

## Competitiveness and Investment Criteria

### Introduction

Pharmaceutical companies operate globally and have bases in a number of countries, which makes investment, especially at the margin, very mobile. The continuing restructuring in the industry has brought with it both the requirement and the opportunity to review the scale and location of activities to ensure that they are carried out in the best available environment worldwide. Moreover, the industry is facing significant shifts in its global business environment. These shifts require large and small firms alike to fundamentally re-think their strategies, approaches to the market and investment decisions.

A number of critical forces are affecting the pharmaceutical industry. Rapid globalization of markets, the ease of global communications and the existence of an increasingly international and mobile pool of scientific and commercial talent mean that firms can serve more markets from fewer locations, while at the same time they have greater choice than ever before of location to consider when deciding where to locate new investments. This is true – to a greater or lesser extent - for all stages of the pharmaceutical value chain from basic research through to commercialization.

At the same time, competition in product markets, cost-containment policies, the emergence of new customers around the world, and shortening product life cycles are altering the economics of the industry. The need to invest heavily in new R&D technology platforms adds to mounting cost pressures. These factors are driving pharmaceutical firms to take a much closer look at what each locale offers in terms of access to required skills, proximity to technical partners, attractiveness of local market conditions, operational costs, and taxation rates. Location decisions are increasingly taken from the perspective of their effect on the overall competitiveness of the global firm.

Decisions and actions taken by Government can have a major influence on investment decisions made by the industry and thereby on the contribution made by the industry to the local economy. It is against this background that new national partnerships between industry and Government must be formed. One of the focuses of this partnership must be on ensuring that the country involved remains a compelling and competitive locale for the development of a vibrant pharmaceuticals sector. It will be important to develop a shared understanding of the interactions between local and global markets, policy and investment decisions.

## Key Criteria for Competitiveness

### 1. Supportive Regulatory Conditions

- A well-regarded registration process for new pharmaceutical products that enables medicines to gain international credence by passing stringent criteria on quality, safety and efficacy. This will encourage pharmaceutical companies to conduct clinical trials and launch innovative products early.
- Key regulations should be conducive to the development and early adoption of innovative new medicines. A key objective in market and product regulation should be to create an exemplar of effective market management in the new, globally competitive marketplace.
- The level of profit or price regulation can affect the attractiveness of a market as a focus for investment. The industry view is that innovation is best supported by price and profit deregulation.
- Prescribers and purchasers should operate within a purchasing framework that enables them to opt to use innovative medicines on the basis of their value and not just of their cost.
- The information available to physicians and patients about medicines will affect demand. Sufficient high quality information needs to be made available for clinically sound judgements to be made on the basis of quality, efficacy and clinical and cost-effectiveness.
- Stable, steadily growing markets that offer substantial size, rapid registration and uptake of new medicines, and competition, will be the most attractive locations to industry for inward investment. Industry investors may view national markets that do not offer these characteristics as 'second-tier'; i.e. they would not be a principal focus for the development, testing and early launch of major new medicines.
- Regulation of pre-clinical research, and public attitudes, need to be developed to support the utilization of new techniques (e.g. genetics) and technologies (e.g. animal research) required for the discovery and development of new products.
- A supportive regulatory environment in other areas, for example employment and environmental laws, will encourage investment.

## 2. Strong Legal Framework on Intellectual Property

- A strong legal framework on intellectual property rights creates a desirable locale for research and development.
- Parallel trade is a significant problem for the innovative pharmaceutical industry. Development of policy should make allowance for R&D costs, maintain the value of intellectual property, underpin companies ability to fund R&D, and reward innovation.
- The international intellectual property system must provide a proper balance between IPR and competition. The lack of effective patent and data protection for pharmaceutical products in many emerging nations is a key challenge.
- Enactment and enforcement of international patent protection and registration data exclusivity to reward innovation and allow funding of R&D in an era of escalating technology development costs is a key factor.

## 3. Providing an Attractive Fiscal/Economic Climate

- Governments must place great importance on providing a good place to do business by creating a stable and competitive economic environment.
- There are a number of reasons why a local economic climate can be an attractive place for business in general. These include steady economic growth, stable inflation rates, and low and stable interest rates, open and outward looking markets, with deep and enduring economic linkages with the rest of the world.
- Subject to the availability of the necessary science base, financial considerations will also influence decisions on investment. The provision of financial incentives to attract new investment in pharmaceutical research, development and manufacturing is an important factor in determining the locale for investment.

## 4. Availability of Specialized Capital

- Receptive financial markets and a well-developed venture capital community are major factors in the provision of the means for translating research into new enterprises and products.
- A nation's capital markets should have liquidity, breadth and the ability to handle large financial transactions. This is of great importance to the pharmaceutical industry as increasing numbers of transactions are cross border, and the ongoing restructuring of the industry requires capacity in the city to handle huge equity sales.

- As companies seek to reduce the risk and increase the productivity of their R&D activities, it is possible that more focus will be placed on the opportunities to use corporate venture capital to make strategic investments. Corporate venturing and other measures can enable large pharmaceutical companies to develop specialist technology in partnership with SMEs, thereby pulling in extra management capacity; and can enable SMEs to develop technology that flows out from the big pharmaceutical companies because it is marginal to their product portfolios.

## **5. Industry/Government Partnership**

- A sophisticated and explicit form of partnership between industry and Government, capable of enabling and meshing many distinct but interdependent actions, cutting across the public and private sectors, is most likely to be effective.
- An integrated approach to Government policy and actions, which brings together healthcare regulation and industrial policy, is likely to be most effective [see PICTF in UK and G10 in Europe].
- More can be achieved through concerted and focused effort than by industry or Government alone. This will apply to initiatives to close the skills gap, attract specialized capital providers, encourage scientific entrepreneurialism and create appropriate demand conditions.

## **6. Access to Skills/ Quality of Science and Clinical research Base/Supportive Climate for Science**

- A key determinant in any investment decision for the pharmaceutical industry is the availability of appropriately skilled staff. To carry out R&D it is necessary to have access to highly specialized skills and as such barriers to R&D tend to be practical rather than financial. Availability of scientific research skills and infrastructure will always outweigh financial incentives or a low tax climate, although financial factors may be decisive in a choice between two locations with the necessary science base.
- The supply of skilled scientists and other technical personnel relies on high quality of scientific education.
- A number of new technologies (such as genomics, bio-informatics) have emerged as critically important to the discovery, development and delivery of new medicines. The speed of the change has meant that the essential skills are in very short supply.
- The required skills in the new technologies that are critical to drug research are different to those resident in most academic institutions today. Training in leading-edge life science technologies such as bio-informatics, genomics and molecular modeling will be key to the future if the right quality of scientists is to be available.

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- There is a need for skilled people across the life science disciplines, as well as in related areas such as healthcare marketing and intellectual property management. The education and employment infrastructure will affect whether such people can be developed in, retained within, or attracted to any particular country.
- A longer-term challenge is to encourage young people to study life sciences. The structures and resources available for successful education and skills development will have a particular influence on whether this can be successfully achieved.
- A world-class research base in universities, research institutions and industrial firms is required to create a productive climate for medical research, clinical trials, and pharmaceutical product testing. The tertiary education infrastructure must be sustained, as companies will invest where there is scientific excellence and access to new technologies. The US inevitably offers most in this regard, but the US universities' approach to ownership of intellectual property rights, leading to premature spin-out and commercialization at too early a stage, can sometimes make collaboration more costly for businesses.
- Investment must also, however, continue to flow into primary and secondary education as well as tertiary. Emphasis should be placed on supporting a conducive environment for science in secondary schools, which will lead to an increase in the numbers choosing science at university, and ultimately the resource base of scientists qualified to carry out R&D.
- Access to new ideas and technology through links with the academic research base and with biotech SMEs is important to pharmaceutical companies. Large firms are entering increasingly into R&D partnerships to share the costs and risks of new product development, access new skills, and reduce the time to market for new products. Many of these partnerships are with small firms specializing in key new technologies. These firms frequently depend on only a few key individuals and, as such, exhibit a particularly high degree of geographic mobility. The most attractive location for investment would have a critical mass of competitive partner organizations. It is therefore a challenge to be more attractive to these firms and individuals than their alternatives around the globe.
- Geographic clusters of pharmaceutical firms, research and training institutions, suppliers of key inputs (e.g. software), venture capital providers and other related entities are essential to facilitate linkages and partnerships critical for industry competitiveness. For such clusters to operate, there need to be strong linkages between commercial firms, research institutions, venture capital providers, training institutions, business schools, and other related entities.

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