

## MSD sues German Merck for using name in US

MSD SAYS it is filing a lawsuit against the German company Merck "regarding their improper use of the name 'Merck' in the United States."

MSD, which has operated under the name Merck in the US and Canada for 125 years, says it is taking the legal action to "protect our long-established brand rights in the United States." The US lawsuit is being filed in the United States District Court for the District of New Jersey.

MSD was established as a subsidiary of its former German parent company in 1891, but became independent in 1917. Now the Darmstadt-based Merck is entitled to use the name in all other territories, as per the terms of an agreement between the two companies, last amended in 1970.

MSD comments: "Our company brand and what it stands for is crucial to our identity and reputation and we will vigorously defend it." A Merck spokesperson told Pharmafile.com the company's lawyers were "looking into the matter."

However the German firm did score a win in a similar UK case contested in January. The High Court stated that MSD had breached an agreement with the company by using Merck alone in the UK either as a trade mark or a name, online or offline. The judge also held that MSD's use of Merck as part of branding on its global websites infringed Merck trade mark rights in the UK.

### MARKET GROWTH FORECASTS

The forecasts draw an optimistic picture. The global pharmaceutical market is expected to grow at a 4-6% compound annual growth rate (CAGR) in developed markets and 7-9% CAGR in pharmerging markets by 2019. The market size for Turkey stood at \$6.2 billion in 2014 and is expected to grow to \$10.9 bn until 2019.

### MARKET ACCESS

Article 15 of the Licensing Regulation issued by the Turkish Ministry of Health (MoH), in parallel with the European Directive 2001/83/EC, foresees that a pharmaceutical product is granted a marketing authorisation within 210 days. This is the explicit rule stated under the Regulation itself, but there is doubt as to whether this is always reflected in practice.

The MoH adopted a parallel application opportunity through which applicants could apply simultaneously for both the GMP certificate and the marketing authorisation. However this opportunity has been introduced only for products that fall under the so-called 'first category' i.e. innovative products that have no generics, and for first generics. Although there are further incentives for GMP auditing for generic products, these are not valid for original products.

### PRICING

After the replacement of a cost based pricing system with the reference pricing system back in 2004, companies announced the cheapest ex-factory price among the reference countries (France, Italy, Spain, Portugal, and Greece) which will be accepted by the MoH as the 'highest ex-factory price'. In addition, it has to

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undergo mandatory discounts applied by the Social Security Institution (SSI), the Health Implementation Communiqué, as well as the commercial discounts made to warehouses and pharmacies.

More dramatically, the Pricing Commission had frozen the exchange rate at 1.9595 Turkish Lira (TRL) until a very recent amendment, due to a court decision. The decision stated that the Commission's failure to make any changes to the current exchange rate is against the law. In line with this decision, the Commission revised the exchange rate, raising it to TRL

2.0787. The court actions are still ongoing and the industry is waiting for better revisions in the exchange rate to give more accurate prices compared with the prices in the reference countries.

### REIMBURSEMENT

As an upside of having the cheapest prices in Europe, the reimbursement levels are relatively high in Turkey. Indeed there are around 8,200 different pharmaceutical products within the reimbursement list of the SSI. In 2014, the SSI financed more than 337 million

prescriptions in total which equals to TRL 16 billion (€367 million).

### FINAL WORD

Considering the expectations, we may conclude that a lot has been accomplished, yet still there is way to go. Along the way, there is no doubt that all the parties, not only the government but also the private players, need to act cooperatively and proactively.

By Özge Atılgan Karakulak, Selin Sınem Erciyas, and Tuğçe Avcısirt Geçgil, of Gün + Partners.

WHEN MERCK unveiled its Africa 2020 strategy in November, there was no shortage of ambition.

The company announced plans to expand across the continent into new territories while upping its workforce to 1,000 from 400 with the intention of more than doubling sales from €200 million to €500 million.

At the same time, the company also opened new offices in Lagos, Nigeria. It also commissioned a new manufacturing plant for diabetes medications in Algeria which will create 500 million tablets a year and enable the country to reduce its import spend.

At the forefront of this strategy is Fritz Sacher, Merck's head of Africa strategy realisation - a role he has held since January 2015. Prior to this, Sacher was managing director of Merck Portugal, with close links to Portuguese-speaking African nations including Angola, Mozambique, and Guinea-Bissau.

He recognises that reaching such goals will require robust planning taking into account the scale of the continent and the health issues it faces, and focusing on the countries with the best opportunities with the correct infrastructure and circumstances.

Sacher comments: "This strategy will be achieved by organisation. Sales are born in people and not the other way round, so

## Merck eyes growth in Africa



we need to set up organisations. We are not covering the whole of Africa, but focusing on a small number of countries. We are already quite well positioned in North Africa: in Tunisia, Algeria, Morocco, and Egypt, and also in South Africa. We are now entering Sub-Saharan African countries like Ghana, Nigeria, Angola, Mozambique and Kenya."

### AFRICAN DIVERSITY

To build on its success in Africa, Merck knows it must be prepared to adapt to changing political and economic situations.

The huge cultural, political and developmental diversity of the continent means there is no one-size fits all strategy that can be successfully implemented across the whole of Africa. Rather strategies must be adapted to the vastly different and variable individual statuses and realities of each country - or at least groups of countries that share similar policy.

Sacher explains: "Africa is not a country like China, which is vast but has a unified culture. Africa is a continent with thousands of cultures, although there are some economic regions where you see similarities and where the countries are working together on economic policy. So I think to understand the culture and manage the diversity is a major challenge. To refine the strategy to groups of countries or individual countries is extremely important. There are countries that will work together, and others that won't."

The countries in which to do business have been chosen based on factors including their size, political stability and importantly, GDP. The economic fortunes

of certain African countries can fluctuate enormously however: even in the last year, Sacher notes, factors like commodity prices, oil and mining outcomes have changed considerably and created problems for the pharmaceutical industry. For example, the price of oil has a dramatic impact on Angola or Nigeria's GDP, and large drops consequently lead to large declines in the country's economic fortunes.

Despite these sorts of issues, however, Sacher says Merck is committed to its presence in these nations, where the company continues to grow and progress, and indeed is looking at additional promising countries for the future, including French-speaking nations like the Ivory Coast and Senegal, which have enjoyed recent stable growth. Sacher adds: "Our goal to double sales means we will need to start to grow businesses South of the Sahara."

### INCREASING ACCESS

Another aim on Merck's agenda is increasing patient access to medicines. During the company's Africa Luminary

Congress in Nairobi in November, capacity building was a focus - not only with regard to projects running in most of the countries in which Merck has an office, but also their neighbours.

Capacity building was seen to be most crucial in cardiometabolic care, particularly in the form of public-private partnerships, but countries also asked the company to provide even greater assistance in oncology, and in particular with improving the supply chain, where Merck's knowledge can have a large impact. It was agreed that the company would set up seminars on this topic.

Another scheme of which Sacher is particularly proud is its introduction of 600 portable testing laboratories for counterfeit drugs, which in some countries can account for up to 80% of malaria medicines. These small kits are capable of testing 75 different drugs, and can be operated by somebody after just a week of training.

Creating a successful strategy in Africa may be a challenge, but the rewards are there if it does it right, not only for the company, but for its patients. The next five years will determine the extent of that success.

Read the full interview on Pharmafile.com