ET EXCLUSIVE Q&A

DR PAUL STOFFELS
CHIEF SCIENTIFIC OFFICER, JOHNSON & JOHNSON

'We are Keen to Use the Brain Power of India for Innovation'

Dr Paul Stoffels, chief scientific officer at Johnson & Johnson, is most recognised in the global drug industry for his contributions in bringing to market a broad range of latest generation anti-HIV drugs. Stoffels, who is also the worldwide chairman of the US drug major's pharmaceuticals group, was in India recently to take stock of his company's operations. In an interview with **ET's Vikas Dandekar** and **Divya Rajagopal**, he talked about J&J's interest in doing more in India and how its clinical development programme in the country is back on track after it was scaled back for a couple of years. Edited excerpts:

How do you look at India in terms of your global research programmes?

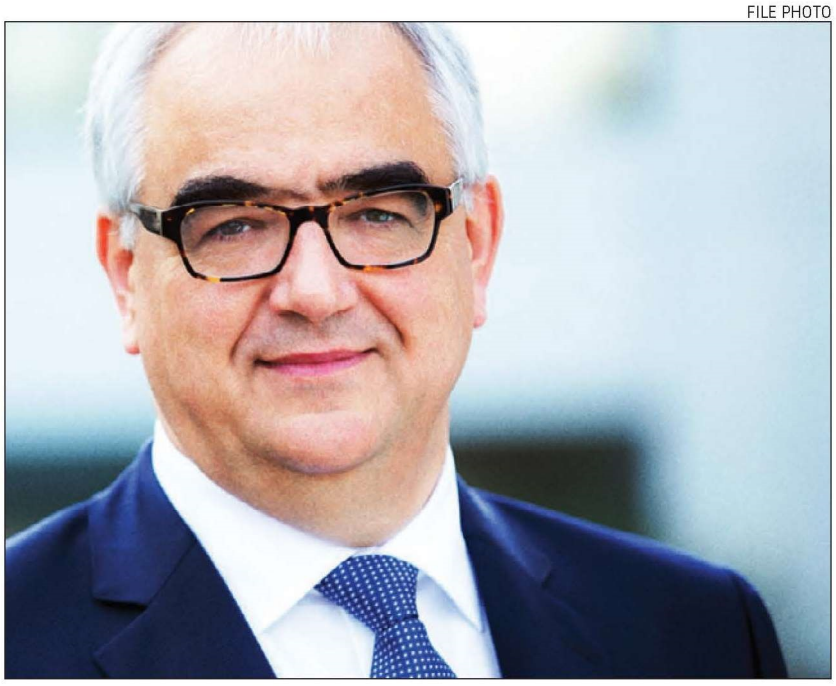
At the moment we don't have any integrated research activity in pharmaceuticals in India. But we have a lot of activities here which supports our global product development. We have an analytical development centre here and a very significant clinical development group here. Unfortunately, for some time we had to slow down (clinical development) due to the government regulations which were very challenging for us as an international company. But now we are starting that. We are going to include India again into our international studies, but it was unfortunate that we had to stop initiating those studies. We also work with several different groups in India. Within those companies, we have specific people working only for us and organised in a way that they interact with us directly worldwide. We have 2,300 people in data management and around 800 people in medical writing supporting our global clinical activities. We also have 1,300 people supporting our global safety programs. We are doing selective collaborations here, which was more intense some years ago. We still have collaborations with chemical groups, for synthesising molecules on doing basic research.

ON CLINICAL TRIALS

If we have a good regulator, we can work together in accelerating our clinical development

What we do in bedaquiline in tuberculosis shows we are going to go very much in applied research, where at the same time we can work on diagnostics to screen people and look for ways to optimise outcome on what we bring, especially with new combinations. We are looking at how we can bring new combinations for multi-drug resistance TB. We are going to work in the same way for HIV drugs in combination therapies with local partners.

I am convinced that we should do more here. If we have a good regulator, we can work together in accelerating our clinical development. If we go from lab to first-in-humans, it is very important to do the translational medicine and pharmacological work, which are the critical steps in product development. I will be definitely back with my team and look into how we can reinvigorate our functions here. We are keen to use the brain power of the country and use it as a source of innovation. India should be able to create a California-like attitude and support entrepreneurship. Why not?



FILE PHOTO

What has changed for you from the time you scaled back your clinical activities here?

I do not know the full details, but what had happened is that we were made responsible for the life-long follow up of a patient after clinical trials for whatever happened as part of a disease. That is a very challenging situation. Let us say if you do clinical trials for an anti-fungal that a patient needs for a few weeks and then in that language, if it is said that we are to be responsible life-long for that specific period, that was difficult to handle because of the risk and the burden on the company to do that. I think many companies stopped doing clinical trials because of the uncertainties involved.

Nobody is to be blamed, but I think everyone underestimated the consequences of this in the country. We have come to reasonable terms now with the government on how that should happen. We are responsible for everything that we do to the patients in the trials and if there is anything wrong we cover them by insurance. But to be responsible to the patient that is unrelated to what we do, that is a big challenge to the company. There were no cases where anybody sued us but legally it made us think twice and we are back on track now.

We have seen in the last year that there is a very good understanding that when we bring drugs that contributes to the benefits of medical care, the regulator wants to get it approved. That time frame is now faster and that gives confidence to the global team that the regulators understand the issues. We have lined up three to four clinical programmes already. When we restart, as in any system, we have to wait and watch a little and understand and then the floodgates can open. Our drugs like Imbruvica and Sirturo have been approved in a fairly quick time. Our discussions with senior government representatives in India have been very positive and they want to understand if we can fill a genuine medical need. I like that and that should be the focus.

At the recent WEF in Davos the issue of global anti-microbial resistance was discussed at great length. How are we moving on that issue given the serious situation?

The issue of antimicrobial resistance has come because of the excessive use of antibiotics. In uncontrolled or partial regimens that builds resistance, the antibiotics will fail. Few things need to happen like faster and simpler diagnostics and then getting to new targets. The world of antibiotics has been stuck in using the old classes or improving that but that small improvement does not help to overcome the resistance. So we need new targets and that requires basic research. The world needs to line up basic research like the National Institutes of Health. Pharma companies and regulators need to work together on new pathways for approvals and we need to limit these drugs to exact indications that they are made for. That is a big challenge. Our bedaquiline worked on multidrug resistance and we got it approved. We immediately went to the Centre for Drug Control and WHO and said let us limit it to the fields of XDR (extremely drug resistance) and multidrug resistance strains, and we controlled its distribution through the governments and that is how it will have its biggest impact. We need faster development of drugs but controlled access, but we need to find a way to incentivize the industry. It's a big effort.

> *Discussions with govt have been very positive*

How do you, as one of the largest healthcare companies, facilitate the acceleration of innovative ideas into real-time projects?

What we try to do in our innovation network externally is to make it easier for people to accelerate science to translational research

ON ZIKA VIRUS THREAT

There is need for basic research in every virus that we know and to get it to a stage that when it breaks out there should be a vaccine available

People think 'let us outsource innovation' but that does not work. You have to have extremely good internal scientists to work with the external groups and so they both form a good partnership.

Given the global threat that the Zika virus poses, how should the world react to such unexpected catastrophes?

I have no opinion on how to control this type of global threat besides what we can do is to help get a vaccine. There is need for basic research in every virus that we know and to get it to a stage that when it breaks out there should be a vaccine available. That should be done with the industry, using its capability of development and production of a vaccine. Basic research should be contributed by the government or institutions, and we can offer our platforms. If we can do that on five to ten viruses, we probably could prevent outbreaks like MERS, SARS and influenza. But Zika was never on the list, so we need to go a stage higher and see more to counter such global threats. Because if we could do it for Ebola, we should have answers for the other diseases.

Given the quick changes that we are seeing in cancer drugs, where do you see cancer treatment is headed?

Cancer therapies that are emerging and in various combinations will become like the present trends seen in Hepatitis C, where the cure rates are improving dramatically. We have to believe in it and then we can put ourselves for the work to make it happen. We have to dream, work hard and make that dream happen.

What would you say about the raging global debate on value versus cost of drugs?

If we don't focus on the value we bring to the patient, we will not get true innovation. If we focus on costs, we stay stagnant. We try to focus on answering 'can we get a disease suppressed or cured'. We invest massively in it and as a company we hope to be able to be compensated for the value that we bring. It has to be value based, but it also has to be a viable business proposal because otherwise we will never get to deploy innovation for access. We have tiered pricing models for what the countries can bear in dealing with diseases.