed



Diverse legal systems among member countries — common law and codified civil laws

OUR LOCAL PHARMACEUTICAL & HEALTHCARE PRACTICE



As the AEC brings together the pharmerging markets of Indonesia, Thailand and Vietnam with the region's frontier markets, our firm can provide valuable input as market access strategies are developed.

Our local experience is extensive — we have been operating in Southeast Asia for over 50 years. Also with offices in seven of the 10 ASEAN nations and correspondent law firms in Cambodia and Laos, we have the most legal coverage in the region. The Firm's 500 ASEAN-based lawyers and a dedicated AEC SubCommittee help pharmaceutical companies navigate the region's swiftly evolving regulations and markets with confidence.

Southeast Asia

OUR EXPERIENCE

Advised Pfizer Inc. on its sale of Pfizer Nutrition to Nestle for USD11.65 billion. We represented Pfizer in Thailand, Vietnam, Philippines, Malaysia and Indonesia.

Acted for Valeant Pharmaceuticals International, Inc. in its USD700 million acquisition of iNova across the Asia Pacific.

Acted for Ramsay Health Care Ltd., an international hospital operator, on a USD525 million joint venture with Sime Darby Berhad across Indonesia and Malaysia.

Formally appointed law firm of Thailand's Pharmaceutical Research and Manufacturers Association (PReMA). Our role includes: working with PReMA in all key policy issues; advising PReMA in key legal and health policy challenges experienced in the industry; and performing a general legal adviser role.

Advised a leading European-based pharmaceutical company on issues relating to termination of distributorship agreements and transfer of medicinal product licenses in Singapore.

Advised Eurocham Vietnam Pharmaceutical Group in developing the first industry code of conduct for multinational pharmaceutical companies in Vietnam.

Brazil

+8.2%

PHARMACEUTICAL
MARKET GROWTH, 2013-14
(projected value: USD26.2 billion)

*source: BMI Brazil Pharmaceuticals & Healthcare Report Q2 2014

+10.6%

HEALTHCARE
MARKET GROWTH, 2013-14
(projected value: USD206.3 billion)

OPPORTUNITY
expanded
health
coverage

MORE PROSPECTS
BUT INCREASED
COMPETITION
BETWEEN LOCAL AND
FOREIGN PLAYERS

8th
largest
pharmaceutical
market in 2013



OUR LOCAL PHARMACEUTICAL &
HEALTHCARE PRACTICE



Our regulatory and IP teams are well aware of the latest events that may affect your business. In Brazil, we work in cooperation with Trench, Rossi e Watanabe Advogados. They have a long track record of work with the pharmaceutical and medtech sectors. Their experience includes FDI issues, cross-border M&A, joint ventures and other partnering. Their regulatory professionals support local dealings with ANVISA and other market access and expansion issues, including the Brazilian approach to data exclusivity. They also have professionals who support the registration and strategic management of intellectual property assets — including patents and trademarks.

MATTERS TO CONSIDER



Higher standards — ANVISA at the forefront, collaborating with COFEPRIS (Mexico) and INVIMA (Colombia)



Mutual respect for each organization's decisions on GMP inspection of foreign manufacturing sites



Government support focused on local and public/private partnerships



ANVISA's involvement in patent decisions complicates patent position in Brazil

Brazil

OUR EXPERIENCE

Advised Merck on the formation of Supera RX Medicamentos Ltda., a joint venture formed for the distribution of pharmaceutical products in Brazil.

Advised Alliance Boots in its entry into the Brazilian pharmaceutical wholesale market through the acquisition of an initial 25% equity shareholding in Athos Farma, S.A., one of Brazil's leading pharmaceutical wholesalers.

Advised Dong-A Pharmaceutical Co. Ltd., the South Korea-based pharmaceutical company, on its USD600,000 acquisition of Milimport Produtos Medicos e Farmaceuticos Ltda., which will give Dong-A Pharmaceutical product distribution access in Brazil.

Advised GE Healthcare on the antitrust aspects of its acquisition of XPRO, a Brazilian medical devices company.

Advised a major healthcare player in a deal with a public laboratory in Brazil to sell vaccines and to enter into a Process of Development of Products, which is an agreement for transferring the vaccine manufacturing technology to the government.

Advised one of the largest pharmaceutical companies in the world regarding campaign contributions in Brazil and compliance with FCPA and other anti-corruption legislation, as well Brazilian electoral laws.

Pacific Alliance

OPPORTUNITY

BOOSTING TRADE

HARMONIZING REGULATIONS

INTER-INSTITUTIONAL
COOPERATION AGREEMENTS

STREAMLINING REGULATORY
APPROVAL PROCESSES

MATTERS TO CONSIDER



Potential delays in approvals



No centralized authorization system



Intellectual property protection



Pricing limits

MEXICO

2011-12 market growth
Pharma: 8.9%
Healthcare: 9.1%

COLOMBIA

2011-12 market growth
Pharma: 7.6%
Healthcare: 5.4%

PERU

2011-12 market growth
Pharma: 5.3%
Healthcare: 6.2%

CHILE

2011-12 market growth
Pharma: 8.9%
Healthcare: 10%

OUR LOCAL PHARMACEUTICAL &
HEALTHCARE PRACTICE



Our Firm has had a strong presence in Latin America for over half a century, well-established in the member countries of the Pacific Alliance. We have been at the forefront of their start in Peru and have closely studied the new trading bloc's agreements. We assess the likely impact of their decisions to help clients identify and properly address emerging opportunities and risks. Our interdisciplinary group of lawyers and scientists work day-to-day on local regulatory and IP issues in each of these markets.

Pacific Alliance

OUR EXPERIENCE

Advised Alliance Boots on its USD638 million acquisition of Grupo Casa Saba, a wholesaler and distributor of pharmaceutical products and a market leader in Mexico and Chile.

Advised ConvaTec on the acquisition of Boston Medical Device, Inc., a distribution company that offers specialized medical devices throughout Latin America.

Advised GlaxoSmithKline on the acquisition of Italmex S.A., a domestic Colombian pharmaceutical manufacturer.

Advised on regulatory, transactional and intellectual property matters in Colombia to multinational pharmaceutical companies, involving distribution, advertising, labeling, commercialization of medicines, medical devices, cosmetics and chemicals.

Advised on implementing comprehensive strategies in Colombia concerning trademark and copyright registration, licensing, enforcement and anti-piracy programs to ensure complete protection of their intellectual property rights.

Advised one of the world's largest pharmaceutical companies on its entry and establishment of operations in Peru.

Russia & CIS



OUR LOCAL PHARMACEUTICAL & HEALTHCARE PRACTICE



OPPORTUNITY

RUSSIA AIMS TO
GROW HEALTHCARE
SPEND TO 7.5% BY 2020
IMPLEMENT NATIONAL
HEALTH INSURANCE

+12.2%

PHARMACEUTICAL
MARKET GROWTH, 2013-14

+7.9%

HEALTHCARE
MARKET GROWTH, 2013-14

*source: BMI Russia Pharmaceuticals
& Healthcare Report Q2 2014

MATTERS TO CONSIDER



Dynamic operating environment



Rapidly changing regulatory standards



Increasing population size and
purchasing power



Significant disease burden

The countries' complex regulatory and IP scene requires a team familiar with local nuances to assist in business decisions.

Present in Russia and the CIS for more than a quarter of a century, we are established advisers to multinational and domestic industry players in the region. Ours was the first international law firm to win a pharmaceutical patent infringement action before Russian courts. We continue to advise on significant issues in the industry, with our regulatory and intellectual property focused teams.

Russia & CIS

OUR EXPERIENCE

Advised the Russian Corporation of Nanotechnologies (RUSNANO) on establishing a joint venture for manufacturing and developing medical equipment for brachytherapy cancer treatment in the Russian Federation.

Advised Alliance Boots plc on all aspects of its entry into the Russian pharmaceutical wholesale market, including due diligence, negotiations and acquisition of Apteka Holding, the fifth-largest pharmaceutical wholesaler in Russia.

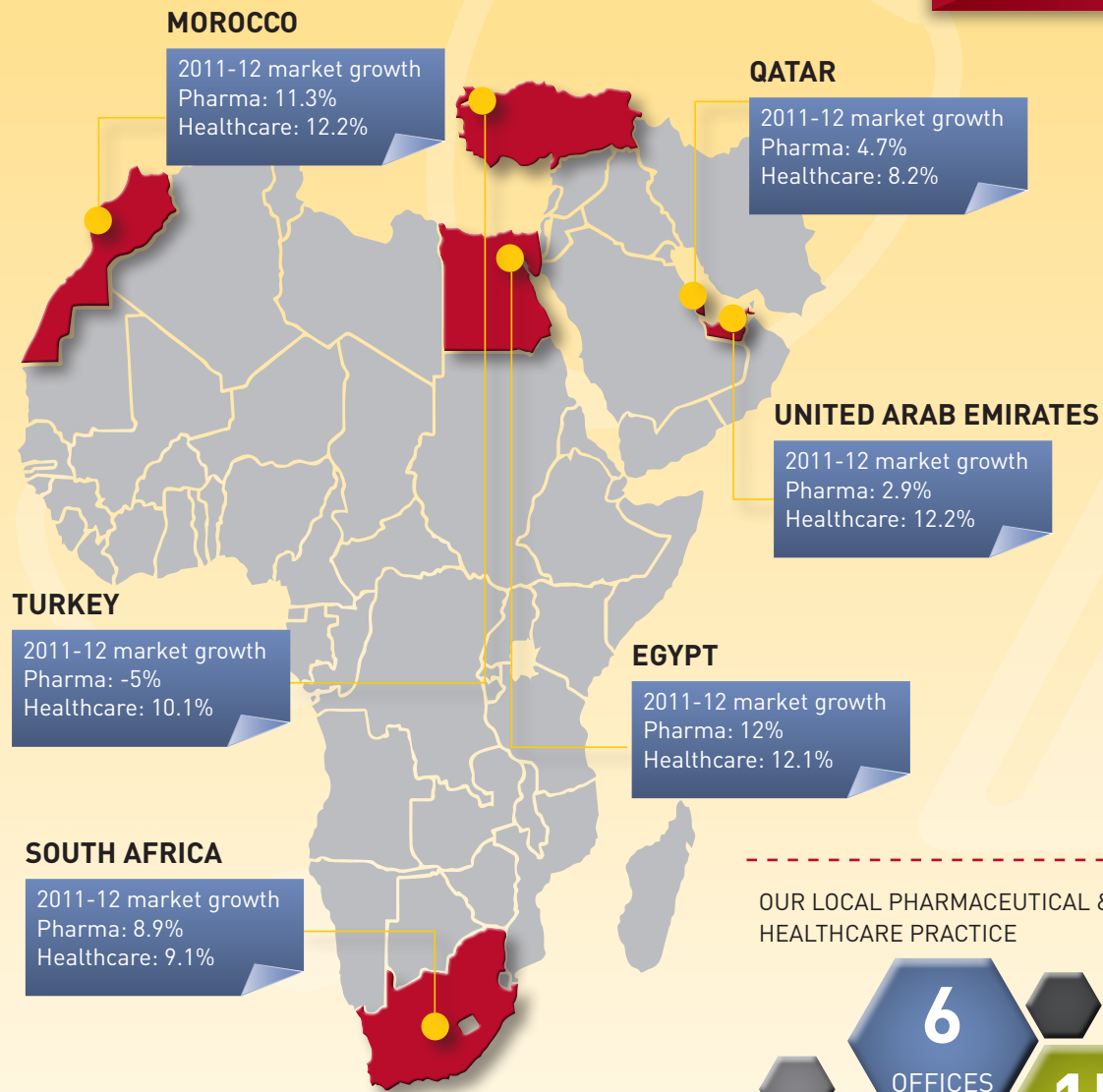
Advising numerous multinational pharmaceutical manufacturers and medical devices manufacturers with respect to their interaction with the Russian antitrust regulator on various competition law and compliance issues associated with abuse of dominance and participation in the state procurement process.

Advising numerous international pharmaceutical and medical devices manufacturers on various regulatory issues relevant to the industry, including interaction with healthcare professionals, pricing, clinical trials, advertising of medicinal products, product registration, and others.

Advised Takeda Pharmaceutical on construction, town planning and utility construction matters in relation to a new Nycomed manufacturing facility in the Yaroslavl region, a landmark project for the development of a pharmaceutical cluster in the region.

Legal advisers to Russia's Association of International Pharmaceuticals Manufacturers for over 20 years and recipients of the AIPM award for "Outstanding Contribution to the Development of the Russian Pharmaceuticals Market".

Middle East, Turkey and Africa



Source: BMI Q2 2014 country reports,
Pharmaceuticals & Healthcare

OUR LOCAL PHARMACEUTICAL & HEALTHCARE PRACTICE



GOV'T REFORM

INCREASING GOVERNMENT
INVESTMENT IN HEALTHCARE

REDUCED AND STANDARDIZED
MEDICINE PRICES

AN AGING POPULATION

OPPORTUNITY

MATTERS TO CONSIDER



Centralized GCC registration is present;
local registration is still sometimes
necessary



Stiff competition from well-established
local generics manufacturers



Political instability in a number of states

Our extensive experience in the META region includes complex matters in the pharmerging markets — Saudi Arabia, Egypt and South Africa.

Active in the dynamic markets of the Middle East and neighboring regions since 1975, Baker & McKenzie is uniquely positioned to help industry players manage the impact of local legal, economic and social transition on their operations. And with a team that includes fluent Arabic speakers, we can work with both English and Arabic documentation.

In Africa, we assist pharmaceutical multinationals establishing branches in South Africa, which many then use as a springboard to tap into the growing consumer market in other Sub-Saharan Africa countries such as Ghana and Nigeria. Through our relationships with trusted African Correspondent Firms, we are able to service the larger Sub-Saharan Africa region from our Johannesburg office.

Middle East, Turkey and Africa

OUR EXPERIENCE

Advised the Menarini Group, the Italian pharmaceutical company, in relation to its establishment of operations in SA and the restructuring of its relationship with Adcock Ingram Limited, the South African pharmaceutical company.

Advised Eli Lilly on the sale of its diabetes business to Batswadi Pharmaceuticals Proprietary Limited, a South African biotechnology company.

Advised Aspen Pharmacare Holdings Limited on a series of strategic transactions with GlaxoSmithKline, including the acquisition by GlaxoSmithKline of a stake in Aspen.

Advised Abraaj Capital, a leading private equity investor specializing in growth markets, in connection with the acquisition of a 40% stake in the Saudi Tadawi Company for Health Care, the largest pharmacy chain in Saudi Arabia.

Advised numerous global pharmaceutical firms on agency and distribution arrangements across the GCC, including de-registration of agency arrangements in both contentious and non-contentious contexts.

Advising a leading global healthcare products company on branding of pharmaceutical and co-marketing issues in Turkey.

Baker & McKenzie has been global since inception. Being global is part of our DNA.

Our difference is the way we think, work and behave – we combine an instinctively global perspective with a genuinely multicultural approach, enabled by collaborative relationships and yielding practical, innovative advice. Serving our clients with more than 4,100 lawyers in over 40 countries, we have a deep understanding of the culture of business the world over and are able to bring the talent and experience needed to navigate complexity across practices and borders with ease.