High hopes for SA pharmaceutical progress this year

By Dr Thomas Kowallik

10 Jan 2018

The world is currently benefitting from a wave of pharmaceutical breakthroughs including targetted personalised treatment and biologics. In South Africa, which has traditionally lagged behind the rest of the world, requiring five to seven years in the licensing of new drugs compared to 18 months to two years in most western countries, there is cause for optimism on progress in 2018.

Dr Thomas Kowallik

We have entered a phase of pharmaceutical revolution where we are seeing a wealth of innovative and more effective new drugs being licensed globally on the back of massive R&D investments, offering new hope for patients, and the availability of next-generation digital technologies to support research and healthcare delivery.

A pharmaceutical revolution

During the past few years, we have seen the hype of the '90s around new drug technologies becoming a reality. If comparing the 2012-2017 timeframe to the years from 2007-2011, the average annual number of new drug approvals in the USA has increased by 46%, showcasing the acceleration in innovation. A significant proportion of new drug approvals have moved from chemical to biological drugs – biotherapeutics - in which drugs are manufactured using a living system such as a microorganism or plant or animal cells.

Personalised cell and gene therapies and regenerative medicine are presenting the promise of effective treatment in ways that were never possible before, for example, through immunocellular therapy that uses a patient's own T-cells to fight cancer. Such a therapy received a breakthrough therapy designation by the US authorities this year. Preventative medicine is also an area of rapid development – as researchers uncover biological pathways responsible for debilitating chronic conditions, promising treatments are in development to actually halt the processes involved in disease progression before debilitation sets in. Current examples are biological products for the prevention of migraine, Alzheimer's disease and recurrent, major adverse cardiovascular events after initial myocardial infarction.

In addition, the digitisation of the industry is helping to drive progress both in R&D and healthcare delivery. Automation and big data analytics are supporting traditional laboratory work; predictive modelling is enhancing the ability to predict outcomes and tailor treatment; and artificial intelligence, internet of things (IoT) technologies and mobile devices are enabling more effective patient monitoring and outcomes assessments. Examples of such developments are smartphone

platforms that have been developed by pharma in collaboration with global leaders in artificial intelligence (AI), that are used by community health workers to monitor the general health of whole families, with a referral function to local clinics only when built-in algorithms indicate increased risk. Testing and diagnostic devices for monitoring chronic conditions such as chronic obstructive pulmonary disease and diabetes, that can be plugged into any smart phone to measure lung function or glucose levels respectively, and then transmit data directly to the treating physician are also available. Telemedicine using smartphones plays a role in serving remote areas or providing a link-in to a specialist physician where needed, to ensure optimal diagnosis and treatment. These 'beyond the pill' solutions are emerging in South Africa and are likely to increase their impact over the course of the next year.

New regulator: new hope of faster time to market

For South Africans, global pharmaceutical innovation has traditionally arrived late due to backlogs in local medicines approval times. However, there is hope that the situation will change in 2018, bringing advanced new drugs to South Africans, far faster.

South African patients will benefit from the arrival of game-changing drugs in their fields, one of which received fast track approval by the MCC due to its breakthrough status which shortened the usual approval times significantly. The new drug reduces the risk of heart failure hospitalisations and cardiovascular deaths following heart failure by 20%; it enables patients to improve their quality of life and represents a new treatment class now available. Another drug under registration is a biological and offers improved psoriasis treatment outcomes with very high skin clearance as well as treating psoriatic arthritis and ankylosing spondylitis.

However, thousands of other drugs still await approval by South Africa's medicines regulators – a process that has traditionally delayed the arrival of new drugs in South Africa by around five years compared to the rest of the world. Such late approvals obviously delay access to new, innovative drugs for South African doctors and patients.

This is especially critical in life-prolonging treatments where delayed approvals have a direct negative impact on patients' survival as they cannot benefit from these new drugs while waiting for these treatment options to be approved and become available in South Africa.

The formalisation of a new regulatory body – the South African Health Products Regulatory Authority (SAHPRA), replacing the Medicines Control Council (MCC) with effect from 1 June 2017, and the announcement of the new SAPHRA Board in October this year, may herald the start of change in 2018. In the meantime, the South African pharma sector is committed to the country's continued participation in clinical trials, ensuring that data from our diverse population contributes to the development of new treatments. SAPHRA could gain confidence on review of registration dossiers from the fact that local investigators (often leaders in their clinical field) have had experience with the product.

The industry is cautiously optimistic that the new body may take a new approach to approvals, such as building on reviews by the US FDA and European Medicines Agency (EMA) while upgrading the full-time review capacity at the new SAHPRA. This would enable reduced review times and bring the benefits of these revolutionary drugs to South African patients faster.

Moves toward an NHI

Another development set to impact health and the pharmaceutical sector in South Africa over the next year is the move towards a National Health Insurance (NHI) scheme. Universal access to healthcare is a noble ambition, which we support wholeheartedly. However, it should be noted that such initiatives are most effective and sustainable when thoroughly planned and resourced with strong partnerships in place.

While we do not expect to see the implementation of an NHI in 2018, we may well see progress made in planning of the initiative. Key will be the coverage the NHI package will offer, what infrastructure and healthcare staff will be available, and ensuring the health insurance will be based on solid and sustainable financing for many years. The financing will also determine how comprehensive the package offered under NHI can be and will be a key design question of the new insurance scheme. The pharmaceutical sector, in particular innovator companies, has a very proactive approach to the changes and is seeking to partner early on with the relevant stakeholders to ensure patient access to the best treatments in a changing healthcare space.

Patient empowerment

Patient advocacy groups will likely play a role in the development of the NHI, amidst another emerging trend in healthcare: the growing role the patient plays in his or her own treatment. Across the world and in South Africa, the emergence of patient associations, pressure groups and advocacy groups; and patient empowerment through social media and digital channels, is giving the patient a voice and moving the patient to the centre of the treatment ecosystem.

These patient groups share learnings and experiences with the disease, and give a feeling of community; and also help the patients' families and social environment to take an active role. In a digital age, many patients now educate themselves before going to see a doctor and also use digital media to learn about their disease.

The patient also plays a key role in the success of treatment and managing his or her disease. It is known that the adherence rate for many diseases is only in the range of 50-60% (i.e. patients only take half of the pills they are supposed to take according to prescription, leading to suboptimal health outcomes). Here, digital technology can help to remind patients to take their medication and document their health outcomes – and even share them with their treating doctor.

With this wave of change and progress underway across the sector, South African patients can start looking forward to improved treatments and enhanced healthcare provision in years to come.

ABOUT THE AUTHOR

Dr Thomas Kowallik is the CPO head and country president of Novartis South Africa & head of Novartis Southern African countries