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To provide every human being across the globe with quality and affordable drug treatment in a manner that supports sustainability

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Medochemie's Yasser Sabra gives a fascinating insight into the branded generic and value added medicine field today, including why the COVID-19 pandemic could lead to a reappraisal of medicine repurposing. Sabra also touches on the firm's operations in the Middle East's biggest market of Saudi Arabia, explaining why the Saudi localisation rush and associated high costs will soon settle down and how Medochemie has managed to establish itself as a key partner to the Saudi MoH, especially for its injectable antibiotic range.

Could you begin by introducing Medochemie Ltd to our international audience?

Medochemie Ltd is a European pharmaceutical company that develops, manufactures, and commercialises off-patent medicines, also known as Branded Generics, and Value Added Medicines.

We have 45 years of history as a pharmaceutical manufacturer; the company was established back in 1976 by a visionary medical doctor, Dr Andreas Pittas, who realised the importance of local manufacturing of medicines in Cyprus. Since then we have adhered to the same company mission and philosophy:

Because Cyprus is a relatively small market, the company had no choice but to go overseas, which is how it managed to expand globally. Today, we are proud to have 13 manufacturing sites, in Cyprus, The Netherlands and Vietnam, all of them designed to comply with European and WHO current good manufacturing practices (cGMP).

Medochemie Ltd has unique commercial expertise based on a global footprint, with 22 operational subsidiaries in Europe and overseas, we export to 107 markets worldwide, from the Far East to the Middle East, Africa, Western Europe, Russia, China, the CIS countries, Latin America, Canada, Australia, and New Zealand. We produce a wide range of therapies with 4,335 active marketing authorizations (MAs) worldwide.

Additionally, we partner with many big multinationals such as Sandoz, Mylan, and Stada with whom we have supply agreements whereby we license out many of our molecules. Recently, we also began collaborating with Pfizer and are now manufacturing some of Pfizer's legacy products in our Medochemie Far East facility.

How does Medochemie differentiate itself in the highly competitive branded generics/value added medicines space?

Our main strength lies in our broad portfolio, especially in injectable antibiotics. These medicines are - and will continue to be - the most valuable weapons in fighting infections across the world, as was made clear during the pandemic. When COVID patients were admitted to ICUs, and intubated they often caught nosocomial infections such as Ventilator Acquired Pneumonia (VAP) that need to be treated with very strong broad-spectrum antibiotics. We manufacture Meropenem, among other injectable antibiotics used for this, and witnessed a worldwide surge in demand last year.

We are proud to have this strong footprint in antibiotics, which positions us as a reliable partner with many governments across the world, especially in the MENA region. For example, our Meropenem was the first generic version to be centrally registered and approved in all the GCC member states in 2016 and we are one of the main partners of the Saudi MoH for injectable antibiotics.

Nowadays we are also focusing on the new emerging therapeutic category known as value-added medicines; well-established medicines which have been proven safe and effective, but require further R&D to be used in different indications.

During the COVID-19 Pandemic, we have seen the repurposing of affordable and safe treatment approaches to address unmet medical needs. For example, Dexamethasone is an affordable steroid that is commonly used. Dexamethasone was repurposed for COVID-19 treatment, it has been shown to reduce deaths by one-third in hospitalized COVID-19 patients receiving mechanical ventilation and one fifth in hospitalized COVID-19 patients receiving oxygen without invasive mechanical ventilation

Therefore, in addition to traditional off-patent molecules, which are mainly for primary or secondary care, and biosimilars (where we do not currently operate), the scope of generic manufacturing is increasing. Most governments are now cognizant of the importance of this industry.

How did the COVID-19 pandemic affect the way in which Off-Patent (Generics) and value-added medicines are perceived?

COVID-19 dramatically reduced the accessibility of care and changed patients' needs in a number of ways. Delivery of medicines and other health products worldwide – were disrupted and faced many challenges. Both governments and industry faced new unprecedented limitations.

The main predicament was how to continue delivering medicines while developing new products for COVID-19 patients and getting them to all corners of the world in no time.

Off-patent (Generic) Medicine has always had important benefits for patients, healthcare professionals, payers and healthcare systems, as a whole, in a sustainable and affordable way.

During the Pandemic, we have seen huge demand for COVID-related off-patent medicines like Paracetamol, Vitamin C, Zinc, and Azithromycin in addition to many other injections used primarily in the ICU.

All countries are today looking at the sustainability of their healthcare systems.

We need to differentiate between tertiary care products, like immuno-oncology drugs, new biologics, cell and gene therapies, and the need for effective affordable treatments for primary care, which already exist and give quick results.

New products like Remdesivir and Tocilizumab were in high demand for treating severe cases of COVID patients in ICUs, but dexamethasone was reliable, cheap, and readily available as many companies are able to produce it. Recently, we also heard about another clinical trial for a

repurposed product which found that fluvoxamine, a selective serotonin reuptake inhibitor (SSRI) antidepressant, significantly reduces the chances of hospitalization and death in high-risk patients with COVID-19. Fluvoxamine is cheap, widely available, and has an established safety profile. If taken shortly after diagnosis, the drug may prevent the immune overreaction, or “cytokine storm,” often responsible for severe disease and death.

It is clear that off-patent (Generic) medicine and Value Added Medicines are essential to improve the equity and quality of healthcare, creating an ecosystem for safe, timely and affordable treatments for patients around the globe, which was greatly proven in the past, during the pandemic, and will continue in the future.

Off-Patent (Generic) Medicines: Essential Contributors to the long-term Health of Society

Should this R&D into value-added medicines be funded internally by private companies like Medochemie Ltd or does European funding should be part of the solution?

Policymakers have an essential role to play. Post-pandemic, discussions are now ongoing through our industry group **Medicines for Europe** as to whether grants can be given by governments for research into this sector and there is a growing cognizance of value-added medicines’ importance in preparing for future pandemics. This can help us in times of great need, saving money which can then be funnelled into research inexpensive fields like vaccines. A small amount of investment into value-added medicines today will definitely pay off in the long run.

What has Medochemie’s trajectory been in the Middle East and what importance does the region hold for the global group?

Historically, due to the geographical proximity between Cyprus and the Middle East, this has always been an important region for the company. Iraq was Medochemie’s first export market worldwide back in 1978, which was then followed by Jordan. For example, in Iraq and Jordan, our brands like Snip for the common cold and Glibesyn for type 2 diabetes – despite being off-patent – are synonymous with the brand themselves.

After the dismantling of the Soviet Union, there was a strategic shift towards the CIS countries, in which Medochemie invested heavily and then we geared for the development of our operations in the Far East.

For that reason, our presence in Saudi Arabia and other GCC States is relatively young, only beginning in 2012, when we decided to enter the Saudi Arabian market. Within three years, we managed to finalise all regulatory frameworks and bring our first products to market.

Despite only being present in Saudi Arabia for approximately ten years, we have already achieved great success, navigating the country's complex regulatory framework, establishing ourselves in the market, and registering 25 products, with more in the pipeline. We are now considered a key partner to the Saudi MoH and have managed to win many tenders, especially for our injectable antibiotics range.

How would you define Medochemie's Saudi strategy today?

We have all witnessed the recent changes in the Saudi market, with greater privatisation and a digital transformation rendering the market completely different to that of five to ten years ago. This transformation of the market has necessitated a significant change in our go-to-market strategy. Nowadays, we are looking towards niche products that are difficult to manufacture, leveraging our good partnerships with large local manufacturers, and which can generate returns quickly.

Working with local manufacturers such as AJA Pharma and Tamer Group is a very important part of our Saudi strategy, especially as these manufacturers have gained certain privileges because of localisation policies. Manufacturing locally can also help us with speed to market – which is crucial in the generics industry – as patents can be applied for earlier than for imported products.

The Saudi government is promoting the localisation of manufacturing but also, like all governments, wants to manage its budgets carefully. Will local manufacturing lead to lower medicine prices within the country?

I do not think so. There has been a realisation, post-pandemic, that what we need is not cost-containment measures, but sustainable pricing and smart procurement policies. If we continue to focus only on price, the same approach cannot be sustained forever. We have witnessed significant increases in API prices, whereby an ingredient jumps by 100 to 200 percent in costs overnight. No supply chain will be resilient in the long run if we continue to focus only on price.

Vision 2030 requires a certain level of localisation, what are the localisation steps that Medochemie is looking to take in Saudi Arabia?

We have managed to comply with all the requirements laid out so far. Medochemie has a scientific office in Saudi Arabia managed by our Saudi colleague, Dr Saud AlQahtani, and our field force, as per the new regulations, is 100 percent Saudi Nationals and includes female Medical Reps as well.

However, in my view, the market will settle down soon. Currently, the turnover of the FF is relatively high as all companies are rushing to comply with the new requirements from the Saudi FDA, which created high demand and increased total packages offered. I believe, very soon, everybody including the big pharma companies will realise that the costs are extremely high and cannot be maintained at such a level.

Might digital tools come to ease some of this cost burden of the high turnover of medical reps in Saudi Arabia?

It must be remembered that our region is not the US or Europe. Digitalisation and online interaction is available but will not be the main driver of the business. Doctors here are busy, it is difficult to get appointments with them, and most are not particularly technologically savvy. At the beginning of the pandemic, everyone was excited to use digital tools and attend webinars, but we saw a high level of burnout and a huge drop in interest after less than three months.

We have witnessed huge advances in digitalisation in Saudi Arabia, serving the patients with the government-sponsored SEHA app for telehealth, and Wasfaty Service from NUPCO, in addition to online ordering through the major pharmacy chains, and all the major hospitals switching to telehealth and homecare in just one year.

However, when it comes to Health Care Providers (HCPs), face-to-face interactions will remain the most important method of communication. We try as much as we can to train our field force for digital interactions; in case we have no other choice to reach doctors during lockdown situations. Nevertheless, in the end, our sales and marketing workforce will remain the foundation of the pharma commercial model and that the cost will be marginally reduced using digital tools.

Do you have a final message on behalf of Medochemie?

I would like to express my gratitude to all healthcare providers across the region for their continuous fight against COVID-19 and I would like to personally thank and show my appreciation for our entire Medochemie MENA team. They are making huge efforts and doing fantastic work in very difficult circumstances. They have been highly committed to continuing working throughout the pandemic.

On a broader level, the pandemic has foregrounded the importance of the pharma industry and we now have a golden opportunity to burnish our industry's reputation as a core element in the healthcare ecosystem.

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