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The EU Marketing Environment: Pharmaceuticals and Japanese Strategy

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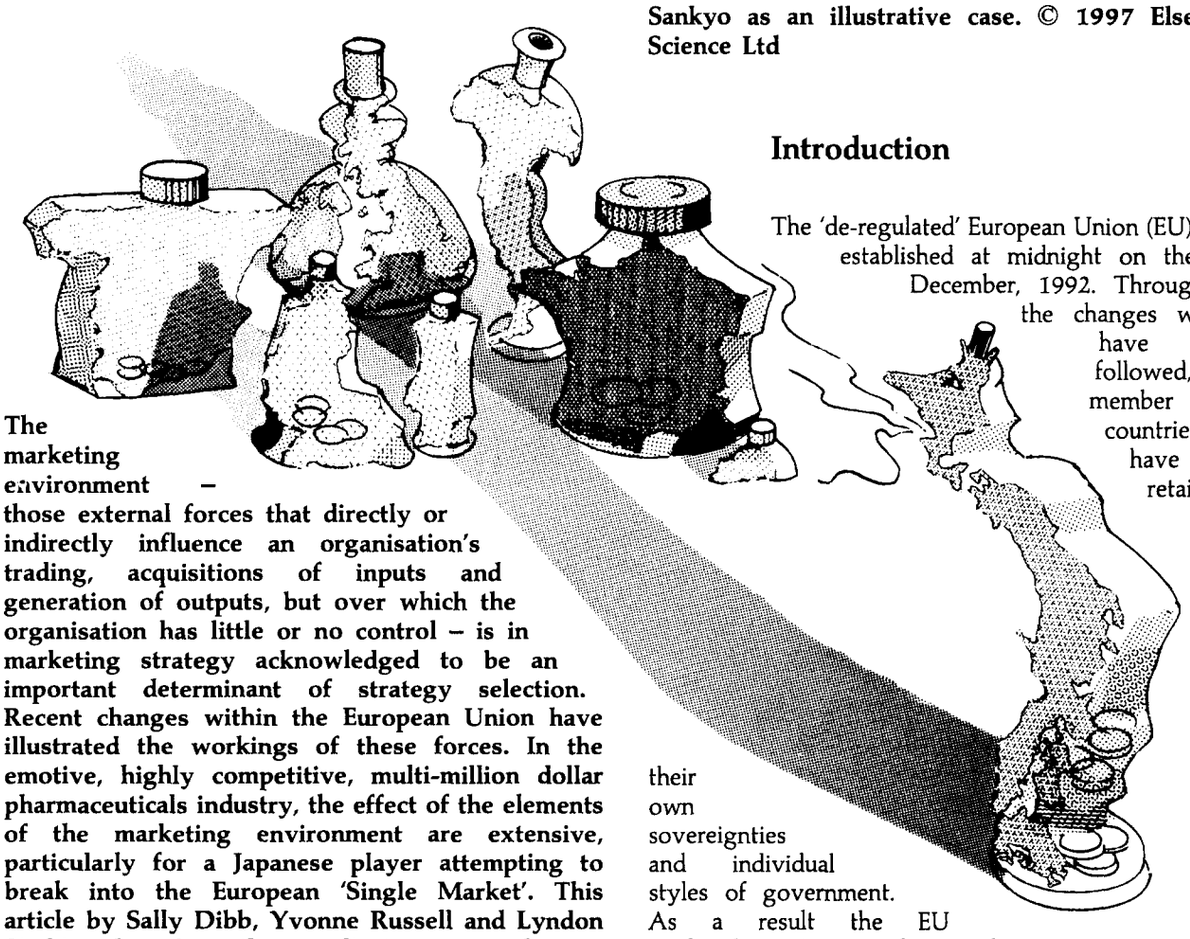


Sankyo as an illustrative case. © 1997 Elsevier Science Ltd

The marketing environment – those external forces that directly or indirectly influence an organisation's trading, acquisitions of inputs and generation of outputs, but over which the organisation has little or no control – is in marketing strategy acknowledged to be an important determinant of strategy selection. Recent changes within the European Union have illustrated the workings of these forces. In the emotive, highly competitive, multi-million dollar pharmaceuticals industry, the effect of the elements of the marketing environment are extensive, particularly for a Japanese player attempting to break into the European 'Single Market'. This article by Sally Dibb, Yvonne Russell and Lyndon Simkin describes the implications in pharmaceuticals of the broader, external trading environment and the marketing environment, using Japan's

Introduction

The 'de-regulated' European Union (EU) was established at midnight on the 31 December, 1992. Throughout the changes which have followed, its member countries have retained their own sovereignties and individual styles of government. As a result the EU marketplace is complex and heterogeneous with more languages than member countries and a variety of

different currencies in use. The continual changes arising from the efforts being made to harmonise national policies, particularly legislatory and regulatory procedures, create an exceptionally dynamic marketing environment. The forces of the marketing environment are acknowledged (Kotler, 1994; Porter, 1985) to be important to any business in any market. With the continual changes being led by the EU's bureaucrats and member states, the already highly regulated pharmaceuticals industry is facing an up-hill task to remain abreast of changes in its trading environment.

Sankyo is Japan's leading pharmaceuticals company (Miki, 1995) with a 4 per cent rise in profits last year and sales of ¥401.5 billion (O'Donnell, 1995). Although less than half the size of the global market leaders, the company has a healthy product portfolio covering a variety of therapeutic categories. Over 90 per cent of its revenue is derived from the domestic market, but reforms and pressures at home have induced the company to intensify its global operations. Not surprisingly, the EU pharmaceuticals market, with its close to 400 million consumers, estimated to be worth $65 billion, seems an attractive proposition for Sankyo, despite the ever evolving marketing environment.

Companies like Sankyo wishing to trade in the EU must become familiar with aspects of the marketing environment which shape the community. For a pharmaceuticals company, this is no easy task. The nature of medicines/drugs and the consequences of their uninformed use mean that, as in other territories, the EU pharmaceuticals industry is highly regulated. One effect of this is that Sankyo is faced with fifteen different national regulatory systems operating under the auspices of the European Commission.

This article reviews the effect of these aspects of the marketing environment on the pharmaceuticals industry in the European Union, using a case study of Japan's Sankyo to illustrate the impact of the key economic, demographic, political, regulatory, legal, technological and socio-cultural factors. Source material for the case study comes from a range of academic, business and statistical publications, supported by observations from a series of personal interviews.

The Marketing Environment

The marketing environment is a set of non-controllable forces which either directly or indirectly influence a business' acquisitions of inputs or generation of outputs. Kotler (1994) defines the marketing environment as '... the actors and forces that affect the company's ability to develop and maintain successful transactions and relationships with its target customers'. The broader marketing environment forces comprise: political, legal and regulatory; economic and competitive; physical; socio-cultural and demographic; and, technological (Dibb *et al.*, 1994).

These forces are generally aspects of the trading environment over which the business has very little direct control, but they are elements which tangibly affect the way in which an organisation can do business and will perform. To monitor the important aspects of the marketing environment and to prepare for the ramifications of any changes, marketers must undertake a continual process of scanning and analysis. Environmental scanning is the process of tracking information from observation, secondary sources (particularly the trade press and government reports), databases, information services and marketing research (Jobber, 1994). Some companies handle this using individual marketing managers or committees whose function is to collect and collate data related to trends in the marketplace and aspects of the marketing environment. Information is circulated via newsletters, e-mail or presentations. Despite the obvious importance of monitoring the external marketing environment, many organisations still make little attempt to do so (Dibb *et al.*, 1996).

Each of these forces has a significant impact on the business' trading conditions; when the marketing environment changes companies face uncertainty: threats but also opportunities (Kotler, 1994). For an organisation to survive and prosper, the marketing environment must be continually scanned so that the company can predict likely outcomes and respond accordingly.

Political, Legal and Regulatory Forces and the Pharmaceuticals Business

The pharmaceuticals industry has been affected by the lack of a standard approach to prove that goods conform to specifications laid down by the standards and regulations stipulated by each country (Scrip, 1996). The most ambitious recent initiative in pursuit of the harmonisation of pharmaceutical legislation involves the European Federation of Pharmaceutical Industry Associations (EFPIA), the US's Food and Drug Administration and the Japanese Ministry of Health and Welfare, which are now co-operating to try to ensure the free circulation of pharmaceuticals products; standardisation of package inserts, advertising and delivery conditions. Other initiatives include the setting up of the EU Committee on Proprietary Medicinal Products (CPMP), which proposes a plan for removing any remaining barriers to the free movement of medicinal products within the EU. Meanwhile, the European Medicines Agency (EMEA) has been founded to manage a new centralised scheme for authorising medicines in the EU single market. The EMEA will also encourage innovation and technical co-operation between member states.

As in all developed countries, the European pharmaceuticals industry is subject to an unusual degree of government control covering areas ranging from drug pricing, advertising and patent protection through to research and development and the safety and efficacy of medicines (*Managing Intellectual Property*, 1995). At a

national level, in the UK the Retail Price Maintenance laws were recently applied by several manufacturers of vitamin supplements to prevent retailer Asda discounting them. Supposedly to protect the retail pharmacies, these regulations clearly impinge on the way businesses can trade. Each country within the EU has its own such legislation and regulation. Additionally, a wide range of EU directives control trading practices inside the Community. Healthcare manufacturers are subject to a range of EU directives relating to product standard agreements, product testing and approval, medical products and implantable medical devices and procurement processes. For example, the 1985 EU Directive on Products Liability, allows damages caused by pharmaceuticals to be compensated for through a special semi-voluntary collective insurance scheme. Although these directives are at different stages of implementation, a bundle known as the 'rational use' package has been introduced specifically to aid the regulation of the pharmaceuticals industry. The main aim of the directives is to remove national differences that impede the single market for pharmaceuticals:

1. Wholesale distribution directive (92/25/EEC): this requires medicine wholesaler to hold appropriate authorisation, to be subject to inspection, to possess adequate and suitable premises and have suitably qualified staff.
2. Classification for supply directive (92/26/EEC): this is also known as the legal status directive and defines the classification into categories of those medicinal products which are, or are not, subject to medical prescription at the time of market authorisation.
3. Labelling and product leaflets directive (92/27/EEC): this defines precise requirements for the information which must be given on the outer packaging and on the enclosed leaflet of information for the patient.
4. Advertising directive (92/28/EEC): this controls the advertising of the different drug categories, prohibiting the advertising of prescription drugs and other specified medicines to the general public and setting requirements on the information which must be given in advertisements for the general public of other non-specified medicines. The directive also sets restrictions on advertising and promotion directed at health professionals, including the use and training of medical representatives, hospitality and free samples; and provides for monitoring by competent authorities of the advertising carried out.

Economic and Competitive Forces and the Pharmaceuticals Business

The formation of the EU has led to a reduction in drug prices. This could amount to as much as 30 per cent in the next five to ten years, as the European market homogenises and prices move toward their lowest common denominator. However, if prices slip too much the industry will lose billions of dollars, leading to a reduction in government revenues and research and development expenditure (Cawthorne, 1989). A number of methods, such as price reforms, the use of limited lists and the substitution of generic products have been employed to control drug prices within the EU.

Price reforms

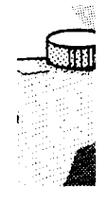
Recent European recession has caused national governments to seek cuts in public spending. Healthcare costs and the price of drugs are coming under close scrutiny. Drug pricing, traditionally the domain of the national governments and the drug companies, has generally increased at a higher rate than inflation. The European Commission has allowed this national control to continue, provided that the prices set do not inhibit free trade within the EU. The price transparency directive, which requires countries to publish details of the systems used to classify products for reimbursement, to fix prices and profits, and to operate positive and negative lists, helps ensure that member states play by the rules. Member states are required to publish at least annually a list of medicines whose prices have been regulated and a complete list of all medicines covered by their national health insurance system, with details of any medicines deliberately not included (Lynn, 1991).

Price reforms, including limits on advertising and profits, have led to declining sales and profits for many pharmaceuticals companies (Schares, 1993). The German and Italian markets have been particularly hard hit. In Germany, a package that included a 5 per cent reduction in prices sent the market into sharp reverse, dropping 11 per cent during the first five months in 1993. In Italy, health reforms introduced in April 1993 led to a decline of 1.8 per cent over the same period. In the latter half of 1993 the UK announced a 2.5 per cent cut in its drug prices. In addition UK GPs have been given control over their own funds which has further influenced their prescribing habits.

Limited lists

These are lists of prescribable pharmaceuticals drawn up by each country's government or national health service. The list dictates which drugs may be prescribed for patients. It results in a number of more expensive drugs being outlawed, or becoming available as over the counter (OTC) medicines (Novack, 1989).

The European Commission's policy of retaining national drug pricing has resulted in wide discrepancies in the prices of pharmaceuticals. As a result, the drug industry faces major threats from parallel importing, as traders exploit the price distortions and take advantage of the free movement of goods. The availability of parallel imports has financial benefits for the governments as these can be passed on to the taxpayers who ultimately pay the country's healthcare bill. However, if trade does start to threaten R&D spending and new drug production, the actual benefits of parallel trading will only be short lived.



Generic pharmaceuticals

These are copies of drugs for which the patents have

expired. Since 1985 they have been the fastest growing sector of the pharmaceuticals industry. Copies of former patented drugs are unbranded and result in major cost savings per prescription.

Over the counter (OTC) trade

A 15 per cent annual increase in European sales of OTC healthcare products was predicted between 1990 and 1995 (Jordan's, 1992 and 1995). France and Germany are predicted to be the fastest expanding OTC markets with 28 per cent and 17 per cent growth, respectively (see Table I). This projected increase is likely to be partly driven by the medical requirements of Europe's ageing population and the switching of increasing numbers of prescription products, that are reimbursable by the state, to OTC status. Since patients pay for OTC products, many health ministries are adopting this strategy to control growing expenditure in the healthcare sector. Many in the drug industry believe that OTC sales will substitute for profits lost as governments restrict the number and cost of prescription drugs.

Culture and the Pharmaceuticals Business

The prescribing habits of doctors in different parts of the EU are affected by cultural differences. As an indication, prescription medicine sales during the first six months of 1993 were only $46 per capita in Britain, compared with $108 in France and $78 in Germany, Italy and Belgium (Abrahams, 1993). These discrepancies in spending are not caused by differing prices for patented drugs, as prices for drugs in France are among the lowest in Europe, while those in the UK are among the highest. Nor are they caused by significant differences in the incidence of diseases or the age structure of the populations. The main differences in spending between European countries are caused by variations in the volume and type of drugs prescribed. A recent study by the Association of the British Pharmaceutical Industry showed that French doctors prescribe five times as many items as British doctors and six times as many as their Danish counterparts.

A second important EU cultural trend has been the move towards self-medication with particular emphasis on preventive medicines and remedies (Harvey, 1994).

Table 1 Main OTC Markets in the EU

Markets	% 1995 Market ($1.45 bn)
France	28
Germany	27
UK	11
Italy	7
Spain	5
Netherlands	4
Belgium	3
Denmark	2
Portugal	1

Source: *Scrip Magazine*, OTC News, February 1996.

Stress on the avoidance of ill-health has led to the provision of OTC prophylactic treatments, such as fish oils and garlic capsules, to guard against heart disease. Sales of vitamins have also increased dramatically, while a large number of anti-smoking aids have recently been marketed as OTC products. For many consumers it seems that the purchase of OTC products is viewed as an alternative means of treating minor common ailments instead of time-consuming visits to the doctors.

Demographics and the Pharmaceuticals Business

The demographic make-up of the EU, in terms of population size and structure, is a key determinant of current pharmaceuticals demand. Overall, the world population is increasing by 1.7 per cent per annum, predicted to slow to 0.6 per cent by the end of the century. The less-developed countries (LDCs) are growing the fastest and presently account for 76 per cent of the population, but less than 15 per cent of pharmaceuticals consumption. The consumption of medicines by the LDCs is predicted to rise dramatically over the next two decades placing great demands on the pharmaceuticals industry.

This increasing population has been accompanied by an upward shift in the median age of the population (*Business Europe*, 1995). The result is a greater number of older people, which has major ramifications for healthcare strategies. For example, drug expenditure per head in the over-65 age group in the EU is five times the level of the rest of the population. Those companies which will benefit most from the changing demographic pattern are likely to be providers for the chronic diseases of old age, such as arthritis, coronary disease, hypertension and central nervous system-related illness. There currently is high investment in the last area, particularly in research into Alzheimer's and Parkinson's disease.

Technological Forces and the Pharmaceuticals Business

The pharmaceuticals industry has enormous investment requirements in the area of research and development, and long lead times for products to come onto the market. These constitute effective barriers to entry because no single national market is large enough to support such high investments. Pharmaceuticals companies have justified the high prices charged for their products by the need to invest a large proportion of their profits in R&D (currently averaging 16 per cent of sales), in addition to the industry's sophisticated technology requirements (Drews, 1995). 1993 European R&D costs totalled $6.5 billion (estimates from the CMR). Britain is Europe's largest investor in pharmaceuticals R&D with spending in 1991 at 22 per cent of the EC total. The 1993 figures show that drug sales are growing at 5 per cent, but R&D costs are

increasing at over 10 per cent per year. Some of the costs of R&D can be attributed to the need to ensure the safety and efficacy of drugs. For example, before applications for product licences are allowed, extensive clinical trials are required to test whether particular compounds can be used safely.

Biotechnology

This is an area in which the pharmaceuticals industry has invested greatly in recent years. In 1990 the sale of biotechnology derived drugs was approximately $1 billion or less than 1 per cent of the total world drug market (*Key Note*, 1992). The costs of R&D are extremely high in the field of biotechnology because of the expensive technologies involved. Total 1992 R&D spend in this area was approximately $5.7 billion (up from $5 billion in 1991). Up to 50 per cent of turnover is spent on R&D compared to a maximum of 25 per cent in the traditional pharmaceuticals industry. However, the total development costs of a biological drug can be up to 50 per cent cheaper than a traditional chemical-based pharmaceutical.

The product development portfolio

Long-term research and development investments are vital to the future of individual pharmaceuticals firms. One of the major requirements of the drug company is a well-conceived product development portfolio which involves choosing the therapeutic areas and finding the innovative compounds, as well as ensuring a speedy development process which manages researchers appropriately and makes effective use of computer technology. In developing the portfolio, a balance is sought which includes a good mixture of safe bets and high risk – high reward products.

Product authorisation

A unified system of product registration especially is likely to benefit all parties. Currently, many technical barriers remain in the pharmaceuticals industry due to the persistence of national drug authorisation regimes. Each EU state requires a separate market authorisation procedure, subject to the requirements of the relevant EU directives and regulations, before a drug can be offered on its market (Kendall, 1993).

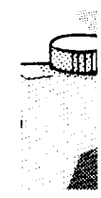
The process of authorisation is supposed to take 120 days. However, with the average delay experienced it is usually prolonged to between 18 to 24 months. This process may have to be repeated in each of the member states, depending on the drug. This in turn significantly increases production costs and accounts for greater than 2 per cent of the total costs of the sector. Unfortunately moves to establish a pan-European system to overcome the present delays and confusion suffered setbacks, although broad agreement was reached in 1992 on a system for authorising new pharmaceuticals products in the EU. It will shortly be possible to market a product approved in one EU country elsewhere without having to repeat the authorisation procedure, once the new system is fully operational.

Japan's Sankyo Competing in the EU

The European drug industry is highly fragmented, with over 2,000 pharmaceuticals companies operating in the EU. This is a successful industry (Davis and Star, 1993) with 11 of the world's top 25 performing companies coming from the pharmaceuticals sector. This success arises from the unique characteristics of the industry. Pharmaceuticals is a highly competitive market, with new innovation and patent expiry continually changing the trading environment. The level of regulation, abundance of patent-created monopolies and regulatory marketing restrictions make it fundamentally different from most other industries. The nature of the customer base is also distinctive, with in most countries, the state as the major purchaser and negligible choice for the end-consumer. The state also subsidises many medicines, notably prescriptions, so the end-user consumer usually pays only part or none of the full cost.

With nearly 400 million consumers who spend more than $65 billion annually on pharmaceuticals, 2,000 pharmaceuticals companies, and over $5.45 billion invested in research, the EU has one of the most extensive and advanced healthcare systems in the world. The major EU markets for pharmaceuticals, in current order of size, are Germany, $14.4 billion; France, $13.1 billion; Italy, $12.4 billion; and the UK, $5.6 billion (Jordan's, 1992). Despite these figures and the fact that the industry still ranks as one of the most profitable in the world, growth rates and profit margins are falling. This is partly due to recent government price cuts and wider availability of cheaper generic drugs. In the EU there is also some resistance to the unification process by drug companies and it is possible that the long term consequences of a unified Europe will result in less profitable business and a progressive weakening of the competitive strength of the European companies (Lynn, 1991).

Sankyo was founded in Tokyo in 1913 and listed on the Japanese stock market in May 1949. It is now the leading pharmaceuticals business in Japan, with 54 domestic and 26 overseas affiliated companies and turnover of over ¥400 billion (O'Donnell, 1995). The company operates largely in the areas of the manufacture and marketing of pharmaceuticals, medical surgical supplies, agricultural chemicals, food products, cosmetics, synthetic chemicals, industrial chemicals and related products. The company's pharmaceuticals sales account for approximately 7.0 per cent of Japan's ¥6,000 billion ($47 billion) total drugs sales (Terazono, 1992). Although the domestic market is Sankyo's main market, the company has a strong presence in East Asia and is making in-roads into the important European and American markets and has ambitions for pre-tax profits of around ¥140 billion (approximately $1.1 billion) by the year 2000. Current prospects for Sankyo look good with a 5.0 per cent average increase in total revenue over the last five years.



Sankyo manufactures and markets a wide range of

ethical, semi-ethical and OTC drugs encompassing a number of therapeutic categories. In 1993 Sankyo's drug production comprised circulatory and respiratory agents (39 per cent), central nervous system agents (14 per cent), vitamin metabolic agents (14 per cent), antibiotics (9 per cent), chemotherapeutics (3 per cent) and others (21 per cent). The company's major focus is prescription pharmaceuticals, where the company has assembled a sound and innovative portfolio including best-sellers Mevalotin, Banan and Loxonin. However, the ethical drug sector is under threat from Japanese government reforms. In 1992 the government lowered the National Health Insurance (NHI) reimbursement system an average 8.1 per cent as well as introducing a new pricing system. The Japanese government is also in the process of identifying prescription only medicine (POM) drugs to switch to OTC status.

Sankyo has a traditional strength in proprietary OTC drugs, and the growing demand for OTC products in Japan means that Sankyo's domestic OTC sales are very strong. The company seeks to achieve further growth in the OTC market and to introduce a wider range of OTC products especially more original vitamin formulas, cold remedies and gastro-intestinal preparations.

Research and Development

Sankyo believes that future success will be driven by its R&D infrastructure. With twelve laboratories and two support departments dedicated to research and development, the company has an R&D expenditure of ¥38.1 billion (9 per cent of turnover). Heavy investment in this area looks set to continue, with regular increases in staffing levels and additional research facilities under construction. Currently there are 37 drugs in R&D at Sankyo, placing the company in the top forty in the industry (Scrip, 1996). Indeed, Tomonori Miki, executive managing director, believes that the company's whole strategy hinges on developing and supplying excellent drugs to the frontier of medical care (Miki, 1995).

Sankyo has established product expertise in the cardiovascular, gastro-intestinal and anti-infectives areas and is focusing particularly on anti-cancer drugs and diseases that affect the elderly. The company's present development portfolio includes products for the treatment of the chronic conditions; diabetes, osteoporosis and asthma. The company also has projects aimed at developing circulatory and central nervous system drugs, anti-infectives, anti-inflammatory agents and allergy treatments. Its innovative oral agent Troglitazone to combat diabetes has recently been licensed to US giant Warner-Lambert for further development and growth (Rodgers, 1995).

Global Strategy

Sankyo's current ranking in Japan and its presence among the top 25 global companies has been achieved by moving away from the domestic market-oriented strategy of the Japanese pharmaceuticals industry. Although the company still has fairly low market share in key US and European markets, it is intensifying globalisation in the wake of recent Japanese Government reforms and the constraints placed on demand in the domestic market. Sankyo's strategy has involved establishing itself as an innovator, increasing marketing and production capacity, substantial R&D investment, acquiring distributors in the US and Europe, setting up joint ventures and acquiring foreign manufacturing bases.

Sankyo's product strategy for overseas development has involved products which have sold well in Japan, thus minimising costs and limiting the risks involved. For example, Cefmetazon was the first overseas drug development in conjunction with Antibioticos of Spain in 1983 and the US company Upjohn in 1985. In the same year Sankyo licensed out its most successful product, Mevalotin, to the US company Bristol-Myers Squibb who launched the product in a range of countries in the EU, EFTA, North and South America and Australasia.

The company's progress in overseas drug development has involved selecting suitably qualified overseas partners to conduct joint research and clinical testing with Sankyo USA, and Sankyo Europe GmbH. Many of the drugs currently under development are in overseas subsidiaries or with overseas partners. These activities should help the company increase its overseas drugs sales from 9 per cent to 20 per cent by the year 2000. The US operation and European base in Germany now have self-contained sales and marketing functions which are expected to be fully operational by 1998.

Marketing in the EU: SWOT Analysis

An analysis of Strengths, Weaknesses Opportunities and Threats provides a systematic approach (Dibb *et al.*, 1996) for identifying factors which will affect Sankyo's business performance and enables decisions to be made regarding the company's abilities to deal effectively with its environment (see Table 2). As the European Union moves to implement directives which will harmonise national policies, Sankyo faces threats from the rapid restructuring of the market as well as from the climate of severe and persistent economic recession. These reforms will inevitably hit the already tightly regulated pharmaceuticals industry. Government cost-cutting especially in the area of drug reimbursement levels and pricing has hit ethical drug companies the hardest. The expiry of patents and changes in prescribing habits by GPs have resulted in increased use of generic medicines. Different fiscal and pricing policies in the various EU countries have led to an upsurge in parallel importing which has markedly influenced the EU pharmaceuticals market. This has also resulted in increasing competition in the distribution and marketing of drugs entering the EU market.

Table 2 SWOT Analysis of Sankyo

Strengths	Weaknesses
• Established company • Global attitude • Manufacturing networks • Distribution networks • Marketing networks • Innovative R&D • Efficient R&D • Advanced technology • Sound product base • Competitor awareness • Communications • Quality assurance • Collaborative skills	• Domestic and Southeast Asia orientation • Little experience in European and US markets • Comparatively low economies of scale • Few established own international brands • Weak international marketing and distribution channels • Large number of licensing agreements
Opportunities	**Threats**
• Relaxation of international trade barriers • Direct investment overseas • Rising standards of healthcare expectation • Less developed countries' (LDCs) growing markets • Increasing standardisation of industry • Global leaders seeking partners to spread costs • Reciprocity of alliances • Niche markets	• World-wide recession • Plateauing of domestic market • Reforms in domestic market • Established global companies • Competition from non-pharmaceuticals companies • National protectionism • Tight regulation • Trading bloc regulations (e.g., EU) • Global pricing reforms • Parallel trading • Patent expiry • Switch of POM to OTC medicines

In order to recoup costs, Sankyo has had to look abroad because its domestic market is no longer large enough to support the volume of sales required to enable profitable business. The company has increased its economies of scale by entering into partnerships and alliances with some of the major drug companies. This has increased its standing in the EU and US markets in which it has very little direct expertise, but Sankyo still needs to build further on its knowledge of international marketing and distribution of pharmaceutical products. Increased presence on the international markets must be established by means of branded products and a move away from the low risk, but equally low margin, licensing of products to foreign companies.

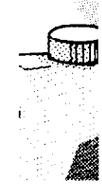
Sankyo has many strengths on which to build. It is well-established with a strong domestic infrastructure, broad expertise and an excellent R&D record. In addition, it has maintained a diversified pharmaceuticals portfolio which is complemented by the existence of its agriculture and special merchandise businesses. The company has kept its R&D costs down relative to those of EU firms, whilst still managing to employ the latest technology and produce innovative products.

Method of Market Entry

The vast cultural differences between Japan and Europe are likely to present difficulties for Sankyo. The languages employed, the working practices in use and the national attitudes to the influx of Japanese business are the main areas which potentially lead to conflict. Sankyo has reduced the impact of possible cultural conflicts by choosing a multi-step strategy to enter the EU market. The major means of entering a market available to an organisation are through direct or indirect export, licensing or franchising, joint ventures or direct investment (Dibb *et al.*, 1994). Sankyo decided initially to enter the EU using licensing, thus giving it time to build an understanding of the marketing environment at the same time as conducting profitable business. More recently the company has concentrated on joint ventures and direct investment.

Initial market entry by licensing agreements

The EU is a particularly complicated market where communication in more than one language and trading in several currencies have become the required way of life. Present regulation of the EU pharmaceuticals industry also presents many difficulties to the non-EU company. Sankyo has avoided confronting these issues head-on by licensing products out to key European pharmaceuticals companies. This is a cheap way of marketing products in foreign markets, but profit margins are much reduced with the licensee taking a large percentage and having ultimate control over marketing methods (Sapienza, 1993).



Joint ventures and alliances

The consolidation of the pharmaceuticals industry is

leading to greater co-operation between competitors. Companies are realising the benefits of pooling resources to increase economies of scale and open up new distribution channels. The high cost of R&D and the expensive technology required are also determinant factors and Sankyo, like many others, has therefore targeted the market leaders in its quest for partners.

In the EU the success of alliances can be very much dependent on the individual country's attitude towards foreign investors. For example, the UK, Eire and Spain openly encourage alliances, whereas France, Italy and Greece have overtly protectionist policies. On the other hand, Germany maintains a neutral public policy posture towards the formation of joint ventures, relying on its complicated banking system as a means of regulation. Sankyo's most important alliance, with respect to the EU market, is with UK-based Glaxo Wellcome. This alliance has provided Sankyo with economies of scale, and access to established marketing and distribution networks both within and outside the EU. Joint ventures are reciprocal in nature and the strong partnership between Sankyo Europe GmbH and Glaxo in Europe is mirrored by the degree of collaboration between Glaxo-Nippon and Sankyo in Japan.

Direct investment

Japanese businesses use English as their second language and have traditionally invested heavily in the UK. However, Sankyo's first direct investment in the EU market was in Germany through the acquisition of Luitpold-Werk GmbH & Co. (Munich), giving a comprehensive sales network throughout West Europe and subsidiaries in 11 countries.

Germany offers major advantages to the pharmaceuticals company. It is the EU's largest market and is a major producer and exporter of pharmaceuticals. In addition, Sankyo has established itself at the geographic hub of Europe with good access to the surrounding markets. This includes the valuable EFTA and promising Eastern European markets. However, a great deal of industrial protectionism is still evident in Germany. Germany has significantly higher wages than Japan, the highest corporate tax rate in the EU and operating costs are among the highest in Europe.

Pricing Reforms

Drug prices are set in collaboration with individual governments so Sankyo is required to implement a policy of different prices in the various EU countries. The different fiscal structures especially indirect taxes, such as VAT, are the major reason for the variations in national pricing policies. The cost of land and labour are also important factors. Pricing is also affected by the presence of 'limited lists'. The blacklisting of certain expensive medicines which will no longer be reimbursed by the relevant national health systems has forced companies to drop drug prices to ensure inclusion on the lists. In order to retain competitiveness Sankyo may also be compelled to reduce prices drastically. The threat of parallel imports will decline with the increase in the harmonisation of drug prices.

Generic Competition

Generic competition, above all, will affect the sales and prices of Sankyo's products in Europe. Doctors are responding to new government guidelines and tighter budget controls by prescribing generics or cheaper, ethical medicines. The European Union favours a system of co-payment of a percentage of medicine cost by the patient rather than the flat rate fixed pharmaceuticals fee now in use. If the end-consumers are made aware of the real cost of the medicine they will be able to make informed choices. In some instances drugs are currently being prescribed that can be obtained more cheaply as OTC medicines. The end-consumer will also perhaps substitute generic OTC products, if available, instead of paying for more expensive prescription-only products. This will place further pressure on ethical drug companies. Sankyo must meet this threat by formulating a strategy which will pre-empt generic competition from competitors against own brand ethical products whose patents are shortly due to expire. The production of generic versions of its international best sellers Mevalotin and Banan would be an initial requirement. There is also a major threat from the current trend to switch drugs from prescription only medicines (POM) to OTC status – a policy increasingly practised by various EU national governments. The increase in the ageing population and the switching of drugs from POM to OTC status are also contributory factors.

If Sankyo is to establish a strong presence in the EU market it must therefore introduce OTC products. The regulatory reforms and price cuts, that have reduced profit margins for the drugs manufacturers obtained from the sale of prescription drugs, have led to increased activity in the marketing of OTC drugs, as many major pharmaceuticals companies have recognised the trend for increased sales over the counter in pharmacists. Sankyo has maintained a diverse portfolio with a strong OTC division, but these strengths are very much confined to the domestic market. Sankyo would penetrate the market more easily by collaboration with a leading EU company in the area of the marketing, promotion and distribution of OTC pharmaceuticals products, such as Smith-Kline Beecham (UK/US) or Hoechst (Germany). This would overcome the problems associated with being a new name in the marketplace. Products would require re-naming and re-packaging for the EU consumer.

EU Economic and Demographic Profile

When deciding on product targeting, Sankyo must give careful consideration to a number of factors, including economic growth, population size, income size, present market size and rate of growth, level of government expenditure on healthcare, legislation on the testing and

authorisation of products. The varying economic and demographic profiles of different member states act to complicate the task, yet some overall trends can be isolated.

Growth of the EU pharmaceuticals market is slowing. However, it still offers many opportunities in the way of niche markets, such as diseases of the ageing population. This sector of the population is steadily increasing in size. Germany has the largest population of over 65 year olds, with the UK the second largest (OECD, 1993). Sankyo has established drug expertise in the areas of cardiovascular, cancer and gastro-intestinal disorders. The increasing incidences of chronic diseases such as diabetes, cancer and asthma, and the continuing AIDS epidemic in the EU also provide lucrative therapeutic areas to be targeted.

The availability of labour with appropriate skills and at the right price is a key determinant in the search for a site to set up a business. Germany has the largest EU workforce supplying a large number of highly skilled workers. However, its labour force commands the highest wages in the EU. In recent years the UK has enjoyed substantial cost advantages over most of its EU rivals to attract foreign investment. The most obvious has been the price of labour which has been consistently below that of Germany, France, the Netherlands and Italy. The high levels of unemployment among skilled workers in many regions of the UK also provide a major attraction to businesses. The Iberian countries, notably Spain, have recorded substantial increases in inward investment in recent years, due no doubt in part to relatively low labour costs.

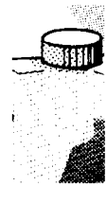
Research and Development

The main lucrative areas of research are already being investigated by the major EU and US drug companies: cancer, neurology, obesity, AIDS, contraception, asthma (Scrip, 1996). This means that in highly competitive areas such as antibiotics, cholesterol-lowering treatments and ace-inhibitors (heart drugs), Sankyo finds itself up against the industry's leaders. To avoid direct and potentially damaging competition, Sankyo has elicited the help of the major EU pharmaceuticals company, Glaxo Wellcome. The biotechnology sector is showing particular potential and the possibilities for the treatment of diseases by gene therapy or antibody targeting are boundless. Sankyo has some biotechnology products already in production and has started to explore the niche markets created by the new technology.

One potential difficulty that Sankyo must handle is that individual EU countries still require separate drug authorisation applications. This has changed with the setting up of the EMEA in 1995, but until the EMEA is fully operational, Sankyo will still have to consider the requirements of the individual EU member states. The EMEA (the European Evaluation Agency for the Evaluation of Medical Products) based in London is to co-ordinate market drug authorisation within the EU. The centralised procedure will be compulsory for all biotechnology products and available on request for any innovative products. Once granted, market authorisation will be valid in all EU member states (*Managing Intellectual Property*, 1995). This means that Sankyo, and its rivals, can look forward to reduced costs and fewer delays in this area within a few years. Intellectual property is another area for Sankyo to consider. Collaborative agreements in biotechnology and pharmaceuticals industries are becoming increasingly the rule (Scrip, 1996), allowing participants to pool resources and spread the cost of research and development so that technological advances can be made. It also brings benefits by spreading the risk and cost of bringing a product to market. The process of collaboration means that important intellectual property rights will be created, transferred, licensed, and cross-licensed.

It is clear that Sankyo's future business strategy must be flexible enough to allow a swift, but informed reaction to be made in the face of the continuing structural changes. Sankyo must continue to analyse and explore potential EU markets to ensure that the company maintains the necessary competitive edge and enjoys commercial success. The pharmaceuticals industry is anyway severely regulated and bound by restrictions compared with most other markets. Not just the legislative and regulatory aspects of the marketing environment, however, are at play in the pharmaceuticals industry. To further complicate the situation, national state governments within the EU have their own requirements, while the EU is continually modifying its views. While the EMEA will inevitably simplify matters with cross-border drug approvals, if other markets in the EU are an indicator, national governments will continue to place their own demands on the pharmaceuticals industry.

The competitive, economic and political circumstances differ country to country and are changing daily owing to the very presence of the EU. The socio-cultural and demographic composition is even more diverse given the very different configurations between the member states of the EU, and even within them. Given the innovative, technical nature of this industry, the technological impact of the marketing environment is always a factor. For a European-based business, such a picture is complicated and at times confusing. The position for a Japanese player is even more extreme, yet clearly Sankyo's potential success depends greatly on its ability to understand and to monitor the quickly evolving marketing environment in the EU.



Conclusions

The complexity of the EU's marketing environment has profoundly influenced Sankyo's EU marketing strategy. In particular, cultural and political barriers to trade have

induced the Japanese company to adopt an initial low risk strategy of market entry. This has involved licensing out its best selling drugs to pharmaceuticals companies that were already successfully marketing medicines in the EU, before establishing a European subsidiary, Sankyo Europe GmbH (Dusseldorf). This provided the company with a base from which to analyse the EU marketing environment and to gain confidence and knowledge of the market. More recently Sankyo has forged valuable and reciprocal alliances with several drug companies, including the EU's principal drug company, Glaxo Wellcome. These provide the essential economies of scale necessary to compete against the leading EU pharmaceuticals companies.

The inherent diversity of the member states of the EU means that significant cultural and legislative barriers to trade will continue to exist. For Sankyo this means adapting itself to the European norm of dealing in several currencies and employing several spoken languages, while adhering to disparate national regulations which operate within the legislative boundaries laid down by the European Union. For example, the pricing of drugs is an area fraught with difficulties, which can only be achieved by negotiation with each of the individual EU state governments. Price reductions in the ethical pharmaceuticals area means that to maintain a presence in the EU and expand its marketing scope, Sankyo will have to evaluate the advantages of operating in the less profitable but more stable OTC market. In addition, the company must take heed of the implementation of limited lists and stricter controls on GPs' spending and consider the in-house production of generic forms of its leading drugs. The effect would be to pre-empt generic manufacturers who are currently on standby to exploit the technology and profit greatly from the drugs upon patent expiry.

The current trends in the EU will in some respects ease the difficulties that Sankyo currently experiences. The steady harmonisation of drug prices is envisaged, as fiscal policies and regulations are more closely aligned. A positive outcome from the tripartite talks on the global harmonisation of pharmaceuticals regulations between the EFPIA (EU), the FDA (US) and the Japanese Ministry of Health and Welfare seems likely, which will resolve problems arising from the currently disparate clinical trials and drug authorisation procedures. The implementation of global regulations in this area will assist with cost parity, the alignment of differing employment policies, competitive practices, labelling, delivery, and trade practices ultimately facilitating movement of medicines within the EU. Nevertheless, despite a German base, the company is Japanese and as such is not prone to the benefits accorded to European rivals.

The marketing environment of the EU faces further rapid changes in the near future. The perceived economic and competitive benefits that membership of the EU accords participating countries has stimulated intense interest from neighbouring European countries. By the year 2000 the EU is predicted to comprise 20 or more states and number well over 400 million people. This will mean an additional influx of different cultures with a finite period of adjustment required as each new country gradually adopts EU policies and practices.

Sankyo's future business strategy must be flexible enough to allow a swift, but informed reaction to be made in the face of the continuing changes. Potential EU markets must be carefully analysed to ensure that the company maintains the necessary competitive edge and enjoys commercial success. The pharmaceuticals industry is anyway severely regulated and bound by restrictions. To further complicate the situation, national state governments within the EU have their own requirements, while the EU is setting its own expectations. Clearly, though, the other aspects of the marketing environment are also impacting on this industry. The competitive, economic and political circumstances differ country to country and are changing daily owing to the very presence of the EU. The socio-cultural and demographic composition is diverse between the member states of the EU, and even within states. The innovative, technical nature of this industry means the technological impact of the marketing environment is always a factor.

For a European-based business, such a picture is complicated and at times confusing. The position for a Japanese player is even more extreme, yet clearly Sankyo's potential success depends greatly on its ability to understand and to monitor the quickly evolving marketing environment in the EU. Scope for growth in its domestic market is now severely limited: the EU is a key target market priority for Sankyo.

The marketing environment includes numerous facets of the broader trading environment, over which a business generally has very little direct control. They are, though, elements which tangibly affect the way in which an organisation can do business and will perform. To monitor the important aspects of the marketing environment and to prepare for the ramifications of any changes, marketers must undertake a continual process of scanning and analysis. Each of these forces has a significant impact on a business's trading conditions: when the marketing environment changes, companies face uncertainty, threats but also opportunities. For an organisation to survive and prosper, the marketing environment must be continually scanned so that the company can predict likely outcomes and respond accordingly. Nowhere can this be more certain than in the pharmaceuticals market in the EU and for a Japanese company aiming to expand its market share.

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