

# Interview: Kanchana TK - Director General, Organisation of Pharmaceutical Producers of India (OPPI)

---



*"A drug policy that enhances access to healthcare, encourages innovation and enables ease of doing business can be the only sustainable way to address the unique healthcare challenges that India faces."*

---

13.12.2017

Tags: [India](#), [OPPI](#), [Association](#), [Pharma](#), [R&D](#), [Innovation](#), [Healthcare](#), [Regulatory Reform](#)

---

*Kanchana TK, director general of the Organisation of Pharmaceutical Producers of India (OPPI), the association which represents the interests of research-based pharmaceutical companies in India, discusses regulatory reform and how OPPI is helping to shape the Indian healthcare system.*

## **Please introduce yourself to our international readers and your journey to becoming head of the OPPI.**

I joined OPPI, a pharmaceutical association representing the research-based pharma companies in India in May 2017; a difficult decision given that I had always previously worked for corporations. I worked in insurance, then consulting, and on to a role in Public Affairs and Policy in the pharmaceutical industry with Bristol Myers-Squibb (BMS). Given how much I enjoyed my policy advocacy work at BMS, I strongly felt I could contribute to policy shaping and make a bigger impact on healthcare policies.

Since the 2000s, there have been lots of changes in the Indian healthcare ecosystem, with a huge focus on health, wellness, prevention, non-transmittable diseases, alternative therapy, medicine, and health insurance. For example, health insurance plans never used to exist as standalone products, but were always bundled with property and casualty insurance.

Nowadays healthcare costs are extremely multifaceted, and I felt that, given my diverse prior experience, as part of the association I could help foster better dialogue between policy-makers and other stakeholders to ultimately leading to benefit Indian patients.

### **What has been keeping you busy?**

[Featured\_in]

2016 was a rollercoaster year with the rollout of two new policies on Intellectual Property Rights (IPR) and National Health. There has been a renewed focus from Prime Minister Narendra Modi on health, with numerous references to the topic in his speeches, from medicines to medical devices; almost as if India has developed a new consciousness of these issues. In the past, the political conversation has centered around topics such as infrastructure, employment or industrialization, but today healthcare is an important ask of the Indian people.

With the current government's focus on health, our role as an association is becoming more crucial. Drawing on our members' experiences in both developing and developed markets, we are able to work with the stakeholders towards a more comprehensive solution to healthcare issues. Additionally, the government is more engaged and open than ever before to non-traditional solutions such as partnerships and alternative sources of financing.

It is important to remember that India is a big country and therefore, finding solutions to healthcare issues is far more complex than in smaller counties. The process might be slow, but a dialogue has begun.

### **Public awareness for health is an effective tool for dissemination. Can you give our readers any examples of how you have raised awareness in India?**

[related\_story]

One example is Anti-Microbial Resistance (AMR), which is a huge problem globally, as well as in India. The 'Red Line Campaign,' launched by OPPI in collaboration with the Ministry of Health (MoH), to curb irresponsible over-the-counter (OTC) use of antibiotics, has been lauded internationally as a campaign that is simple but effective for the common man. The campaign is set to be included as part of the London Science Museum's India Season later this year.

### **The new draft Pharma Policy is focused on the affordability and accessibility of medicines for all. What do you make of the proposal and do you think it is actionable in its current form?**

I think the time is right to have a new National Pharma Policy and that this is a fantastic move. However, we believe this policy cannot be implemented without meaningful stakeholder consultations; including not just pharma companies, but patient groups, regulatory experts and so on. Pharma policy covers an enormous range of issues; from regulatory issues such as promoting Good Manufacturing & Laboratory Practices in the manufacture of drugs, quality control, and streamlining of drug approval process to encouraging R&D for drug discovery; and working towards global best practices; not just pricing.

The government must make sure that all stakeholders are involved and have been consulted thoroughly. This is a disruptive process that will hopefully lead to better access and affordability. The concern we have as an industry is, while we support the focus on quality which is crucial, and all our member companies adhere to good manufacturing practices and comply to stringent globally accepted quality standards, there needs to be a uniform manufacturing standard for India and the government is working towards it. Additionally, we believe the proposal in the new draft on bioavailability and bioequivalence (BA/BE) studies is very important because that was previously not there for many medicines and is important for the patient.

We are in discussion on many issues and the government itself is having inter-Ministry stakeholder meetings; highlighting their more concentrated, collaborative approach for the best interests of the patient.

**Many stakeholders have raised concerns on the Policy. What is the OPPI take on this?**

OPPI is cognizant of the Government's measures to promote the use of generic medicines however, prior to any decision being taken in said regard, we urge that adequate steps are taken so as to ensure uniform quality & standard of drugs across states in India and all drug manufacturers mandatorily follow WHO GMP manufacturing practices.

Secondly, brands are there for a reason: they denote quality; the years or how much a company has invested in R&D globally; how much you care about the patient; and whether you have pharmacovigilance and sometimes continued medical education in place. I do not think that it is in the best interest of the patient for brands to disappear completely.

What the government is trying to fix is what they believe to be unethical practices. However, this can be fixed through better implementation of the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) which is currently voluntary. Removing brands completely would be throwing the baby out with the bathwater, so to speak, and the wrong approach.

A drug policy that enhances access to healthcare, encourages innovation and enables ease of doing business can be the only sustainable way to address the unique healthcare challenges that India faces.

**What has been the impact of the growth of the Indian market on your member companies?**

Our companies operate in two markets: branded generics and patented medicines. India is a very difficult market for both. Both markets have seen decreased levels of growth in recent years. The situation is complex, but we believe that India has a potential for growth if policies that allow for it are finally put in place.

China today is investing a lot in regulatory reform; meaning that at some point they will be ready for a sophisticated healthcare system. However, India is not investing in long-term processes, but rather knee-jerk fixes. There is no clear objective and therefore no clear solution. Therefore, we believe that these policies and broad guidelines are the first baby steps towards creating something more robust. The government needs to have a long-term vision and decide strengthening regulatory systems; increase healthcare budgets; look at new healthcare financing models; improve or collaborate with health insurance; and collaborate with drug makers to allow different pricing models to the patient.

**What is the future for multinational companies coming to the Indian market?**

Most big players are already here, whether with a small or a large presence. Many are here as importers only. However, for an organization to have a sustained presence here, they must be allowed to operate freely. If we say that we are open to foreign direct investment (FDI), then we need to put policies in place to support this and truly act on ease of doing business.

A quick comparison with China. Recently enacted changes in the China Food and Drug Administration (CFDA)'s regulatory policy is expediting drug approval pathways and permits research-based companies to defray huge capital expenditures by allowing the outsourcing of manufacturing. In 2010, the CFDA revised its GMP standards, and at the beginning of 2017, the regulatory body also announced plans to replace current GMP certification of every five years with a dynamic unannounced inspection system. These policy moves are intended to bring China's GMP code in line with that of EU and U.S.

The Chinese biopharma industry is also making significant investment in bioprocessing, including adopting more advanced technological platforms (SUT, modular factory, mammalian-cell-based

bio-manufacturing systems, etc.).

**Can you give us an overview of your current member base?**

We have around 30 multinational pharma companies from Europe, the US, Japan, the UK. Some are here in a smaller capacity all depends on the market and in areas they are active. Some of them believe India is the right market for only certain therapeutic areas. In fact, some of our members have been present in India for over 100 years and have been part of India's pharmaceutical growth story.

**What are the key areas of focus for OPPI?**

There are four key areas we focus on at OPPI. The first and most important is our ethical code of marketing practices. We are highly ethical. We have a code that we follow voluntarily. All our members are signatories to it and we take that very seriously.

The second area is IPR; for us, Intellectual Property is very important as it's the bedrock for innovation. The third is access and the fourth is pricing.

**In your article 'The Power of Innovation,' you mention that there is much more that can be done in terms of drug development in India. What could help drug development and innovation in India?**

India is great at re-engineering; however, we are not great at innovation. Looking outside of medicine, I cannot recollect the last great car, device, or phone we created.

One thing that I think that the government should do - especially for illnesses that are "Indian" such as dengue, elephantiasis, and encephalitis - is come forth and invest in developing a vaccine, medicine or pill, along with industry. To collaborate and innovate something, this has not happened yet but there is a lot that we could do, purely for the Indian population. Those are areas where the State is responsible for its people.

The problem is not the lack of intellectual talent, but a lack of infrastructure. Where do we go? There are few national labs and national R&D centers. In fact, according to an article in Scroll.in (May 2016), over the last ten years, 332 out of the 579 medical teaching institutions in the country have not produced a single research paper. There is no intellectual sophistication. A world class center, bringing together a university with a couple of companies to create a consortium would be a great initiative, but we have not seen anything of this sort.

Fostering innovation is not limited to adapting counterfeit, trademark or piracy laws, it's beyond that. We are diluting innovation, rather than creating it. There is an opportunity there.

**Is India setting a good example for its neighboring countries in terms of healthcare development?**

**Is India setting a good example for its neighboring countries in terms of healthcare development?**

I wish it did. India continues to be one of the poorest performers in its region in terms of quality and accessibility of healthcare, ranking at 154, far below China, Sri Lanka and even Bangladesh, according to the Global Burden of Disease study published in the Lancet in 2017.

In India, the total expenditure on healthcare as a percentage of GDP is just 4 percent, while in the US it is 17 percent (World Bank Report). According to World Health Organization (WHO) data, for countries performing best in the healthcare sector, the US ranks 37, while India stands at 112. We have neither the wrong nor right model in India and the opportunity exists in this huge space between wrong and right. We can become the country that leads the way in regulatory, financing, insurance, expansion and innovation.

**How is OPPI shaping the Indian healthcare system?**

It is a collaborative effort between OPPI, our member companies, patients, and the media. The media has been very fair in reporting. OPPI, the government, the media, and the patients are all learning because we are shaping something new. We are not taking any global model and implanting it in India. India cannot replicate any model of any country. We need to come up with something new, taking something good from China, the UK, the US, or even from Bangladesh. There is no single model or solution as in smaller Asian countries such as Malaysia or Indonesia.

Solutions therefore must come from multi-stakeholder engagement; sometimes from the government, sometimes from the industry, sometimes from patient groups, sometimes from the media. We are all responsible for shaping healthcare for India and that is why it is exciting.

**As a prominent woman in a male-dominated industry, what advice would you give your younger self?**

The very same advice that I grew up with: that success has no gender. Ever since I was 13, I have always believed that there is nothing that anyone cannot do. Of course, gender discrimination and damaging stereotypes exist; but my advice to all women is to say, "I am not going to let any of that

bother me.”

Personally, if I want to be heard and believe I have something to contribute, I am not going to back down.

I would also like to give a message to the women in Pharma. I think that there is a lack of women leaders in this arena. This is something that we need to address globally not just in India. I really don't see why we shouldn't have more women in leadership roles.

### **What is your final message to our international readers?**

Everything you hear about India is both true and contradictory. When I say India is modern, it is traditional; when I say India is poor, it is rich. India is a land of paradoxes but also of opportunity. India is bidding to lead G20 in 2019, will also include healthcare on the agenda.

I think India needs to be indulged – I know that this is a strange choice of a word – because the opportunities here and the scale of influence that the country has is so large.

This is because we influence the rest of the world, and if do not have the right policies, half the world will probably not have the right health policies.

[See more interviews](#)