

# Along the Value Chain 打造完整价值链

China is already the second largest pharmaceutical market in the world and with increasing concerns about health, the market is sure to grow. **Hong Chow**, General Manager of Roche Pharmaceuticals China, talks with **The Bridge** about the China market and how one of Switzerland's most successful companies has positioned the country as an integral part of its world operations.

by **Mark Andrews**

随着人们对健康越来越关注，中国已经成为了全球第二大医药市场，并且市场需求仍在增长。罗氏制药中国总经理周虹对话《桥》杂志，探讨了罗氏作为瑞士最成功的企业之一，是如何将中国市场的布局纳入其全球战略中不可分割的一部分。

作者：**Mark Andrews**



## Can you outline Roche's history of operations in China?

Roche first came to China in 1926, but at that time we only had a commercial presence. Then in 1994, we entered China by purchasing our current site in Shanghai's Zhangjiang Hi-Tech Park and built a manufacturing plant. In 2004, we were the first multinational pharmaceutical company to establish a fully-owned research site in Shanghai. Then in 2007 we brought in clinical development - initially it was only for China and then it was upgraded for development work for the whole APAC region.

## What is Roche's business focus in China?

We are now one of the first drug companies to establish a full pharmaceutical value chain spanning from early stage research to development, manufacturing and commercialization of novel medicines in China. The research work we do here is not just for China, and the Shanghai site is our third largest strategic centre globally. Currently we market 16 products covering eight treatment areas, mainly oncology, virology and transplant.

## Why has Roche chosen Shanghai as one of its three main R&D centres in the world?

Our business expansion goes where the patients are. And if you look at oncology Chinese patients account for 25% of the world's patient population and there is still a high unmet medical need. Our purpose is "Doing now what patients need next." We focus on science to meet patients need. Roche is the pharmaceutical company with the highest R&D spend globally, and we spend almost 20% of our sales on it worldwide amounting to CHF9.9 billion in 2016. In China we have decided to increase investment and build a new innovation centre here with an investment of an additional RMB860 million.

## What specific research work is targeted for the Chinese population?

Our research site in China focuses on hepatitis B (HBV) because it is the most prevalent disease in China. There are about 90 million virus carriers and so it is high on the medical need list. The first result from our research activities here is that we will see a couple of compounds soon entering into human phase 1 trial for HBV. To date we have filed over 160 patents - half of them have been granted - which show our high productivity. We have said at the start that we are 'in China for China' and of course if we are successful we will bring the compounds to the world. We are in China for the world too.

## Can you outline the recent changes made by the Chinese Food and Drug Administration (CFDA) and how they affect you?

In the 13th five-year plan China states that it wants to become a leader in biotechnology. In order to become a leader, China needs to create an innovation eco system. This includes a regulatory framework to bring new drugs to market much earlier. In the past, it would often take an additional four to six years after US approval to get Chinese approval due to differences in requirements. From the end of 2015, we are very happy to witness the Chinese government's determined initiatives to accelerate new drug approvals. On March 17, 2017 CFDA released the "Adjustments to relevant issues regarding the imported drugs registration (draft for commenting)". These adjustments aim to encourage innovative drugs (not approved worldwide) to conduct clinical trial simultaneously with Global after China

## 您能否讲讲罗氏进入中国市场的大致历程?

早在 1926 年, 罗氏就进入了中国市场, 当时我们的业务主要集中在药品销售。1994 年, 我们正式落户上海张江高科技园区, 自此迈出了布局中国市场的第一步。2004 年, 我们率先设立了罗氏在发展中国家的第一个研发中心, 这也是跨国制药公司在上海独资建立的第一个研发中心。2007 年, 我们成立了罗氏药品开发中心服务中国市场, 之后药品开发中心升级, 服务整个亚太地区的药品开发工作。

## 罗氏在中国市场的业务重点是什么?

在大型跨国药企中, 我们率先在中国建成了包括研究、开发、生产、营销等环节在内的完整医药价值产业链。我们的研发不仅仅为了满足中国市场, 上海也正向着成为罗氏全球第三个战略中心的目标迈进。目前我们拥有 16 个产品, 涵盖了 8 大类治疗领域, 主要集中在抗肿瘤、抗病毒和移植领域。

## 为什么罗氏要选择上海作为其全球三大研发中心之一?

患者在哪里, 我们的业务就做到哪里。就肿瘤而言, 中国的患者人数占据了全球患者人数的 25%, 大量患者求医问药的需求尚待解决。我们的理念是“先患者之需而行”, 专注于用科研满足患者的需求。在全球制药企业中, 罗氏的研发投入是极高的——我们的研发投入占销售额的将近 20%, 2016 年投入高达 99 亿瑞士法郎。我们决定还要继续加大科研投入, 在中国我们投资了 8.63 亿元人民币, 在上海打造新的罗氏创新中心。

## 何为“专为中国人制定的科研工作”?

在中国的研发主要专注于乙肝病毒方面, 因为它是中国最普遍的疾病。中国大约有九千万乙肝病毒携带者, 所以还有很多未尽的医疗需求。目前我们已经取得了阶段性进展, 新的化合物即将进入乙肝病毒的第一阶段人体临床试验。今天, 基于研发中心已经诞生了 160 项专利, 其中一半已被获授权, 这也见证了研发的高效。我们一开始就决心要“立足中国, 造福中国”, 当然如果我们成功了, 我们也将给世界带去研发的新药。我们在中国不仅为中国, 也为世界。

## 能否简单介绍一下最近中国国家食品药品监督管理总局颁布的一系列(政策)变动? 这些变化对罗氏有何影响?

在“十三五”规划中, 中国明确了要成为生物科技领域的领头羊。为此, 中国需要营造创新的大环境。这也包括法规监管体系的调整, 让更多的新药早日在中国上市。由于以前历史的原因, 中国新药上市的时间要比欧美国家慢了 4-6 年。不过, 在食药监局的改革下, 新药审评审批的速度已经有了很大的进步。就在 2017 年 3 月 17 日, 国家食药监总局还发布了《关于调整进口药品注册管理有关事项的决定(征求意见稿)》, 鼓励境外未上市的新药经批准后, 在境内外同步开展临床试验, 也让我们看到了政府对加速新药上市的积

HA approval, so as to shorten the approval time gap compared to other countries. The positive moves are promising for Chinese patients and also for innovation-driven companies like Roche.

We will actively cooperate with Chinese government to shorten the approval time for new drugs. At present, we are able to conduct phase III trials in China simultaneously in global. We expect to see earlier approvals of our 'new-to-China' products (products already launched in USA, Japan and Europe) that benefit more Chinese patients.

### How do you see the Chinese pharmaceutical market changing?

With the new policy and the 13th five-year plan putting more emphasis on innovation, we really see a more favourable environment. Trials are starting earlier, requirements are harmonised, there is lots of emphasis on developing science talents and we are in an industry where this is our core competence. So overall, I am very optimistic.

In Roche, we rely a lot on collaboration so it makes it easier for us to be able to collaborate with local academic institutes and companies. Our new innovation centre will enable us to do this better with both local companies and academics because we will have this big open space where we will have laboratories, and it will provide a platform for exchange.

### The pharmaceuticals industry had a troubled time in China a few years back with concerns over ethical practices in the selling of drugs. How has the industry made progress in addressing these issues?

Joint efforts have been made to promote and strengthen ethical business practices in the pharmaceutical industry. At Roche we use very high compliance standards and for us it is a good development, because it means the whole industry environment becomes more compliant. Our peers and our customers are operating in a much more compliant environment.

Compared to those companies outside the pharmaceutical industry, we have much stricter rules than most because our products are drugs, and we are in the business of saving lives. In terms of interaction with our customers we apply very stringent rules that are not found in other industries. Having said that, we have introduced a lot more mechanisms to ensure a full compliance, and we do lots of training, not only classroom-based, but also training via WeChat and webcasts.

### What do you think China can learn from Switzerland with regard to innovation?

Switzerland although it is a small country has a lot of great companies and we always say in Switzerland that innovation is without national boundaries. Swiss companies are open to the world and tap into innovation globally and I think this is a Swiss advantage.

Swiss culture and that of Roche is diverse and inclusive, very open to ideas, and so we really encourage different thoughts, diverse talents and create an environment in which people can speak out and put their ideas forward. Our approach is very innovative in creative thinking, but at the same time we are also very disciplined when it comes to quality assurance; we apply very stringent processes to ensure high quality and compliance standards. People say we operate like a Swiss watch, precise and reliable. ○



极行动。相信这将促进跨国药企进一步投入创新药物研发，加快新药中国上市时间，同时也可以吸引更多境外创新药物进入中国，从而使中国患者得益。

而罗氏也将积极配合政府，缩短

新药上市进程。目前罗氏已经基本能做到中国和全球的三期临床同步开发，我们希望在不久的将来，每一个中国的患者，都能和欧美的患者同步，第一时间用上最适合他们的创新药。

### 您怎样看待中国医药市场的变化？

“十三五”规划着重强调了创新，我们期待看到更良好的大环境。临床试验提前了，要求与国际标准看齐，科研人员受到了越来越多的重视，在一个以科技人才为核心竞争力的行业里，这是很重要的。总而言之，对此我持非常乐观的态度。

在罗氏，我们的科研需要大量的共同协作，这些大环境的变化让我们在与本土的学术机构和企业的协作中受益匪浅。此外，我们新的创新中心提供了一个开放式的空间，在开展科研实验的同时也提供了一个交流的平台，将使我们能够更好的与本土的企业与学术机构深入协作。

### 多年以前，中国的制药行业曾因药物销售过程中的规范问题受到过质疑。在这个问题上有什么进展吗？

在各方的努力下，整个行业的业务实践更加规范了。而罗氏，我们始终遵守高标准的企业合规。行业的健康发展，对我们而言是非常重要的，因为整个大环境更加有序了——我们和客户都能在一个更规范的环境中经营业务。

与非制药行业的企业相比，我们的规定和要求更严苛，因为我们的产品承担着拯救患者生命的责任。在与客户的互动中，我们推行非常严格的规定，这在其他行业中是很少见的。为此，我们引入了更多的合规管理机制，以确保把合规落实到位，同时也为员工提供了很多培训，不仅采用传统的课内教学方式，还使用微信和网络的平台。

### 您认为在创新方面，中国可以向瑞士学到些什么？

虽然瑞士是个小国，但却有许多杰出的企业，我们总是说，“在瑞士，创新没有国界”。瑞士企业面向世界开放，总是走在全球创新的前沿，这是瑞士创新的优势。

瑞士的文化，或者说罗氏的文化都强调多样性、包容性和开放性。我们鼓励思想的碰撞，多样化的人才，积极创造一个让大家都能够畅所欲言、实现想法的氛围。我们的创造性思维非常大胆，但在质量品质上仍恪守严谨；我们有非常严格的流程来确保高品质、高标准。人们常说罗氏就像一块瑞士手表，精确又可靠。○