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The pharmaceuticals industry in Japan: current trends and emerging business opportunities for EU-based small- and medium-sized enterprises

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Contents

List of abbreviations used in this Report:

AI: Artificial Intelligence

ALT: Automated Laboratory Tests

BOJ: Bank of Japan

FDA: Food and Drug Administration (United States of America)

FDI: Foreign Direct Investment

GDP: Gross Domestic Product

IPR: Intellectual Property Rights

IT: Information Technology

JIT: Just-In-Time inventory management system, one of the fundamental techniques for controlling wastage, costs and efficiency associated with the Toyota Production System (**TPS** – see below)

JPMA: Japanese Pharmaceutical Manufacturers Association

K.K: *kabushiki kaisha* (Japanese), variously translated into English as 'Co., Ltd.', 'Corporation', 'Incorporated' (Inc.) or as 'joint stock corporation'. The K.K. is the most widely utilized form of legal incorporation in Japan.

M&A: Merger and Acquisition

METI: Ministry of Economy, Trade and Industry (Japan)

MD: Medical Doctor

MHLW: Ministry of Health, Labour and Welfare (Japan)

MOFA: Ministry of Foreign Affairs (Japan)

NIS: National Innovation System

OTC: Over-The-Counter: i.e. drugs that can be bought at pharmacies and drugstores rather than issued only by prescription at hospitals and clinics

SME: Small- and Medium-sized Enterprise. Readers should note that SMEs can be defined differently according to nationally defined economic system and business sector (See **Footnote #6**, page 18)

STEP / PEST / STEEPLED analysis: **S**ocial-cultural, **T**echnological, **E**conomic, **E**cological, **P**olitical, **L**egal, **E**thical and **D**emographic factors – used in processes of environmental scanning, the purpose of which is to identify key factors and trends describing a targeted strategic business environment: e.g. markets for pharmaceutical products and services in Japan.

TPS: Toyota Production System – see 'JIT' (above).

Executive Summary

This Report highlights distinctive features and current trends in the structure and development of the pharmaceuticals industry in Japan. Drawing on evidence generated by Japanese and non-Japanese researchers along with insights from industry insiders in both Japan and in Europe, this Report makes practical suggestions towards guiding small- and medium-sized enterprises (SMEs) based in the European Union (EU) that are looking to establish and / or develop positions in Japanese markets for pharmaceutical products and services, including medical devices and other health-related products and services. Towards this objective, this Report concludes with five primary recommendations:

i) Research, develop and introduce to Japanese consumers pharmaceutical products and services that are perceived as being so scarce and specific to market needs and expectations that consumers, medical doctors, regulators and other key stakeholders defining the Japanese market can be persuaded to import and distribute these.

ii) Partner with large pharmaceuticals manufacturers in Europe that already have established positions in Japanese markets for pharmaceutical products and services.

i) Partner with EU-based SMEs that already have established positions in Japanese markets: for example, by making research, development and clinical trial agreements with these SMEs.

ii) Attract the attention in Europe of Japanese pharmaceuticals manufacturers such that they invest in a strategic alliance and thereby offer access to Japanese markets for pharmaceutical products and services.

iii) If the SME does not already own or control distribution of a pharmaceutical product or service that does not offer proven vaue added in terms of scarcity and / or specificity relevant to current and emerging Japanese markets, do not invest in entering Japanese markets and instead invest vital resources in other more accessible markets: for example, emerging markets across South and Southeast Asia.

This Report details the rationale behind each of these recommendations for strategic thinking and action: for example, by identifying and highlighting distinctive features in the structure, development and trajectory of the pharmaceuticals industry in Japan that might over time be perceived as market entry barriers that EU-based SMEs might currently experience and / or perceive. It is fair already to emphasise that it is generally difficult for new entrants to gain access to markets for pharmaceutical products and services in Japan remain relatively difficult for new entrants. Nonetheless, after reading this Report it is to be hoped that EU-based SMEs might be

encouraged systematically to begin identifying business opportunities in respect of establishing and / or developing positions in Japanese markets for their products and services.

1 Introduction

This Report is designed to inform managers in European companies about the evolving structure and development trajectory of the pharmaceutical industry in Japan generally, and specifically about current trends in the industry that might create business opportunities for small- and medium-sized enterprises (SMEs) that are based operationally in the European Union (EU) and are seeking to develop or extend positions in Japanese markets for pharmaceutical products and services. Giving particular context to this Report is the Economic Partnership Agreement (EPA) negotiated between the EU and Japan in December 2017. According to the European Commission (2018), this EPA is designed to:

- Remove trade barriers between the EU and Japan across a range of business sectors
- Help "shape global trade rules" to further align with EU standards and values
- Signal that both the EU and Japan are willing to cooperate in order to counteract protectionism.

From the official EU perspective, those sectors that are expected to benefit most from the recently negotiated EPA include pharmaceuticals, medical and agri-food (European Commission, 2018). Examples from each of these sectors from a Japanese perspective are highlighted in this Report.

Recognising that EU-based SMEs in particular might benefit from a removal and / or reduction of trade barriers, the aforementioned EPA envisages a business environment for pharmaceutical products and related services that should first appear and then in practice become more accessible: for example, by making it easier for EU-based SMEs to:

- Find out which Japan-specific rules might apply to their products and services
- Identify key features in the current regulatory environment for pharmaceutical products and services in Japan
- Understand and navigate customs procedures for the export of these products and services from the EU to Japan.

Against the background of recent trade negotiations between the EU and Japan, this Report seeks to give EU-based SMEs insights into the current structures and trends in the pharmaceuticals industry in Japan and, accordingly, offer practical advice about how these SMEs might take advantage of trends signalled by the aforementioned EPA in

order to enter and / or develop existing positions in Japanese markets for pharmaceutical products and services.

As detailed subsequently in this Report, trends in the economic, political and legal and demographic environments for EU-based SMEs entering Japanese markets appear promising. To illustrate, Japan remains by global comparison the fourth largest economy by measures of Gross Domestic Product (**GDP**); Japan's *per capita* output growth current outstrips current averages among the thirty-four member states of the Organization for Economic Cooperation and Development (OECD, 2017). Across major business sectors, trends in job creation continue to move upwards across major industrial and commercial locations in Japan, while skilled labour shortages continue to suggest business openings for non-Japanese companies able effectively and in a strategically targeted manner to compensate for these shortages.

The search for new sources of knowledge and skilled labour is prompting many Japanese manufacturers to seek assets overseas. Japanese companies across a number of key business sectors continue to record high profits, and several of these are looking to invest profits overseas: for example, through the acquisition of companies - and especially SMEs - in Europe that can strengthen global supply chains and consolidate the positions of Japanese companies in European markets (Jackson and Matsumoto, 2017). To illustrate, Japanese companies in Europe currently employ more than 600,0000 people; Japan remains the EU's second biggest trading partner (by volume) in Asia (after China) and the sixth largest EU trading partner worldwide. Currently, the EU exports each year over €58 billion worth of goods and €28 billion worth of services to Japan (European Commission, 2018)

However, and despite these promising domestic trends, it is important to recognise that Japanese markets by tradition have appeared relatively closed to non-Japanese entrants – a perception and a reality that are likely to continue for some time. Japan remains the third largest nationally defined market for the sale of pharmaceutical products and services, trailing only to the United States of America (USA) and China (UNCTAD, 2017). As illustrated in this Report, companies that populate the Japanese pharmaceutical industry continue to invest heavily in research and development, increasingly targeting new technologies and procedures in pharmaceutical manufacturing and, by extension, in related sectors such as 'biopharma' and 'biotech' (Jackson and Debroux, 2009).

Regardless of these emerging trends in investment, the premise for strategic decision-making in Japan remains distinctly institutionalised towards doing things in a 'Japanese way' (Boyer, 2014; Lechevalier, 2014) – as illustrated in this Report, an institutionalised mind-set that continues to shape consumer perception along with stakeholder expectations in current and emerging markets for pharmaceutical products and services in Japan. Despite the enduring challenges posed by actual and perceived barriers for entry, it is hoped that this Report might offer EU-

based SMEs some practical guidance towards overcoming these barriers and subsequently establish successful land sustainable positions in markets for pharmaceuticals and related products and services in Japan.

1.1 Regulatory environment

From an outsider prespective, distinctive features of the regulatory environment are of primary strategic salience in Japan and in other nationally defined markets for the development, distribution and sale of pharmaceutical products and services. Interprting and negotiating to regulatory requirements (by law) and expectations (by custom) – for example, in response to social, cultural, legal and ethical levels of tolerance - is commonly recognised as a major factor impinging on the strategic 'room to manoeuvre' of SMEs, and this regardless of whether these SMEs operate within Europe or in Southeast Asia - a region receiving increasing amount of outbound foreign direct investment (**FDI**) from Japan (METI, 2013, 2017). For, adopting a systems perspective on the Japanese pharmaceutical industry and the management thinking that serves to structure and drive it, it is important that EU-based SMEs start from an acceptance that Japan remains relatively 'closed' when compared directly to European or other globally connected markets for international business and trade (Gerlach, 1992, 2014; Jackson, 2013; Lechevalier, 2014; Jackson, 2016; Jackson and Matsumoto, 2016).

Set against this broad regulatory background, the aforementioned Agreement (EPA) recently discussed between the EU and Japan might prove to be a milestone of still incalculable significance for EU-based companies generally, and (we can speculate) for SMEs especially. The scope of the EU-Japan EPA is wide-ranging and albeit, still general in terms of detail. However, the sentiments expressed and the direction of EU-Japan trade apparently aspired to in the December 2017 EPA already now suggests consequences in relation to strategic consideration across a number key and connected issues of direct relevance to pharmaceutical companies. These include: regulation, intellectual property (IP) rights, patenting, pricing, packaging and distribution. We illustrate and exemplify several of these vital strategic considerations in this Report and in the accompanying Webinar. For now, we can recognise that the 2017 EPA maintains the EU's 'right to regulate' in respect of pharmaceuticals and other products and services (European Commission, 2017:6), an emphasis that (apparently) senior politicians in the soon-to-leave United Kingdom appear willing to subscribe to (*The Guardian*, 2018). As illustrated subsequently in this Report, SMEs in Europe can expect regulators overseeing developments in Japan's pharmaceutical industry resolutely to maintain their own embedded approach towards regulating domestic markets for pharmaceutical product and services.

1.2 Demographic shift

In terms of population trends, Japan can be regarded as a rapidly 'ageing society' (Kohsaka, 2013): in other words, a society within which older people tend to be living longer (though not necessarily in good health) while people of child-bearing age appear less willing to start families, or increasingly seek medical advice and intervention in order to do so (Audibert and Glass, 2015). Compounding this demographic mix, successive Japanese governments appear to echo a consistently expressed wish among their constituents heavily to restrict and regulate inward migration (Kingston, 2103).

Outside observers of Japan can identify a confluence of trends termed 'demographic shift' or a complex process whereby trends in social development generate significant levels of overlapping cultural, political, economic, technological, ethical and even geographical consequences for societies (Dicken, 2010) – in the case of Japan, a confluence of actual impacts and potential consequences that challenge existing assumptions about the sustainability of society itself (Walker, 2015). Current trends in Japan appear both similar to and distinctly different from processes of demographic shift currently observed in (for comparison) China and Germany (Hayutin, 2008). Comparative measures relevant here include: fertility and birth rates, life expectancy (longevity), proportion of population aged 65 and over, median age in society, median age in employment, and worker-to-retiree proportions (Jackson and Debroux, 2016). For purposes of global, national and regional comparison policy makers along with academic and business researchers asses and correlate these variables against data tracking processes of urbanisation, net immigration from outside the respective country or region, and / or net domestic migration from rural areas to urban areas (HDI, 2017).

In Japan specifically, social researchers, economists and national policy makers are using conceptualisations and measures of demographic shift to describe, explain and predict social, cultural and economic implications of *kōreikashakai* (population ageing) for younger, older and (potentially) immigrant workers in an increasingly 'hyper-aged' Japan (Shimazaki, 2012). Such findings give context to management researchers examining and comparing (for example) the market segmentation strategies of companies competing in what appear to appear newly emerging markets: for example, studies of 'grey' and now 'silver marketing', comparing trends towards targeting ageing and retiree populations in Germany and Japan (Kohlbacher, Güttel and Haltmeyer, 2012). These trends not only impact on populations of current or prospective consumers, they also impact on the ability of companies to identify, respond and (where appropriate) exploit the business opportunities generated by such trends (Jackson and Debroux, 2016).

1.3 Emerging business opportunities for European SMEs

As previously mentioned, the recently negotiated EU-Japan EPA anticipates emerging trends and, by

extension, business opportunities for European SMEs: prospects are that established product and service quality standards, consumer protection and demographically structured institutions in both Japan and the EU look set to converge and become more harmonised. The European Commission predicts that this newly agreed EPA "will bring concrete benefits to European exporters and consumers alike" by (for example) "removing almost all custom duties" – a move that supports estimates for future exports of processed food from the EU to Japan to rise "by up to 180%" while exports of chemical products in the same direction "could rise by over 20%" (European Commission, 2018).

Correspondingly, this Report attempts to shed some early light on an emerging setting that suggests an increasing number and diversity of business opportunities for EU-based SMEs seeking to develop or extend positions in Japanese markets. To illustrate briefly: the aforementioned processes of demographic shift evident in Japan are impacting on pharmaceutical manufacturers generally and specifically in terms of their current research and development (R&D) and innovation capabilities. As a strategic corollary, how these manufacturers respond to such pressures influences the interest of key domestic stakeholder groups including health care policy makers and insurers, employers, drug regulators and distributors (Nakagawa, Watanabe and Griffy-Brown, 2009; Jackson and Debroux, 2009; Sueki, 2016; Debroux, 2016). These pressures on established Japanese pharmaceuticals manufacturers simultaneously create potential business opportunities for producers and providers originating outside Japan: for example, European SMEs with opportunities to supply and or partner with Japanese companies to meet shifting health care demands and expectations among consumers in Japanese markets (Taplin, 2007, 2009).

Overall, this Report seeks to identify demographic regulatory, policy and general business factors and trends that both distinguish Japanese markets for pharmaceutical products and services and simultaneously appear to offer business opportunities in these markets for EU-based SMEs. The Report provides case studies and other industry-specific insights that designed to offer practical advice to European SMEs who might perceive opportunities to satisfy these shifting demands and expectations with their own pharmaceutical products and services and / or though partnering or other forms of strategic alliances with domestic Japanese companies operating and investing both inside and outside of Japan. In conclusion, the Report offers practical suggestions that might guide EU-based SMEs towards negotiate their entry into the distinctive regulatory, demographic and business environments that give emerging context to the pharmaceutical industry in Japan.

1.4 The structure of this Report: key questions

Against the background of aforementioned factors and trends influencing current and emerging strategic business contexts to the pharmaceuticals industry in Japan, this Report is structured towards addressing three main questions:

i) In terms of its history, structure and current patterns of development, what are distinctive features of the pharmaceuticals industry in Japan?

ii) How open are Japanese markets for pharmaceutical products and services to non-Japanese companies, and especially to SMEs from Europe?

iii) What business opportunities currently exist for European SMEs seeking to invest in Japanese markets for pharmaceutical products and services?

Addressing the first question, this Report gives some historical and contemporary context to how the pharmaceuticals industry in Japan is structured, illustrating with brief case studies of major market players – both Japanese and non-Japanese. Particular attention is given to the enduring influence of established institutional factors that serve to define Japan as a context for doing business generally and in domestic markets for pharmaceutical products and services particularly.

Towards addressing the second question this Report highlights key strategic factors that serve and continue to define Japanese markets for pharmaceutical products and services, giving particular attention to how European SMEs are currently challenged to negotiate the regulatory environments governing the production, distribution and sale of pharmaceutical products and services in Japan.

Finally, the third question is addressed by identifying and highlighting emerging business opportunities for EU-based SMEs that are seeking to establish and / or expand positions in Japanese markets for pharmaceutical products and services. Against this newly forming background, practical suggestions are given towards helping European SMEs invest in a targeted and effective manner in Japan.

Through each stage of the discussion, readers of this Report are guided to a range of relevant academic literature, publicly available business analyses and institutional resources relevant towards helping European SMEs to formulate strategies for engaging with markets for pharmaceutical products and services in Japan. A series of Appendices add background detail to some of the main discussion points raised in the main text of the Report.

Finally, the References and Appendices added to this Report guide readers to current examples of reliably researched and easily accessible industry-relevant sources of business information. In an attempt to obviate undue replication of information available from these sources, this Report offers relevant and more immediately vivid practical guidance to EU-based SMEs by citing from real-life case studies of SMEs in Japan and from SME managers, business consultants and other senior players who regularly interact with these SMEs in both Japan and Europe.

2 The structure and development of the pharmaceuticals industry in Japan

This Section of the Report gives a brief historical context to the pharmaceuticals industry in Japan, highlighting how key elements in its current structure and path of development derive from the 'borrowing' and importation of technologies and production processes from Europe and in more recent times from the USA and other global markets. Specifically, the discussion in this section of the Report is designed to begin answering the following questions:

- In terms of its history, structure and current patterns of development, what are distinctive features of the pharmaceutical industry in Japan?

- To what extent and with what effect might EU-based SMEs perceive these distinctive features of Japan's pharmaceutical industry as barriers to market entry, and why?

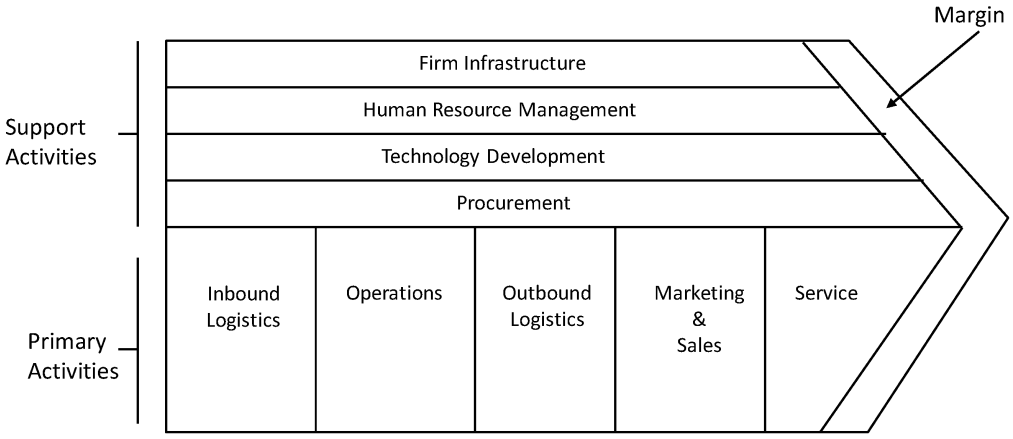
2.1 The pharmaceuticals industry: a global perspective

In global (English language) terms, reference to 'pharmaceuticals' signifies manufactured products generated by a particular industry across which companies compete in various business sectors for the commercially-oriented research, development, production and distribution of drugs and treatments that can be used socially as medications[1]. **Figure #1** (below) illustrates how pharmaceuticals manufacturers generally operate in the form of a value-chain: that is, investing a series of operationally sequenced activities that should – when a company's products and / or services come to market – add value to current and future customers (Porter, 1985). **Figure #1** can be used to illustrate generally how pharmaceutical products and services are created: for example, medicines (drugs[2]) as products along with the equipment needed to administer these drugs to patients; advice and promotion as services designed to bring these drugs to market attention and subsequently offer after-sales advice to customers.

[1] For the purpose of consistency, in this Report we use the term 'company' as a general term covering more differentiated concepts such as 'firm', 'enterprise', 'corporation' or 'organization'. When referring to SMEs, we assume current European Commission definitions of this form of company.

[2] In this Report the terms 'pharmaceuticals' and 'pharmaceutical products' are at time used interchangeably with the term 'drugs' – a term commonly used in Japanese-style English and which was borrowed from American English. To illustrate, the 'Information On Regulatory Affairs' guidance issued by the Japan Pharmaceutical Manufacturers Association (JPMA) includes references to 'Office of New Drug' and 'Drug Marketing Approvals' (JPMA, 2015).

Figure #1: Pharmaceuticals (drugs) manufacturing depicted as a value chain



(**Source**: Porter, 1985; Jaradat et.al., 2017: 12)

In order to be competitive within and across nationally defined markets – for example, 'Japanese' markets for medicinal drugs and treatments – companies need to offer products and services that are differentiated such that they are perceived as being i) *scarce* and ii) *specific* according to current or future market demand. . Consequently, invoking principles of 'scarcity' can help explain the dynamics of market supply and demand, including channels of distribution: for example, are the goods (drugs) that consumers - for example, patients - might need available where these patients can access them and at a price they are willing to pay.

Simultaneously, markets can be envisaged as being driven by questions of specificity in relation to whether the drugs available to customers / or clients – for example, doctors and hospitals - at any one place / time might be the 'right' drugs in terms of their efficacy and therefore as a relevant and timely treatment for a patient's medical and / or health needs or expectations. As explained subsequently in this Report, medical doctors (MDs) play a pivotal role in Japan towards defining these market needs and expectations – a service for whioch they expect to claim a significant proportion of the 'margin' (profit) illustrated in **Figure #1** (above). As discussed subsequently in this Report, the institutionalised expectations commonly referred to in Japan as "doctors' margins" (see **Box #10**, page 51) reamin a major network barrier to new market entrants.

2.2 The pharmaceuticals industry in Japan: a brief history

Of particular relevance here are technologies for the extracting, fermenting and processing of natural ingredients and the formation of synthetic chemical compounds imported from Germany and other European countries during the 1870s. These (for Japan) new technologies were added to the range of traditional fermenting and processing

technologies in industries such as the brewing of rice wine or *sake* (Hara, 2008). This approach towards importing and, later, re-engineering) European and 'western' technologies before blending them with traditional Japanese approaches continues to influence the education of pharmacists along with the mind-set of managers in the pharmaceutical industry in Japan.

Consequently, the historical origins of 'pharmacy' and 'pharmacology' as fields of modern research along with the development, production and distribution of 'pharmaceuticals' as an industrialised commercial activity in Japan can be traced back to Europe. Around the middle of the nineteenth century in Europe and then in the United States of America (USA), local apothecaries prepared and sold plant-based treatments, combining later to research, produce and export drugs such as morphine and quinine. Multinational corporations such as Pfizer, Merck, Eli Lilley, (Hoffman-La-)Roche, Glaxo Smith Kline (GSK) and their brands began life as networks of regionally located apothecaries (McGuire et.al, 2007**).**

During the early years of the Meiji Restoration[3], Japan attempted to become a 'modern' state, pushing through radical and rapid processes of industrialisation and, subsequently, militarisation. One source for this national / nationalistic drive came from the knowledge gained by groups of senior Japanese officials and nobles whose 'missions' to western countries in order to learn first-hand about the technologies and institutional and economic development policies. Japanese officials recognised 'western' economies generally as industrialised and 'developed' in comparison to Japan and other East Asian regions. During this period, Germany was regarded as a 'new' nation and thus as a suitable role model for Japan in relation to political, social and economic development: for example, the emphasis given by German governments to 'national economics' as opposed to the more 'individualised' economics of early industrial nations such as Great Britain and the USA (Walker, 2015). Following the Meiji Emperor's lead, national policy makers in Japan openly recognised and discussed Germany as a global industrial leader in chemical processing and modern or 'rational' drug discovery and development and chemical synthesis (Hara, 2008). During the leading historical example of this achievement being the pharmacist Friedrich Sertürner and his discovery of morphine in 1805 (Sneader, 2005)[4].

During the period overlapping the late Meiji and early Taishō eras (1900-1915), a number of new pharmaceutical manufacturers were founded. These specialised in the production of 'western' medicines. As illustrated in Appendix

[3] Periods of Japan's ancient and modern history and calendars are recorded according to Imperial eras. Those defining the modern era are: Emperor Meiji (1868-1912); Emperor Taishō (1912-1926); Emperor Shōwa (1926-1989). The reigning Emperor (soon officially to retire) is Emperor Akihito, whose Era (1989-to present) is termed *Heisei*. Official documents for government and (often) business purposes still use the year of an Emperor's reign. To illustrate, the current 'western' calendar year (2018) is in Japan simultaneously recorded as 'Heisei 30'.

[4] This cultural influence extended until recently: for example, those students taking pharmacy as a specialist subject at National Universities in Japan would be expected during their studies to gain a reading knowledge of German, much as school students in Japan and Korea continue to be tested on their ability to read extracts of ancient poetry in 'Classical Chinese'.

#1, branded companies such as Sankyo, Dai-chi and Ban-yu continue to exist. During the First Great War in Europe (1914-1918), Japan took the diplomatic, political and business opportunity to stop recognising the validity of patents owned by German pharmaceutical companies, thus further prompting the domestic and independent manufacture of 'western' pharmaceuticals. When the Pacific War (1937-1945) concluded with the dropping of thermonuclear bombs on the cities of Hiroshima (Western Japan) and Nagasaki on the southern island of Kyushu, US American and other allied military forces occupied and administered Japan bringing with them a new range of technologies and medicines to the country: for example, penicillin (Hara, 2008; see **Box #1**, page 19).

Several of the larger and most established pharmaceuticals companies in Japan – names such as Takeda, Tanabe, Shionogi, Fujisawa and Ono (see **Appendix A**) - had begun life as wholesalers of traditional herbal (Chinese) medicines (Hara, 2008). These and other newly established pharmaceutical companies quickly assimilated western technologies, as did Japanese society as a whole during the Meiji Restoration era. The establishment and rapid expansion of a national rail transportation network is one such example. This expansion led in turn to the creation of tramways that prompted and connected the development of new suburbs around existing urban centres. At the national level, one observable result is the concentration of populations into cities that congregate along Japan's Pacific coastline: for example, connecting industrial cities such as Kobe and Osaka (in the *Kansai* region of Western Japan), through Nagoya, and further on through Yokohama and Tokyo (Eastern Japan), and then further northwards to the Tohoku region and Sendai[5].

Prior to 1945, Japanese pharmaceuticals companies sought to establish and then improve the specificity of their knowledge resources, skills and relevant technologies by building on existing and traditional knowledge, skills and technological expertise in sectors such as fermenting of food and beverages: *tofu* (soy bean curd) and *saké* (rice wine), for example. These traditional knowledge resources, skills and technological expertise could be transferred across sectors: for example, in the manufacturing of medicines drawn from combinations of naturally occurring ingredients. The Japanese pharmaceutical manufacturers that emerged from these assimilation and transfer processes became successively more effective when competing in domestic markets on the strength of their respective R&D, production, marketing and sales capabilities. We have seen how the primary sources for the development of these intellectual, practical and business-oriented resources informing and underpinning these capabilities can be found in Europe – a tradition upon which EU-based SMEs might credibly re-connect with and further build on today.

[5] Among the Missions sent from Japan to Europe were those whose task was to learn about steam engine technology and, subsequently, the development of railway networks. They concentrated their attention on the United Kingdom, resulting in the situation today where trains and motor vehicles in Japan continue to 'drive on the left'. The 1964 Olympics in Tokyo prompted a surge in R&D in transport technologies, resulting in today's world famous network of 'bullet trains' (*shinkansen*) connecting the major population and industrial centres from the city of Fukuoka / Hakata (on the southern island of Kyushu) to Sendai in the north. For a fuller history of Japan's remarkable *shinkansen* network, see Hood (2006).

2.3 Enduring and emerging structures of Japan's pharmaceuticals industry

From 1945 and through the economic boom years of the 1960s the Japanese pharmaceuticals industry was focussed on creating and supplying domestic markets for its products and services. Until recent times, this domestic focus became embedded systematically to the exclusion of non-Japanese competitors (Roehl, 2014). In short, the primary market focus for Japanese pharmaceuticals manufacturers during their modern history has been on catering to the demands of domestic markets that, in turn, are distinguished by the systematic intervention of government and 'national economic' policies and regulations. However, these companies simultaneously record relatively modest sales volumes and profit levels when compared directly to global rivals (PWC, 2011; Roehl, 2014).

Given that the majority of shareholders and stakeholders in Japanese pharmaceuticals manufacturers are domestic, the institutionalised weight of business performance expectation tends to be expressed in a distinctively Japanese form of 'patient capital'. From a perspective of drug technological development, this 'patience' might appear to stifle innovation and instead encourage 'me-too' drug development for existing and pre-determined markets (Jackson and Debroux, 2009; Roehl, 2014; Jackson and Matsumoto, 2017). A further factor here is the influence that medical practitioners (doctors) in Japan have over identifying and interpreting market demand (see **Box #10**, page 51). To this day, this institutionalised distribution network continues to form a potentially high barrier to market entry for non-Japanese outsiders.

According to Sugiyama (2002), during the industrial and economic 'boom' years of the 1980s to the 1990s Japanese companies tended to view mergers and acquisitions (M&As) with / of other Japanese companies as a strategic opportunity to improve their speed of technology development and innovation. Similar to family businesses faced by succession problems (Goydke, 2014), Japanese pharmaceutical companies that perceive a lack of 'in-house' capabilities look for and / or seek to incorporate 'new blood' through the merger or acquisition of familiar yet relevantly differentiated assets. Consequently, companies that are newly formed through processes of domestic tend to proceed and emerge in a form that is recognizable to the domestic markets they are targeting (Herbes, 2014): in other words, the financial, reputational and other resource-heavy risks generated inherently by M&A activities are perceived as manageable (Matsumoto, 2014). For this reason, many large-scale M&A activities in Japan tend to be concentrated in technology-based and research-intensive industries and sectors: for example, the 2005 merger between Daiichi and Sankyo in the pharmaceuticals industry (Jackson and Matsumoto, 2017).

As illustrated in subsequent sections of this Report, the geographical, cultural and technological proximity of companies operating in certain industries and sectors has encouraged new 'cross-over' entrants to domestic markets for health care products and services from other manufacturing sectors: for example, Kirin (beer fermentation) and Asaha Kasei from chemical processing (Roehl, 2014).

In Japan as elsewhere in the world of business, news of an impending merger or acquisition can positively boost share price and / or investor sentiment, and particularly if a newly formed company is perceived to bring as a stronger degree of market credibility and sustainability of performance: for example, where the M&A outcome offers a company fuller strategic control over R&D pipelines and / or distribution and sales networks within Japanese markets (Khojasteh and Abdi, 2016). This traditional and (by global comparison) markedly incremental approach to M&A investments in domestic markets for pharmaceuticals manufacturing in Japan extends to overseas markets for such activities: for example, the international joint venture (IJV) negotiated between Takeda Chemical and Abbot Laboratories in 2008.

Conversely, the few (to date) examples of inward FDI to Japan in the form of M&A activities indicate similar patterns of flow: for example, in 2014 Roche of Switzerland added to a previously established investment in order to gain a controlling stake in Japan's Chugai, thereby making positive headlines in Japan and in Europe as one of the smoothest and most enduringly successful cross-border acquisitions (Herbes, 2014). Japan-specific research by Pucik (2008) emphasises how the Roche-Chugai acquisition remains a relatively rare example of cross-border acquisition success in large part because each side shared a sense of urgency in creating and communicating a shared vision.

Overall, distinctive features of management and corporate communication in Japan might be perceived as posing another potential and high barrier to European SMEs seeking to enter Japanese markets for pharmaceutical products and services. In a concluding Section of this Report we offer practical recommendations towards how SMEs in Europe might - in practical terms – overcome these barriers.

2.4 Roles of SMEs

As in Europe, small- and medium-sized enterprises (SMEs) in Japan play a vital role in provided economic development, innovation, and employment: re-invoking **Figure #1** (page 12), we can recognise business opportunities for SMEs with the capacity to bring specific knowledge, skills, technologies and other sources of 'value added' to an industry's development. As discussed subsequently in this Report, such opportunities might derive from specialist 'value-adding' activities such as R&D or marketing (promotion, distribution, and so on). SMEs might idedntify opportunities in from providing services relevant to linking effectively between core elements of the value chain: for example, advising Japanese companies about the regulatory environment for pharmaceuticals development in the EU in relation to activities such as arranging or conducting clinical trials of new drugs.

According to Japan's *Ministry of Economy, Trade and Industry* (METI), SMEs in Japan account for 99.7 % of all registered companies and employ 70% of the national workforce. Recent government statistics recognise how SMEs add 50% of all value to manufacturing sectors and remain prominent as independent entities in sectors such as wholesale, retail and construction (METI, 2015). In terms of size, Japanese SMES in manufacturing tend to employ up to 300 people; those in the retail sector up to 50 people[6]. Companies registered with fewer employees in each sector tend to be categorized as 'micro-enterprises' (METI, 2015).

As in many EU countries, Japanese SMEs are commonly under family ownership, and as is the case with family-owned businesses generally in Asia and in Europe, key strategic concerns include the longevity of the company: in other words, a key and constant strategic challenge is the smooth transfer of the business to future generations though processes of business succession. However, and unlike family business in other East Asian cultures, family businesses in Japan are open to succession to non-family members, if the survival and sustainability of the business is perceived as being better served in this way (Lituchy, 2002; Jackson and Tomioka, 2014). Correspondingly, SMEs and family businesses in Japan are accustomed to using domestic and usually region-specific M&As to overcome challenges to business succession (Goydke, 2016).

As with larger companies in Japan, SMEs and their owners tend emphasize the company as a 'community of stakeholders' including owners, family members, supplies and (above all, perhaps) existing customers (Miyajima, 2007). A decision by owners of Japanese SME to 'sell' this community to another non-Japanese company might be interpreted by community insiders as representing not only a business or 'entrepreneurial failure', but also a failure of 'Japanese-ness' (Nakamura, 2002; Bestor, Bestor and Yamagata, 2013; Sugimoto, 2014).

Generally speaking, when undertaking to compare the strategic roles and influences of SMEs across business sectors and / or nationally defined industries and markets it is common in academic and business research to start from an assumption that SMEs operate from a weaker resource-base than larger or more connected companies (Barney, 1991; Griffy-Brown and Chun, 2007). Correspondingly, empirical research by Storz (2006) suggests how SMEs across business sectors in Japan continue to be perceived as 'weak players' (*jakusha*)– a perception that leads to the reality that many SMEs operating in the Japanese pharmaceuticals industry become almost by default subject to alliance and supplier / distribution demands determined by more established companies (Taplin, 2006). Correspondingly, the extent to which managers of Japanese SMEs can continue to maintain control of key strategic

[6] As readers of this Report are probably aware, definitions of 'small- and medium-sized enterprises' (SMEs) various across regionally and nationally defined political economies. For example, SMEs in Europe are generally considered to employ 250 people or fewer; SMEs in the USA and Japan tend to be defined slightly differently (OECD, 2005). For example, SMEs in Japan can number up to 300 employees in manufacturing, one hundred or fewer in services, and 50 or fewer in retail (METI, 2013). Apart from 'total number of employees', other defining variables include relative value of wholly owned assets ('stated capital') and ownership profile relevant to calculations of corporation tax on sales and / or profits.

resources such as patents and other IP assets is assumed to rely on the extent to which each SME could align itself to the strategic expectations of larger companies in Japan: alternatively, SME owners and managers need to position their company as a trusted recipient of support or subsidy from national and regional governments. On this basis, Storz draws series of international comparisons of SME business performance before concluding: "The realization that American SMEs created highly innovative goods and new employment opportunities and that Japan did not have this form of young, dynamic risk ventures [has been] a shock for the political class in Japan" (Storz, 2006:88).

To conclude this brief industry-specific discussion, it is worth pointing out that SMEs in the Japanese pharmaceuticals industry continue to be targeted by a series of government-sponsored initiatives, often impressively funded. One recent attempt is a 2013 'Revitalisation Plan' that envisages 'structural reform' with the purpose of 'revitalising industries'. One telling target formulated under this initiative admits the need to 'establish a system which enables challenges to frontiers being free from anxiety': inspirationally, the initiative also targets SME involvement towards Japan becoming 'the world's leading IT society' (METI, 2013). As discussed by Jackson and Debroux (2009), various national and regional government initiatives in Japan over previous years have included: extensive and prolonged investments in centres of research and innovation and in the SMEs electing to network with them; direction of financial and human resources towards the laboratories of universities that SMEs commonly appeal to for R&D support. However, despite such initiatives there is still no strategically effective or visibly influential 'Silicon Valley' cluster-equivalent in Japan.

As suggested in a concluding section of this Report, the policy-driven drive to digitalise drug development - for example, compound modelling - along with the strategic integration of information technology (IT) and artificial intelligence (AI) systematically into processes of new drug development, production innovation and pharmaceutical marketing and distribution offers business opportunities for EU-based SMEs already expert in these fields.

Box #1: Patterns of development in the Japanese pharmaceuticals industry: antibiotics

Drawing on research by Hara (2003, 2007) along with Howells and Neary (1995) and Thomas (2001), it is possible to gain an overview of distinctive and enduring features in the structure and patterned development of the Japanese pharmaceuticals industry. For, according to Hara (2008:16): "Technological change is not a random phenomenon. In any field of practice, we can identify several persistent patterns with a specific direction of technological change, which last for a certain period of time". Further echoing Hara (2008), it is possible to do this in a vivid manner by focussing on the development of antibiotics in Japan: for example, (in terms of domestic market sales) 'blockbuster' drugs such as Pansporin® and Takesulin®, for which Japanese pharmaceutical giant Takeda gained approval in 1980, along with market rivals Flumarin® (by Shionogi) and Cefzon® (by Fujisawa), for which the Japanese regulatory authorities granted approval in 1988 and 1991 respectively.

These four antibiotic treatments find their pharmaceutical origin in 1943, when the Japanese military first became aware of penicillin. In pursuit of their own production, the Japanese government immediately set up a Penicillin Committee, bringing together senior figures and experts from fields of medicine, pharmacology, agricultural science, biology and chemistry along

with senior military officers with practical insights into the wounds and infections commonly affecting military personnel in Southeast Asian theatres of conflict (Howells and Neary, 1995; Hara, 2003). By 1945 around 80 Japanese companies were manufacturing large amounts of penicillin-based products.

Building on traditional knowledge, skills and technologies linked to fermentation and chemical processing across a range of sectors (See **Box #8,** page 33), among these companies were food makers, liquor makers, textile makers and chemical processers (Hara, 2008). The mass production led to a loss of profitability in markets for antibiotics, meaning that as few as 13 branded companies were involved by the 1970s. However, the 'intellectual resources' that participants had created during the rise and decline of this particular market became quickly transferred and strategically assimilated across a range of antibiotics development and manufacture along with development in other product niches (Hara, 2008).

In terms of the emerging structure of the Japanese pharmaceutical industry, a number of patterns are apparent in the development of penicillin manufacturing. The first is the impact of government intervention and definition of market need: the setting up of the Penicillin Committee in 1943. A second feature is the role and influence of highly positioned individuals in Japanese society. To illustrate, Hara (2008:22) explains how two senior members of the Committee went on to influence the development of antibiotics manufacturing in Japan. One was Hamao-sensei[7], then a Professor at the University of Tokyo – still Japan's leading academic institution - and subsequently Director of Antibiotics at Japan's National Institute of Health. His discovery of the drug kanamycin became commercialised by the company Meiji-Seika and was marketed worldwide – albeit, to limited success. A second leading figure was Hosoya-sensei, also a former member of the Penicillin Committee and a researcher at the University of Tokyo, whose drug trichomyin was launched in 1952 by the company Fujisawa, initially as an antifungal treatment.

A third distinctive feature of drug development and commercialisation in Japanese markets is the central role taken by domestic manufacturers, and largely to the systematic exclusion of non-Japanese rivals. As illustrated elsewhere in this Report, regulatory agencies such as the Ministry for Health, Welfare and Labour (MHWL) are instrumental in maintaining this situation in accordance with the international trade and competition policies implemented by successive Japanese governments.

Japanese markets for pharmaceutical products and services were made more open to non-Japanese players during the 1990s – one reason being to bring new and more innovative technologies and more specific sources of knowledge into an otherwise stagnating economy (Thomas, 2001). However, the legacy of the patterned development of the Japanese pharmaceuticals industry as illustrated by the example of antibiotics continues to hinder the entry of non-domestic manufacturers to this day.

[7] In Japan's still hierarchical society, senior experts such as medical doctors and university professors tend be addressed in speaking and in writing with the honorific title 'sensei' (teacher) after their surname. This custom is applied to both males and females and whether the addressee is physically present or not.

3 The pharmaceuticals industry in Japan: strategic business environment

This section of the Report highlights key strategic factors that serve and continue to define Japanese markets for pharmaceutical products and services, giving particular attention to barriers (real and / or perceived) that EU-based SMEs might encounter when attempting to enter and / or develop positions in markets for pharmaceutical products and services in Japan. Particular attention is given to negotiating the regulatory environments governing the production, distribution and sale of such products and services in Japan. Specifically, the discussion in this section of the Report is designed to answer the following question:

- How open are Japanese markets for pharmaceutical products and services to non-Japanese companies, and especially to SMEs from Europe?

3.1 Environmental scanning

Readers of this Report are probably familiar with frameworks commonly used for the identification and analysis of factors that appear to define and distinguish the structure of national markets for business: a process referred to strategically as 'environmental scanning'. Familiar frameworks include STEP and PEST, where the target strategic business environments described in relation to the 'Social-cultural', 'Technological', 'Economic' and 'Political' factors. These factors are identified singly, and then analysed in terms of their assessed current status combined with observations of their ongoing interaction. To illustrate, techniques of targeted environmental scanning can serve towards identifying possible barriers to market entry for new products and services – as described, for example, in Box #1 of this Report. The analysis is conducted diagnostically (cross-sectionally) during a limited period of time. For further reliability, the analysis can be conducted longitudinally (iteratively) in order to give a more reliable basis for predictions of emerging business or market trends.

Of specific relevance when identifying factors and analysing business trends and opportunities in Japanese markets is an extended version of the STEP/PEST framework: namely, STEEPLED. Here, factors related to 'Ecological' (geographical, climactic, and so), Legal', 'Ethical' and not least 'Demographic' developments within a target market are brought - singly and in combination - into the strategic analytical mix.

As stated in Section 1, the overarching purpose of this Report is to inform managers in EU-based SMEs that are seeking to develop or extend positions in Japanese markets for pharmaceutical products and services. Consistent with this purpose, there follows now an overview identifying prominent and Japan-specific STEEPLED factors that might appear – initially, at least – as barriers to SMEs currently formulating and pursuing such strategic intents. For reasons alluded to earlier in this Report, we begin our identification with reference to 'D' (demographic) factors.

3.2 Demographic factors

In general terms, 'demographics' describes a systematic and scientific approach towards generating (usually) quantitative data in order to characterise and compare populations across national, regional and other socially-defined contexts in relation to variable measures of age, gender, ethnicity, socio-economic status, educational background, employment experiences, and so on. (Jackson and Debroux, 2016:6). As highlighted in the Introduction to this Report, by international comparison Japan can be characterised as a markedly and rapidly ageing society Japan. As highlighted in **Box #1** (page 19), this trend impacts on the general public health of the national population and, as a corollary, on observed incidences of disease. Invoking the 'value chain' model presented as Figure #1, current and emerging demographic trends in Japan suggest opportunities for companies with the capacity to predict and / or cater for market demand for a number of pharmaceutical products, medical devices and related services, including vitamins and food supplements, products to enhance physical mobility, care home facilities.

As discussed by Jackson and Debroux (2016), current demographic trends in Japan impact on employment across a range of business sectors, including in the pharmaceuticals industry and related sectors such as health care. A related factor here is the on-going reluctance of successive Japanese governments to allow anything resembling high volume immigration: the number of legally resident non-Japanese people in Japan remains fairly constant at around 1.5% of the total population. Even professionally educated and / or technically qualified employees are few in number when compared to nations competing strongly in global pharmaceuticals markets such as the USA, Germany and Switzerland. Japan has never seen the type of 'talent attraction' policies pursued until recently by governments in Singapore. There is evidence of some movement in relation to the current 'trainee visa' scheme – a legal ('L') factor when using STEEPLED analysis. This might result in more care workers arriving from countries such as The Philippines, Indonesia and Vietnam.

Of more immediate interest to EU-based SMEs might be the growing concentration of investments in new technologies such as robotics and artificial intelligence (AI). One outcome is a new generation of service avatars – a technological ('T') factor that indicates patterns of product and service innovation and development that, in combination, might enable Japan to manage public health demands generally and the health needs and expectations of its elderly residents specifically.

3.3 Ethical factors

Developing an international business perspective, Kline defines 'ethics' as:

- 'The identification, assessment and selection of values to be used as standards for judgement and guidelines for action. Values lie at the heart of all decisions, providing the normative basis for choosing among alternative conclusions and courses of action' (Kline, 2005:2).

In Japan, medical doctors subscribe (in principle) to what is commonly referred to as the Hippocratic Oath: essentially, that a doctor should take all professional and practical steps to avoid 'doing harm' to patients in their care. Specifically, the Japan Medical Association (JMA) states that the "mission" of medical science and health care is to "cure diseases" and "to maintain and promote the health of the people", expecting that medical practitioners (physicians) "should serve society with a basic love for humanity" (JMA, 2018). The pivotal and vital roles that medical doctors (MDs) play towards structuring the pharmaceuticals industry and driving its associated markets in Japan are illustrated subsequently in this Report. For now, it is worth noting that reference to 'ethics' in Japan as elsewhere in the world expresses a socially-culturally constructed argument leading to actions that social actors (such as companies) might take and / or the responses they might make to the action of other social actors. Generally speaking, where these actions and responses become a subject of dispute, there commonly ensues some invocation of law – the 'L' factor in STEEPLED analysis.

3.4 Legal factors

As a non-legal expert attempting to gain some initial insights into how legal factors describing one context for business might be similar or different to those describing others, it is useful to adopt a systems view in order to make the inevitable complexities of legal detail appear more accessible and negotiable. To illustrate, we can begin with an appreciation of 'Japan' as a nationally, politically and (as we later emphasise) geographically defined and distinct business system. According to Redding (2009) adopting a business systems perspective entails regarding the Japanese economy as "a process affected by the logics of economic behaviour, but also by culture, history, and specific societal events and experiences" and, as a distinct business system, recognising how Japan and its economy are "affected by external influences such as world markets, technology and changes of values" (Redding, 2009:10).

Redding's invocation of 'values' serves to connect the 'legal' factors discussed here with the 'ethical' factors discussed above and the 'social-cultural factors' to be discussed subsequently in this brief STEEPLED analysis. For now, we can connect with Redding's invocation of 'history' as one contributing influence to the current state of Japan's legal system, recognising that the tradition of legal thinking and practice draws in large part from (Chinese) Confucian traditions of rote learning and public service towards selecting and training experts (*sensei*) whose

primary civic and moral duty would be to promote stability and continuity to society. Once this tradition had been established, Japanese society became a system essentially 'closed' to outside influences between the 17th and 19th centuries and the advent of the aforementioned Meiji Restoration.

Echoing earlier discussion in this Report outlining the development of the pharmaceutical industry in Japan, traditions associated with the legal systems of Germany continue to play a salient role in Japanese law and in professional training for commercial and business legal practice. During the military occupation of Japan by American forces after 1945, there was a major restructuring of legal, business and education systems in Japan: however, core elements of tradition were preserved, such as the symbolic role of the Emperor (Shaffer et. al, 2012; Hahn, 1984).

More recently, it is relevant to recognise how legal factors governing developments in the Japanese pharmaceuticals industry appear to be converging incrementally towards global standards of legal interpretation and practice – unsurprisingly, perhaps given the increasingly global scope of pharmaceuticals companies themselves. One recent example in Japan is the (2014) *Law for Partial Revision of the Pharmaceutical Affair*. The official reasoning behind this law was to further ensure "the safe and swift provision of pharmaceuticals, medical devices, etc" (MHWL, 2014). The emphasis is on safety; or, rather, on the avoidance of outcomes that might be challenged legally: for example, as lawsuits seeking damages. These include patient accident or injury from using faulty or poorly designed medical devices and poisoning or infection from using certain combinations of pharmaceutical products. The 2014 *Partial Revision* law does further work to define more precisely boundaries around and between business and product sectors: for example, in relation what is / are classified as foods, beverages and cosmetics. Consequences of this move towards clearer precision and differentiation include corresponding clarity with regard to packaging and labelling – a source of potential concern and (for producers and traders) extra cost in a society that places such emphasis on appearances, not least in respect of how goods – including ceremonial presents, retail goods, and even holiday souvenirs – are wrapped prior to purchase and / or presentation[8].

A major contribution of the 2014 law was an attempt to define "regenerative medical products" separately from 'pharmaceutical products' and 'medical devices'. Echoing a global ethical debate, 'regenerative medical products' are defined in the 2014 law as "processed (e.g., cultured) human cells that are used for the purpose of (1) reconstruction, repair or formation of human body structure or function or (2) treatment or prevention of disease" [or] "those [products] that are used by introducing into human cells for the purpose of gene therapy" (MHWL, 2014).

[8] Visitors to Japan soon recognise a major deficit in all regions (though less so in Tokyo) of reliable translations from signs and other public information sources from Japanese into (for example) English. Given the emphasis on safety through increased transparency of sector- and product-specific information required by the 2014 'Partial Reform' and subsequent laws and regulations seeking global convergence, this deficit in foreign language competency is likely to be exacerbated. Correspondingly, lawyers licensed to work in Japan through the medium of languages other than Japanese remain at a premium.

As illustrated subsequently in this Report in the form of a company (SME) case study from the fertility treatment sector, the legal environment for the development of new drugs, treatments and procedures remains at a surface level perhaps familiar and – in specific legal terms – predictable to expert practitioners in international business. However, the underlying historical, ethical and social-cultural factors that give shape to the business systems of Japan might surprise even these practitioners, as especially when seeking to enter Japanese markets for pharmaceuticals products and services[9].

Box #2: The patenting system in Japan

According to Hara (2008), Japan's patent system in the fields of chemical processing and drug development had operated under a process patent regime. This allowed Japanese pharmaceuticals manufacturers to "produce copy drugs if they found different production processes" (2008:29). Hara goes on to cite the example of Takeda's production and subsequent sale of their cephalexin antibiotic using technology and knowledge first developed by Eli Lilly (USA) and Glaxo (UK). In 1976 Japan adopted a more internationally standard product patent regime. This allowed producers in Japan an (on average) 15-year window of exclusive rights from publication of the patent and with the legal condition that the application period did not exceed 20 years (Howells and Neary, 1995). Noting the industry-wide expectation that investments in R&D and new drug development tend to be highly resource intensive, Hara (2008) suggests that Japanese pharmaceutical companies were attracted to invest in antibiotics because these drugs tended to require a relatively short development period because the specific legal and general social environments - including intertwined networks of market competitors, regulatory agencies and medical doctors – were accustomed to working with these types of drugs.

3.5 Political factors

In October 2017, the sitting Prime Minister of Japan, Shinzo Abe, led his Liberal Democrat Party (LDP) to a sweeping electoral victory. This was Prime Minister Abe's fifth career election victory. If Mr Abe remains in office for another four years he will become Japan's longest-serving Prime Minster since the end of the Pacific War in 1945. Given the enduring weakness of party political opposition, the LDP can be expected to further accelerate and consolidate the reforms they announced during their ascent to government in December 2012; namely, the so-called 'three arrows' policy of i) monetary easing by means of polices and practices emanating from the Bank of Japan (BOJ) designed to keep short-term interests low; ii) longer-term government investments in infrastructure and tax breaks

[9] Two illustrations of direct relevance to this discussion and that might or might not be familiar to readers of this Report: Japanese people who have lived or worked in Europe in countries where there have been recorded incidences of Creutzfeldt-Jakob disease - a fatal brain disorder, initially thought to occur after people ingested infected meat - are routinely prevented from donating blood in Japan; a human embryo in Japan is usually not considered an entity with rights: the right to life begins at the moment of birth. In the context of this current discussion, it would be a mistake to explain this convention to 'culture'. In countries such as Korea and Thailand, where business, management and legal practices are equally influenced by traditional Confucian values, children when born are considered to be already 'one year' old and thus social entities with rights.

for selected corporations; iii) encouraging corporate and market structural reforms such as promoting employment opportunities for women in Japan. In combination, these government policy 'arrows' should serve to help mitigate demographic pressures on employment – including an ageing population (the majority of whom appear routinely to vote LDP), a falling birth rate, and falling productivity in some formerly strong business sectors such as manufacturing in consumer electronics (Jackson, 2017).

As evinced across EU governments, reforms tend to come in policy waves in Japan. Unlike their counterparts in Europe, government reforms in Japan tend to originate in a mix of government, corporate and other nationally embedded institutional interests (Lechevalier, 2014; Jackson 2016; Jackson, 2016). To illustrate, Kingston (2013) notes how the care home sector in Japan has become especially effective at lobbying LDP politicians, probably because their constituents tend to be found among the growing population of elderly people and their families.

However, major government-led reforms should interest readers of this Report. For example, Roehl (2014) highlights a series of reforms around the mid-1970s that impacted significantly on established structures and strategic management practices across the Japanese pharmaceutical industry. These included a change in the laws governing intellectual property (**IP**); a concerted attempt to combine with domestic pharmaceutical manufacturers and health insurers to control the rising costs of health care (see Section below); and a relaxing of the restrictions to foreign companies setting up and operating independently in Japan. Firstly, changes to the laws governing IP signalled a step towards harmonizing with IP regulations and patenting standards already established among leading western economies. Previously, Japanese pharmaceuticals manufacturers had benefited from opportunities legally to produce drugs that already existed – in Japan or elsewhere – by applying different production processes, thereby challenging the authority of existing patents in Japan and overseas. The extent to which European SMEs might benefit from this change in strategic focus is discussed in more detail subsequently in this Report.

Another key government-led reform from the mid-1970s was the political pressure put on Japanese drug manufacturers to control costs and, by extension, reduce the price of drugs where existing price structures (see **Box #3**, page 28) could no longer be justified if and where similarly efficacious drugs and treatments such as 'generics' were available to consumers (and their doctors) on the Japanese market. In short, the Japanese government chose to intervene in the domestic market for health care, thereby impacting on the profits expected by drug manufacturers and their shareholders. As illustrated in **Boxes #3** and **#9** (pages 28 and 49, respectively), this government-initiated intervention is illustrative of a strategic and public policy mind-set whereby the retail price of a drugs or treatments can be determined only to a limited extent by the cost of its production and development; rather, the market price of a pharmaceutical product should be determined over its life-cycle by its relative efficacy. According to Roehl (2014), this thinking contrast starkly with market mechanisms in the USA, where drugs can be sold and prescribed at high levels of profit for as long as the patient lives.

A third government-led reform highlighted by Roehl (2014) involves the 'opening up' of Japanese markets to non-Japanese companies. This involved ground-breaking moves to allow foreign companies to move funds – and profits – freely across national borders. The aforementioned changes to IP protection allowed foreign companies protection to promote and sell their patented products independently in the Japanese market and without (for example) needing to license profit-seeking products to Japanese partners. This move also encouraged new competitors from within Japan to markets for health care products and services: for example, and as mentioned in the Introduction to the Report, Kirin (from beer fermentation) and Asaha Kasei (from chemical processing).

American Merck was early mover into the Japanese pharmaceutical industry when buying a substantial share in Japan's Banyu; as will be discussed in the Webinar accompanying this Report, Germany's Bayer was an early mover towards establishing a firm and respected position in the Japanese pharmaceutical industry. Nonetheless, Japan has adopted and persistently pursued a 'protectionist' trade policy after from 1945 onwards (Hara, 2008). Specific to the pharmaceuticals industry, capital transactions in and out of Japan were heavily restricted until 1967, while it was only from 1975 onwards that non-Japanese pharmaceuticals manufacturers could trade in without a Japanese partner in domestic markets. Despite recently heralded changes in the direction of international trade policy, the expectation among Japanese companies today remains that the non-Japanese companies own the IPR of new compounds while Japanese companies receive licenses to trial and sell them in Japan (Hara, 2007).

As detailed subsequently in this Report, the strategic logic supporting this mind-set remains compelling: Japanese companies are embedded in and have systematic access to the networks that drive markets for drug consumption: for example, the networks of medical doctors, university hospitals and 'drug store' chains where medicines and treatments can be dispensed (See **Appendix B**). Secondly, being involved in the distribution and sale of 'western' products keeps Japanese companies busy and their employees in value-adding work. Thirdly, receiving western drugs under license and analysing or 'reverse-engineering' them adds value to the R&D activities of Japanese pharmaceuticals manufacturers (Hara, 2008).

Box #3: National health insurance systems in Japan

In 1961 - the beginning of a period when Japan's population and economy was set to 'boom'- a Nationwide Comprehensive Health Insurance System, was established: as a consequence, the pharmaceuticals industry in Japan 'boomed' also. Whether in private practice or in private, national or regionally administered hospitals and clinics, doctors receive patients and prescribe treatments within a national health insurance system. All Japanese citizens and residents must pay into some form of health insurance scheme. Currently, approximately one third of Japan's population (around 127 million people) is registered onto a National Health Insurance scheme, one third onto a scheme administered by the Japan Health Insurance Association (a privately owned consortium), and another third onto schemes administered by company-specific employee unions – so-called 'enterprise

unions' (Hagiwara, 2014). Under these various schemes, the aforementioned demographic profile of Japan's increasingly ageing population becomes a key factor. To illustrate: in 1973, the government introduced free medical services for the elderly. As resulted, elderly people visited local clinics more often and – given the boom in the manufacture of antibiotics – these were often prescribed as treatments "even for a cold or flu" (Hara, 2008:28 – see **Box #1**, page 20).

Under the government-sponsored National Health Insurance System, patients with insurance cover (each resident carries a health insurance ID card) pay for treatment and medications through a 'co-payment' scheme - a lump-sum payment that usually flows directly to the prescriber of the medication or treatment: the doctor. The levels of required co-payment are set by the government, advised, for example, by the Ministry of Health, Labour and Welfare (MHLW) along with representatives of the pharmaceuticals manufacturers. People in Japan aged between the start of compulsory school age (six years old) until age 69 pay a 30% contribution to the total cost of most drugs they receive on doctor's prescription. People aged 70 to 74 pay 20%, unless they have an income comparable to an employee with an average salary, in which case they also pay 30%. As an indication of current government thinking with regard to funding health care and negotiating the looming 'time bomb' of caring for an increasingly aged population, the co-payment for this later age cohort has been 'frozen' at 10% from April 2018 (MHLW, 2018). Other factors at play here include the balance of employer contributions to each employee's health insurance cover - which can vary greatly: for example, depending upon whether the employee is working for a public or private sector organisation or company, and whether their employment contract is with a larger or smaller company (Druse, 2013) and shifts in the statutory retirement age in Japan from 62 (currently) to 65 in the year 2025 (Debroux, 2016; Sueki, 2016).

In some respects, therefore, the structure of health insurance in relation to generational needs might appear familiar to European audiences in that it appears oriented towards offering a freely accessible and all-inclusive system of public health and welfare services rather than run as a business, where those who cannot afford insurance cover might – under normal circumstances- receive no health care, as appears to be the case (for example) in the USA. However, one distinctive feature of the Japanese system the relatively low per capita investment in health care provision in Japan when compared (for example) to levels of investment commonly seen in established welfare states such as Germany and Sweden.

Despite the growing costs of medical care that might be expected in a rapidly ageing society, "Japan spends less than half per capita of what the United Sates does on health care" (Kingston, 2014: 192). Furthermore, the elderly in Japan tend to be on average far healthier into advanced age than their American counterparts (see **Box #4**, page 31). As a consequence, companies competing in the pharmaceuticals industry in Japan can see opportunities for developing positions in business sectors such as pharmaceutical, cosmetic and medical device manufacturers along with (for example) health insurance providers to devise 'silver market' strategic to anticipate and cater for demand – opportunities that might become more open to EU-based companies also.

3.6 Ecological factors

Echoing Jackson and Matsumoto (2016), outside observers should first recognise Japan geographically as an archipelago of over seven thousand islands. The four most populated islands support a mountainous and forested terrain that offers few natural resources to support human society or economic activity. During the aforementioned Meiji Restoration, little attention was given to learning from the construction of canals seen during the early industrialisation of (notably) the UK and France, Japan continues to have a very limited number of navigable rivers or canals. Consequently, Japan can and should be defined as an ecological system by the mountains that divide it and, above all, the oceans that surround it and which, over time, have provided its people a major source of nutrition and, militarily, a defence against invasion (McKinstry, 2002).

What may not be immediately apparent to outside observers is that the geography of Japan supports considerable social and cultural diversity. For example, Sugimoto (2014) refers to describe Japan as 'a conglomerate of sub-nations' and thus a reflection of its geographical and climatic diversity, from the Scandinavian climate and cuisines of the northern islands such as Hokkaido compared to sub-tropical climate and lifestyles of Okinawa in the far south. Sugimoto (2014) observes how local cuisines vary: for example, from the saltier and heavier soy sauces used in 'Tokyoite' cooking compared to the lighter and less salty sauces commonly prepared in the Kansai region: for example, in Kyoto. Sugimoto finds evidence for correlation between regional variation, life expectancy – on average, highest among women in Okinawa – and vulnerability to patterns of disease: people in western Japan (Osaka, for example) are more likely to suffer and die from cancers while people in eastern Japan (Tokyo, for example) are more likely to suffer strokes (cerebral apoplexy), while this living in central Japan are more likely to suffer or die from heart attack or other forms of cardiac arrest (Sugimoto, 2014:70).

As detailed in a following Section of this Report, medical doctors are the ones inputting data into the statistics produced by Japan's Ministry for Health, Labour and Welfare (MHLW); consequently, they are the ones most likely to observe patterns of health and disease at the regional, prefectural and even community level of data collection and analysis. From the perspective of Japanese drugs manufacturers, therefore, doctors have immediate knowledge of local market demands. Accordingly, companies (for example, non-Japanese companies) without access to such local knowledge and experience might be prone to overgeneralise about the health and disease patterns impacting on a population of 127 million Japanese and thereby on the expectations that doctors across regions are willing to help distribute to local markets.

Box #4: Mortality, health and happiness in Japan

According to a recent Human Development Report (UN, 2016), average life expectancy among Japanese people has risen from 76.2 years (in 1980) to 83.6 years in 2013. Equivalent figures for Germany, France and Switzerland are 73, 74.1 and 75.7 years, improving to 80.7, 81.8 and 82.6 years respectively. It is unsurprising, therefore, that company managers and academic

researchers who until recently appeared excited by business opportunities purportedly generated by investing in processes of 'grey marketing' now talk eagerly in terms of 'silver' or even 'platinum marketing', and especially in reference to ageing societies such as Japan.

Until the 1950s the primary cause of death in Japan was tuberculosis (TB), with pneumonia as one of the main contributing causes. Investments in national infrastructure including sanitation (water supplies) and education drastically reduced infant mortality rates after 1945: today, Japan is the world's biggest donor of aid in relation to improving water supplies and sanitation technologies and infrastructure to developing economies (MOFA, 2005, 2017). The rapid production and widespread distribution of antibiotics (see **Box #1,** page 19) has been a major factor towards improving public health. Since 1985, the three leading causes of death in Japan are cancer, heart disease and cerebrovascular diseases (MHWL, 2015). Pneumonia remains a major threat to public health, and with a rapidly ageing population, diseases such as Alzheimer's and dementia present growing challenges across Japanese society.

In respect of now established global measures of 'happiness' or 'subjective well-being' (SWB), Japan each year ranks around 50 in the world, by global comparison, with Norway topping the ranking (Happiness Report, 2017). However, Japan scores very highly on measure such as feelings of (physical) security and social support or "having some one to count on in times of trouble" (Helliwell, Huang and Wang, 2017).

3.7 Economic factors

Japan remains by global comparison the fourth largest economy by measures of GDP and Japan's *per capita* output growth currently outstrips averages among the thirty-four member states of the Organization for Economic Cooperation and Development (OECD, 2017). Today, Japan remains second only to Mainland China among the EU's trading partners in Asia and the EU's sixth largest EU trading partner worldwide. Currently, the EU exports more than €80 Billion worth of goods and services to Japan annually (European Commission, 2017). Research by Jackson and Matsumoto (2016, 2017) demonstrates how flows of outward-bound FDI from Japan continue to target overseas or cross-border acquisitions – a trend that should interest SMEs in Europe both as potential targets for such strategic investments, and in respect of their role in EU-based companies that might be subject to M&A activities funded in from Japan.

To illustrate the scale of these activities, Jackson and Matsumoto (2017) assess that the total value of Japanese acquisitions in Europe reached €86 Billion in 2016, three times higher than the total value of domestic transactions within Japan. The total number of recorded cross-border acquisitions was 635 - a record high and representing an increase 13.4% increase from 2015 (*Nikkei*, 2015). Overall, the primary destination for Japan-sourced FDI has been Europe, where the total value of the acquisitions has been €46 billion - more than half the total volume of FDI sourced in Japan. During 2016, Japanese companies made 156 acquisitions in Europe, of which 41 were in the UK

and 26 in France (*Nikkei*, 2017). For example, Japan's Asahi Group Holdings have been investing €7.3 billion towards buying beer brands from American-Belgian conglomerate Anheuser-Busch InBev, including Czech brand *Pilsner Urquell*, Poland's *Tyskie* and *Lech*, Hungary's *Dreher*, and Romania's *Ursus*. When complete, this latest acquisition by *Asahi* will represent both the company's largest (to date) overseas investment and further add to its existing European portfolio that includes SABMiller's Italian brand *Peroni* and Dutch *Grolsch* (Reuters, 2016). The recent EPA discussions between the EU and Japan are likely to increase the range and scope of such investments.

By further global comparison Japan remains the third largest nationally-defined market for the sale of pharmaceutical products and services, trailing only to the United States of America (USA) and China (UNCTAD, 2017). As illustrated in this Report, companies that combine to form the Japanese pharmaceuticals industry continue to invest heavily in research and development, increasingly targeting new technologies and procedures in pharmaceutical manufacturing and, by extension, in related sectors such as 'biopharma' and 'biotech' (Jackson and Debroux, 2009). As mentioned previously in this Report, Japanese pharmaceuticals manufacturers have an historically established tendency to license and otherwise 'borrow' pharmaceutical products from European rivals that – because of their relative specificity and scarcity - appear profitable for distribution and sale in Japan. As discussed later in this Report, institutional factors distinctive for Japan currently act as barriers to the mass import of related pharmaceutical services. One outcome of this institutionalised 'embeddedness' is that strategic thinking and decision-making in Japanese pharmaceuticals manufacturers continues to express established and, indeed, institutionalised propensities towards doing things in 'the Japanese way' (Boyer, 2014; Lechevalier, 2014; Jackson, 2016; Jackson and Matsumoto, 2017).

On the specific point of institutions, the Bank of Japan (BOJ, founded in 1882) plays a pivotal role in Japan's economic system in that it serves to formulate and implement government policy: for example, supporting and assessing the impact of the aforementioned 'Abenomics'. The BOJ routinely issues long-term bonds that finance such policies, a level of government borrowing that reaches around 200% of GDP. For now, the BOJ also guarantees the stability of the Japanese Yen (JPY) as a domestic currently and works to maintain the currency's status as a global reserve currency – an approach that appears sustainable as a result of the Japanese economy continues to function as a relatively 'closed' system and one that is predominantly domestic in policy orientation and – in systems terms – supports the creation of politically and ecologically / geographically defined markets for financial transactions (Matsumoto, 2014). In Japan, and by any global economic measure, money is currently 'cheap'. More broadly, the economic systems shaping their country of origin mean that Japanese companies with leading positions in domestic markets are cash rich and looking to invest overseas, and especially in Europe (Jackson and Matsumoto, 2017).

Consequently, one immediate option for EU-based SMEs to gain access to Japanese markets for pharmaceutical products and services would be to form a strategic alliance with a Japanese company seeking value added through mergers, acquisitions, joint ventures or other forms of strategic alliance in the EU.

Box #5: The pricing system for pharmaceutical products in Japan

The development of national health insurance system was outlined in **Box #4** (page 31), where (for example) attention was given to distinctive features of the system designed to prescribe drugs to patients. Here some insights are given into the regulatory system governing the prices at which drugs can be retailed in Japan – a system that (as discussed subsequently) continues to act as a major barrier to new market entrants.

Echoing Hara (2008), the retailing price of medicines and medical treatments in Japan has been determined by governments since 1950 with the introduction of the Nationwide Comprehensive Health Insurance System (see **Box #4**, page 31): the result is a series of nationwide regulated and rigorously enforced 'price lists' for the sale of pharmaceutical products in Japan. Government policies targeting free prescription medicines for the elderly – an important constituency in the ruling LDP party's electorate - have understandably had a huge impact of the nation's finances and (by corollary) remains a rich source of profits for Japan's pharmaceuticals manufacturers. During the 1970s, the MHLW has intervened occasionally to reduce list prices: however, in negotiation with the manufacturers, the drugs that are regulated to be sold less expensively are commonly those that were anyway reaching the end of their profit-generating life-cycle and - where strategically convenient - were set to be replaced by drugs that could prove more efficacy and thus a premium price (Hara, 2008). As a consequence, there continues to be a systematic and (for many treatments) substantial margin between the list price of a drug and its market price, an thus a distinctive opportunity for Japan's governments to regulate for and / or against new market entrants: for example, by blocking the attempts of on-line retailers such as Japan's Rakuten to market and sell pharmaceutical products in Japanese markets (Bloomberg, 2013). Legal wrangling around established regulatory structures continue, not least as the boundaries between 'medical' products and 'cosmetic treatments' or 'health supplements' become increasingly blurred.

One point of reasoning behind the current regulatory and price list system is that the margins allowed within domestic markets generate funds that can be invested reliably and over the necessary years in domestic R&D (Howells and Nealy, 1995). These margins simultaneously act as major incentives for doctors to prescribe certain drugs over others – a system of influence and distribution discussed in more detail subsequently in this Report. For now, doctors and pharmaceuticals manufacturers in Japan see little incentive to dismantle the current system, while their patients appear to have little appetite to see a system that appears currently to function (on its own systematic terms) effectively and predictably for an as yet untried, unfamiliar or 'imported' system (Kingston, 2014).

3.8 Technological factors

As mentioned previously in this Report, towards identifying, assessing and comparing factors that combine to form a distinct and nationally or regionally defined strategic business environment - in this case, a STEEPLED analysis applied to the pharmaceuticals industry in Japan - there is an opportunity to develop a systems approach. This approach is firmly established when describing and comparing systems of technological development or innovation: a so-called 'National Innovation Systems' (NIS) approach. Correspondingly, readers of this Report are referred back to **Figure #1** (page 12) when considering an authoritative definition of NIS proposed (1997) by the Organization for Economic Cooperation and Development (OECD):

"Technology-related analysis has traditionally focused on inputs (such as research expenditures) and outputs (such as patents). But the interactions among the actors involved in technology development are as important as investments in research and development. And they are key to translating the inputs into outputs. The study of ***national innovation systems*** directs attention to the linkages or web of interaction within the overall innovation system" (OECD, 1997:2 – ***our emphasis***).

Again invoking **Figure #1** (page 12) and further strategically relevant details of the 'Value Chain' model designed by Michael Porter (1985), it is relevant to identify 'technological development' as a 'support activity' and, by Porter's conceptualisation, as a key (internal) organisational source driving the strategic process of adding value from early to later stages of product and service development. Specific case studies of how this value chain can inform strategic decision-making by managers in SMEs seeking to enter and develop positions in Japanese markets are presented later in this Report. For now, highlighting examples of traditional *saké* brewing in Japan (see **Box #8**, page 42) and subsequently what became known worldwide as the 'Toyota Production System' (**TPS**) in automotive manufacturing can serve to illustrate how technological development acted as a value-adding investment for Japanese pharmaceutical manufacturers (Jackson and Debroux, 2009).

Readers of this Report are likely to be familiar with Japanese concepts such as *kaizen*, 'quality control circles' and 'Just in Time' inventory management (**JIT**). Echoing Abo (2014), *kaizen* can be interpreted as a philosophy or approach towards 'continuous improvement': it expresses an *a priori* recognition that any product or manufacturing process can be improved incrementally, generally with a focus on reducing flaws or wastages in the system that do not serve to add value to the overall production process. As highlighted previously in this Report, the business foundations of the modern Japanese pharmaceuticals industry can be found in approaches adopted by domestic manufacturers - several of them traditional *saké* brewers - towards identifying and improving *kaizen*-style on features of western-origin pharmaceutical products. The output of this investment became such that the products

brought to market were perceived as (in market value terms) sufficiently scarce and (in product quality terms) as sufficiently specific (for example, in terms of their efficacy) and thus in demand among growing populations of consumers. As discussed in more detail subsequently in this Report, key external sources that have (echoing Porter's value chain) 'supported' drugs manufacturers in their efforts towards technological and related product and service development in Japanese markets include influential stakeholder groups such as government ministries and medical doctors.

Re-focussing now on company-specific (internal) sources of incrementally added value, the workers who form what have become internationally known as 'quality control circles' under the aforementioned TPS, routinely apply *kaizen* approaches in order to create specific places and times across value-chain activities and together develop and share 'rational' approaches to problem identification and solving (Nakajo, 2014). With a focus on 'quality', in *saké* brewing these physical and contigual 'time / places' are traditionally called *ba* – physical spaces adjacent to production lines, where teams of workers communicate, suggest and work towards improving their contributions to the overall product-specific value-chain processes by assuming roles of apprentices and be dedicated to learning from each other and, over time, aspiring to the status of team leader: in *saké* production, *tōji* or 'Master Brewer'. Nonaka and Takeuchi (2004) apply this comparative approach towards describing and explaining the function of *ba* as locus for the project team working and quality creation processes that contributed to Toyota's innovative and (in the industry-specific context) remarkably efficient research, technological development, product engineering and bringing to market of the original hybrid-motored passenger vehicle, Toyota's *Prius*.

Because of the input of ingredients and fermentation processes necessary to produce several common varieties of *saké,* the retail shelf-life of these products can be severally limited: for example, two weeks before the quality of the wine deteriorates to the extent that it becomes undrinkable. Extending this output of the value creation strategically beyond the boundaries of the brewing company itself and into its distribution networks, it is common to include retailers and large customers of the product into the logistics stages the value chain: for example, assuming a mutually beneficial understanding of 'JIT' inventory management, seeking the advice and expressions of demand among groups of external stakeholders into account during the 'inbound logistics' stage of the value chain depicted by Porter (1985). As illustrated earlier in this discussion in relation to 'demographic factors' shaping the strategic business environment for pharmaceutical products and services in Japan, medical doctors in both urban and rural areas play a vital role here – a network of mutually recognised and negotiated interests that already now can appear as a potential barrier to market entry for European SMEs attempting to enter and develop positions in Japanese markets.

Box #6: Consumer behaviour and the 'Country of Origin' effect in Japan

Consumer behaviour can be defined as the systematic study of how individuals, groups and organisations perceive, recognize, select, buy, use and dispose of goods, services, ideas, or experiences to satisfy their needs and wants (Kotler and Keller, 2006). Echoing Kotler et. al. (2008), when companies can elicit how consumers perceive and differentiate between products and services an then observing their buying behaviours, they might subsequently be able to describe, explain and (ideally, in strategic terms) predict how consumers – individually and collectively – might behave. Studying consumer behaviour specific to certain markets or sectors helps companies make decisions about how, where and when to improve or attempt to substitute an existing product or service: in the case of pharmaceuticals products and services, making them appear more specific and timely in the perception and experience of consumers. Accordingly, companies seeking to develop existing positions in Japanese markets, or bring new and / or differentiated products and services to them, can study consumer behaviour in the pharmaceuticals sectors in Japan and make decisions about introducing new or differentiated products or services, about promoting and / or distributing them, setting prices – taking into account the regulated listings (see **Box #5**, page 36) – investing in and developing other strategic marketing activities.

Jackson and Tomioka (2004) made a longitudinal study of attempts made by Japan's Fast Retailing Corp. Ltd., who at first struggled to sell their brand UNIQLO ('unique' – 'clothing') in Japan: in the early years, the brand appeared to have more success penetrating European markets such as London in the UK. The initial problem was one of consumer perception: the clothes were made in Mainland China, following a business model developed in Hong Kong's fashion retail market. Consequently, the 'Country of Origin' (CoO) perception among Japanese consumers was initially that he clothes would of poor quality and rough in terms of finish and texture. According to Jackson and Tomioka (2004:217), the UNIQLO brand was targeted primarily at the lower- to mid-price sensitive 'middle class' – which in Japanese social perception at the time meant everybody who was neither 'super-rich' nor 'poor'. Anticipating some resistance among Japanese consumers to buy and wear lower-cost yet high quality casual clothing in Japan, the company appealed -in an explicitly modest promotional style - to their target consumers' sense of individualism. This (at the time) striking appeal in retrospect can be said to illustrate how forward-thinking and perception of emerging social and cultural trends that managers and marketers at Fast Retailing have been. This once underlying trend towards diversity is becoming more apparent across domains for social interaction, be these found in the workplace, in the family, and / or in contexts for expressions of consumer behaviour (Sugimoto, 2014; Bestor, Bestor and Yamagata, 2013; Assmann, 2014). Consequently, one of the UNIQLO brand's breakthrough slogans was: "Our clothes are not branded on the outside, because we want to promote yours sense of style, not our brand name".

As recommended in a concluding section to this Report, for historical reasons EU-based SMEs competing in sectors related to health care can learn from the experiences of other sectors entering Japanese markets. As a general rule, European SMEs manufacturing in technology-based sectors can assume to start from the advantage of positive perception, and especially when assuming that the products and service they are offering are perceived by Japanese consumers as being scarce, specific, timely and offer a reliable balance of price to quality: one approach towards identifying how such consumer behaviours shift is

to analyse consumer behaviours in price- and quality-sensitive sectors such as 'medical tourism' in Europe (Carrera and Lunt, 2010) and across East Asia (Lunt, 2014).

Specific to providing pharmaceuticals products and services in Japanese markets, EU-based SMEs can follow the lead of (now) successful and established brands such as UNIQLO and invest in communicating to Japanese consumers – initially, with some explicit degree of modesty about the competitive levels of efficacy and accessibility offered by their products or services - and thereby work towards influencing positively the perceptions and experiences of Japanese consumers.

One practical example would be to study and learn from the regulations and social-cultural conventions informing labelling and packaging of pharmaceutical products specific to Japanese markets – illustrations of which will be given in the Webinar accompanying this Report.

3.9 Social-cultural factors

Attempting to offer a comprehensive discussion of combined and overlapping 'social-cultural' factors relevant to a STEEPLED analysis of Japan would go far beyond the scope of this Report: readers are referred to some of the accessible books on these topics cited in this Section. For, an overarching purpose of this Report is to give some strategic background to the structure and development of the pharmaceuticals industry in Japan, and the discussion thus far has already detailed how the structure and development of this industry can appear not only universally similar in terms of its focus on human life, health and well-being, but also in terms of its reliance on technological developments coupled with the knowledge that people and companies accumulate, share and transfer across 'value-adding' business and industry-specific networks (see **Figure #1**, page 12).

A key theme emerging from the analysis presented in this Report that Japanese markets for the development and distribution of pharmaceutical products and services are – by international comparison – distinctive. As discussed in more detail in a following Section, this outcome of Japan's 'distinctiveness' comes as a result of the systematic development of institutions and industry-specific networks that have developed and become established over time (Lechevalier, 2014; Jackson, 2016). Almost inevitably, when discussion turns to generalised notions of 'cultures', notions of 'diversity', 'difference', and / or 'distance' spring to mind: in the case of Japan, it is common to see and hear invocations of 'remote' and 'unique' [10].

Correspondingly, and of direct relevant towards guiding non-Japanese business people towards understanding

[10] In its original meaning, the English word 'unique' (Latin: *ūnicus*) denotes 'singular' or 'incomparable', or even 'unequalled', 'unparalleled', or 'unprecedented'. The discussion thus far in this Report offers many examples illustrating how the pharmaceuticals industry in Japan is not – by any critical international comparison - 'unique', taking into account its history of product and process derivation and adaptation and its increasing inter-connectivity with global business and technological developments.

more about the strategic context for the pharmaceuticals industry in Japan, the following discussion highlights two themes that business research and practical experience suggest are distinctive for Japan:

- *Keiretsu*-style strategic thinking among managers in Japanese pharmaceuticals companies;
- Styles of business communication and relationship-building designed to promote knowledge creation and sharing and to structure business networking.

3.9.1 *Keiretsu*-style strategic thinking

Re-invoking the OECD (1997) definition of NIS presented in the previous Section, a general understanding of national innovation systems (NIS) "can help policy makers develop approaches for enhancing innovative performance in the *knowledge-based economies* of today. The smooth operation of innovation systems depends on the fluidity of knowledge flows – among enterprises, universities and research institutions" (OECD, 1997:2 – *emphasis as in original*). As highlighted earlier in this Report, in addition to emphasising the 'fluidity' of knowledge flows in relation to technological and product development, it is relevant to ask questions about the 'patterns' (Jackson and Debroux, 2009) or 'pathways' (Hara, 2008) of these strategic knowledge flows within and between Japanese companies and institutions.

In contexts for Japanese business and management, *keiretsu* can be translated as 'succession' or 'linkage' (Aoki and Lennerfors, 2013): as a formalised network, it can be visualised as a spider's web and conceptualised as 'close interfirm relationships' (Gerlach, 1992). In an earlier Report, Jackson and Matsumoto (2017) gave detailed examples and illustrations relevant to EU-based SMEs of how '*keiretsu*-style strategic thinking' influences how Japanese companies and their managers commonly approach the management of risk, notably in contexts for overseas M&As. In short, Japanese managers tend to look for relatively low-risk-steady-yield' investment opportunities; as a strategic norm, they should proceed in contexts of ownership and control that are established and familiar (Matsumoto, 2014). It is for this combination of reasons that - from an outsider perspective - inter-industry relationships and cross-institutional networks shaped by *keiretsu*-style strategic thinking in Japan embody and express a strategic 'state of mind' that by international comparison can appear to be distinctly 'Japanese' (Gerlach, 1992[11]. An enduring level of distinctiveness that overall appears to offer a highly appropriate and

[11] There is evidence that this institutionalized 'state of mind' among managers and investors particular to a so-called 'Japan Inc.' is shifting and, in global business terms, hardening. For example, Toshiba's recent troubles appear to have motivated neither 'insider' *keiretsu* partners (from *Mitsui*) nor non-*keiretsu* affiliated investors in Japan to provide money and other resources that might be interpreted as 'saving one of our own' by means of an attempted financial, political or social 'bail out' (Financial Times, 2017).

informative point of reference when identifying the current and emerging structures defining the Japanese pharmaceuticals industry along with the flows of knowledge that serve to develop it and add value to it.

As a consequence, non-Japanese entrants to markets for pharmaceutical products and services in Japan will probably need to differentiate themselves by being either exotically specific and timely in their perceived 'non-Japaneseness' or conform to established Japanese consumer expectations, hence demonstrate themselves as expert practitioners in managing the 'Country of Origin' effect discussed in **Box #6** (page 36).

Box #7: Community and communication in Japanese society

Giddens and Sutton define 'society' as 'a system of structured social and institutional relationships within a boundaried territory' (2013:1071). Over time and within geographical boundaries, societies appear as communities of people at regional and (where politically arranged) at national level. Perceptions of urgency influence the intensity with which communities bond – a process that much more enduring, perhaps, when people are exposed to regular threats of extinction. Japanese society is constantly threatened by natural disasters such as volcanoes, earthquakes and *tsunami*. One metaphor commonly associated with how Japanese business networks endure is *unmei kyodotai* or 'community of fate' (cf. Debroux, 2003).

Echoing Senior and Swailes (2010:4), 'at the simplest level' organisations can be interpreted as physical spaces in which people routines work and interact with each other. In the Japanese context, the rice field (田) suggests a microcosm of Japanese society and work culture. As with traditional *saké* manufacturing, the cultivation of rice remains a seasonal, location-specific and labour-intensive activity. Consequently, until the introduction of 'western' knowledge and technologies during the Meiji era, early Japanese capitalism was essentially subsistent, demanding long-term and (euphemistically speaking) 'back-breaking' commitment of its community members – a commitment discernible even today in the work ethic of Japanese employees (Dore and Sako, 1998; Jackson and Tomioka, 2004) along with extensive community engagement in voluntary work, especially among elderly members of Japanese society (Sugimoto, 2014).

As illustrated later in this Report, geographically (ecologically), historically and institutionally defined patterns and pathways of knowledge sharing in Japan might help explain why many Japanese managers continue to lack confidence communicating in English and in other foreign languages. However, this distinction can only partly be attributed to nationality. To illustrate, the IMD Business School in Lausanne (Switzerland) publishes an annual ranking of 'global talent' and 'world competiveness' that include comparative measures related to 'training and education'. Of the 63 nationalities surveyed, Japan averaged a ranking of 31st in this category compared to the USA at rank 33rd and Switzerland at 25th (IMD, 2017). In specific reference to competence in foreign languages for business, Switzerland often appears top of the IMD rankings with Japan far below (although still ahead of the USA).

Given the communitarian roots of Japanese society and the work ethic that serves to develop and sustain it, pharmaceuticals products are perceived as specific if they add value to it: for example, enabling people top continue working and contributing to

society even though they might (by western definitions) be 'ill', elderly or otherwise infirm. Consequently, one important line of 'over-the-counter' (**OTC**) drugs in Japan is one that allows people to turn up at work despite having a cold or other socially and (perhaps) stress-induced ailment. The drugs include painkillers, cold remedies, facemasks, pep pills, and other such treatments and devices commonly distributed and sold 'OTC' at drugstiores and pharmacies (see **Appendix B**).

3.9.2 Styles of business communication and relationship-building

The aforementioned OECD definition of NIS emphasises how:

- "Both ***tacit knowledge***, or know-how exchanged through informal channels, and ***codified knowledge***, or information codified in publications, patents and other sources, are important. The mechanisms for knowledge flows include joint industry research, public/private sector partnerships, technology diffusion and movement of personnel" (OECD, 1997:2 – ***our emphasis***)

The term 'tacit knowledge' linked to 'implied' communication of meaning and transfer are knowledge are established in research attempting to identify and explaining distinctively 'Japanese' approaches to knowledge transfer and product / process innovation (Nonaka and Takeuchi, 2004). As illustrated in the practitioner interviews presented later in this Report, the communication and negotiation of 'tacit knowledge' balanced with 'codified knowledge' highlighted in the OECD (1997) definition of National Innovation Systems can be further explained in social-cultural terms relevant to business communication in Japan.

To illustrate, Hall (1976) distinguishes between so-called 'high' and 'low context' communication cultures. In 'high context' cultures people tend to understate their observations and emotions: the meaning relevant towards making sense of a current situation is assumed to be 'in the person' as opposed to 'read' in detail from the person's visible behaviour. In contrast, people in 'low context' cultures tend to prefer information to be made explicit and shared as a common point of reference rather than 'private' to individual interpretation. In Hall's analysis, Japanese people tend to prefer high context styles of communication: each person should understand what needs to be said or left unsaid by their recognition of the social, cultural and sub-culturally defined communication context. By the same comparative analysis, people in low context cultures such as those common in Europe tend to prefer people to 'speak their mind' in order to reduce ambiguity and / or avoid misunderstanding [12].

[12] Many established models exist that that claim to describe differences between nationally defined cultures: for example, comparing and contrasting 'the Germans' and 'the Dutch', 'the Chinese' and 'the Japanese'. The models and assumptions commonly appear in discussions designed to contrast management thinking and styles of communication: i.e. emphasising

Developing on Hall's analysis, people negotiating social relationships in so-called 'high context' cultures tend only to invest in social relationships they believe will bring mutually beneficial rewards: giving h tacit approach of much relationship-building interaction, the expectation is that these relationship (investments) will take time to develop and, as a consequence, should be protected from immature breakdown.

Further drawing on Hall's (1976) distinction between cultures of preferred communication styles, and specific to the type of 'codified knowledge' highlighted in the aforementioned OECD definition of NIS, this Report later presents evidence to suggest that stakeholders interacting across the pharmaceuticals industry in Japan commonly assume that regulations (as 'codified knowledge') remain open to interpretation and negotiation, regardless of their explicitly official form and status. Indeed, one interviewee introduced later in this Report (when pressed on this point) talks about the 'regulations' governing markets for pharmaceutical products and services to be comparable to 'conversations', emphasising simultaneously that companies do and should act within legal and ethically-defined bounds.

Box #8: The development of the Japanese pharmaceuticals industry in four products.

i) **Traditional sake**

Ozeki Saké Brewing Company is located in Hyogo Prefecture in Western Japan – the region achieving the greatest annual volume of output. Ozeki is one of the oldest among the remaining 1,300 breweries in Japan - down from 3,229 in 1975 (Craig, 2017). Founded in 1711, this still family owned-business appointed their first female President on April 1st 2017. Although commonly translated into English as 'rice wine', the brewing and fermentation processes used to make saké are quite distinct from those used to make (for example) European wines. Depending on the balance or selection of ingredients, and the specific fermentation processes chosen, Ozeki produces six main types of saké, with retail prices ranging accordingly. In terms of packaging and distribution, Ozeki was the first brewer in Japan to sell their product in an 180 millilitre drinking jar rather than the industry standard 1.8 litre bottles – a product launched to coincide with 1964 Tokyo Olympics. Maintaining "Pioneer Sprit" as a company slogan, Ozeki was the first traditional saké brewer from Japan to set up production in the USA (Craig, 2017).

ii) **Aspirin**

differences ahead of potential commonalities. As with the aforementioned 'Japan is unique' claim, we recommend such generalizations be assumed and / or applied with caution.

"Aspirin" is the brand name of a drug invented over 100 years ago by Bayer AG in Leverkusen, Germany. Aspirin can be taken by mouth as a painkiller and antipyretic, and has been used in space by NASA astronauts. Over years, Aspirin gained a reputation in western countries as a painkiller; later, research evidence approved by European regulators confirmed indicators of Aspirin's efficacy as a treatment for preventing cardio-vascular disease (CDV). In 2001, The Japanese government licensed the sale of Aspirin as a treatment against blood clots, the drug being distributed by Bayer AG's Japanese affiliate, Bayer Yakuhin Ltd. In Japan, aspirin is available to buy at retail drugstores as an over-the-counter (OTC) medication in packages of up to 30 pills. However, in the market for general painkillers Japanese consumers appear to be remaining loyal to domestic brands such as Bufferin®, marketed by a detergent company (Lion Corp). Note: The case of Bayer AG's aspiring and its entry to Japanese markets for pharmaceutical products will be discussed in more detail in the Webinar accompanying this Report

iii) **Pepcid**

In 1985, Japanese pharmaceuticals manufacturer Yamanouchi launched an indigestion ('heart burn') drug famotidine under the trade name Gaster. It proved to be a blockbuster product in the Japanese market, not least among hard-working (and hard-drinking) 'corporate warriors' (salarymen). Lacking international marketing expertise, Yamanouchi enlisted the help of US drugs manufacturer Merck Sharp & Dohme: Gaster became Pepcid. Domestic success became global success - so much so that it attracted the attention of several global competitors, who began to produce and brand their own versions of the drug. Several of these were challenged by Yamanouchi-Merck; many international lawsuits ensued. Nonetheless, the drug Pepcid remains a "revolutionary" breakthrough in Japanese and then Japanese-American drug development and marketing (Roehl, 2014).

iv) **Contraceptive (birth control) treatments for women**

Although various birth control drugs had been available publicly for around thirty years in many developed economies, such treatments only became legally available to women in Japan in September 1999. According to the World Contraceptive Use 2014 Report, the most common form of contraceptive method in Japan in 2005 was male condoms at around 40% and birth control pills at a mere 1%; comparable figures in the USA were 11% and 17%, respectively. There is evidence that many Japanese pharmaceutical companies wanted to sell such drugs in Japan. However, the MHLW resisted attempts to allow trialing and approval procedures in Japan. Did the MHLW's fast-tracking of approval for the male impotency treatment (Viagra) prompt a re-think on Japan approving female use of the 'Pill'? What do the institutional barriers (Martin, 2000).

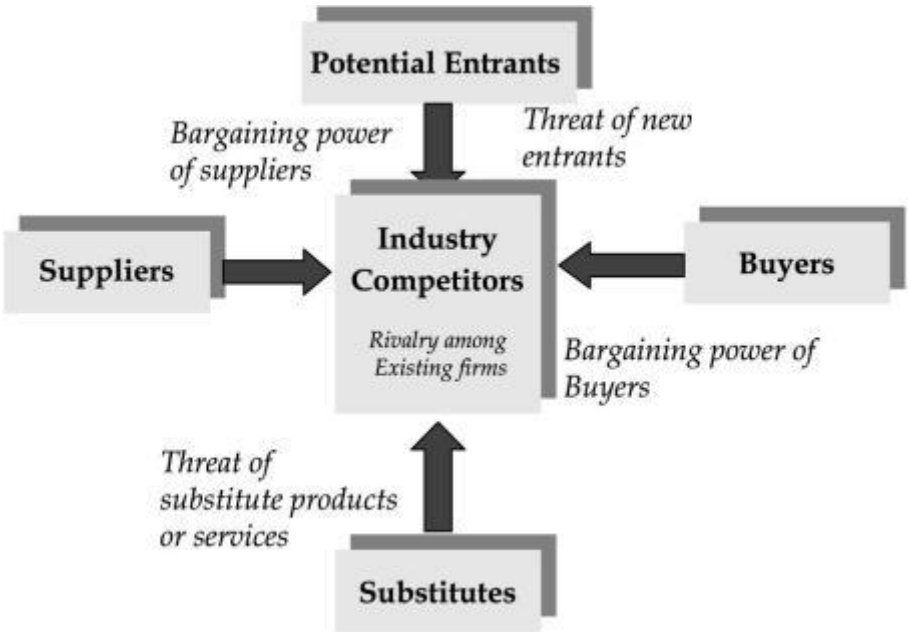
4 How open are Japanese markets to non-Japanese companies?

Having now explored in some detail the history and distinctive features in the emerging structure of the Japanese pharmaceuticals industry and related business sectors have developed, it is appropriate now to switch to a European perspective and ask the second key question giving direction to this Report; namely:

- How open are Japanese markets for pharmaceutical products and services to non-Japanese companies, and especially to SMEs from Europe?

Based on what has been presented and discussed thus far in this Report, the immediate answer appears to be: 'not very'! However, in order to work towards a more balanced and considered answer to this question, it is both possible and appropriate to take a more balanced view: for example, by applying the type of 'Five Forces' model devised by Michael Porter (1979).

Figure #2: Porter's FIVE FORCES model



(**Source**: Porter, 1979; Karagiannopoulos et.al., 2005:4)

4.1 Assessing ease of entry to Japanese markets: a 'Five Forces' model

Porter's 'Five Forces' model can be used to guide companies and their managers towards assessing the

competitiveness of their current and / or target business environments, and on this basis to begin formulate strategies that i) might enable them to develop their current position in an existing market and ii) might facilitate their entry into a market that is new or relatively unfamiliar to them. In this sense, identifying which factors might be facilitators to entry is parallel to identifying potential barriers to entry: for example, an analysis of barriers that in combination might be assessed as so insurmountable that any attempt to enter the target market would appear to be a loss-generating exercise.

As depicted in **Figure #2** (above), the Five Forces that make up the model are:

i) Competitive Rivalry

In the context of this Report, the 'competitive rivalry' along with the strategic business environment giving context to this rivalry has been detailed in the STEEPLED analysis and through preceding Sections giving examples from and insights into the current and emerging structure and essence of Japanese markets for pharmaceutical products and services. Although not exhaustive, the examples presented and discussed above give managers of EU-based SMEs insights into the number and relative strength of rival companies along with how the quality of products and services competing in these markets is assessed and the markets themselves are structured: for example, by the interventions of regulatory agencies and by the behaviour of customers. In respect of attempting to compete in Japanese markets for pharmaceutical products and services, EU-based SMEs need to appreciate the historical embeddedness of how Japanese companies 'compete': for example, with an emphasis of investment in domestic markets and the nurturing of existing institutionalised business and political networks through the expression of the aforementioned *keiretsu*-style strategic mind-set.

ii) Supplier Power

The examples presented and discussed thus far in this Report give indication of (for example) how prescription costs and retail prices for drugs are regulated and some indication of how supply and distribution channels are controlled. Supporting insights have been given into how companies and customers in Japan interact such that customers tend to remain loyal to certain domestically produced treatments and services, and why. Consequently, in respect of attempting to compete in Japanese markets for pharmaceutical products and services EU-based SMEs need to gain access to networks of medical doctors (MDs) and to the domestic market information that affords these MDs their elevated and pivotal status in the Japanese pharmaceutical industry (see **Box #10**, page 51).

iii) Buyer Power

Once again, the apparent inelasticity of retail pricing systems appears to be a key and distinctive factor here. In addition, there is the apparent inertia of current consumers in Japan, along with relative lack of incentive to innovate on the part of manufacturers and the regulators whose interventions structure the markets, keeping these more 'closed' than 'open' or 'free'. Consequently, in respect of attempting to compete in Japanese markets for pharmaceutical products and services EU-based SMEs will need to establish an initial market position as a foundation upon which to appear 'familiar' and / or a 'trusted partner' in domestic markets. Examples of how such positions might be gained are illustrated by the case studies noted below (**Section #6**), and in more precise strategic detail in the Webinar accompanying this Report.

iv) Threat of Substitution.

From a European SME perspective, the 'threat of substitution' on the one hand relates to the legal enforcement of patents and other IPR arrangements for products that might be distributed to markets in Japan. Conversely, the 'threat of substitution' element in the model can be interpret as an opportunity to bring to market products that might outperform existing domestic rivals: for example, in terms of their efficacy in relation to their cost of production and export to Japan. Unfortunately, and as we illustrate in more detail (below), there is evidence to suggest that existing suppliers to domestic markets in Japan – and both Japanese and non-Japanese-owned companies - continue to benefit from the relatively 'closed' confluence of systems that serve to define the dynamics and boundaries of these markets.

Furthermore, the markedly conservative expectations promoted by MDs in relation to cost-efficacy of drugs distributed and sold leave little space or margin for generic products or services. Consequently, in respect of attempting to compete in Japanese markets for pharmaceutical products and services EU-based SMEs will need to offer to the Japanese market products and services that are perceived as being precisely differentiated in terms of the relative scarcity and specificity: for example, in terms of their timeliness relative to market demand and their efficacy in comparison to domestic brands. The examples of *Viagra* and *Aspirin* (**Box #8**) stand as enduing and high profile points of reference in this endeavour to bring substitute products successfully to Japanese markets.

v) Threat of New Entry.

Similar to the converse perspective suggested in relation to 'threat of substitution' above, if EU-based SMEs are confident that they have products and services of sufficient scarcity and specificity to succeed in Japanese markets for pharmaceutical products and services, then the investment required to establish a position there might be assessed as being too vulnerable to new entrants, and especially if regulatory agencies in Japan shifted

policy advantages away from EU-sourced products and services in favour of targeted new entrants. For example, where a less costly though equally efficacious rival supplants one SME's branded drug or treatment. As with the 'threat of substitution' element discussed above, it is possible for SMEs from Europe to act as 'new entrants' to Japanese markets by identifying opportunities to be accepted as in demanded substitutes to already established rival products: that is, assuming that these SMEs can work to shift social perception, as illustrated briefly in the example of UNIQLO from the fashion retail sector.

4.2 Major barriers to market entry: institutions

Looking again at **Figure #2** (page 45), in addition to identifying factors that might help or hinder EU-based SMEs gaining entry or developing existing positions in Japanese markets for pharmaceutical products and services, it is strategically vital also to identify factors or - using Porter's terminology – 'forces' that appear to influence how each set of factors interacts and evolves towards creating a combination of market dynamic and trajectory.

Two linking factors appear to be key towards predicting what might be major barriers to SMEs attempting to enter Japanese markets: i) institutions such as Japan's Ministry of Heath, Labour and Welfare (MLHW); and ii) existing networks of medical doctors. As suggested already in the Report, these two linking factors appear also to demonstrate something distinctive about Japanese markets for pharmaceutical products and services along with the relative 'openness' of these markets to new entrants from Europe.

Japan's MLHW can be defined as a public sector institution similar to counterparts that operate in the member states of the EU along with transnational institutions that regulate and advise across the political and economic boundaries of individual member states. Echoing Barley and Tobert (1997:94), institutions such as Japan's MHLW and the EU's European Medicines Agency (EMA) are similar in that they represent 'socially constructed templates for action, generated and maintained through on-going interactions'. In contrast to commercial organisations or 'companies' as discussed in this Report, institutions such as the MHLW and the EMA appear more embedded in social, historical and political contexts rather than seeing their activities business-economically defined as is the emphasis among 'for-profit' organisations. Senior and Swailes emphasise how institutions 'once created' commonly 'restrict actions within them' (2012:99). Drawing on institutional theory and social-psychological concepts such as embeddedness and path-dependency, the implication is that patterns of ritual and routine developed within institutional contexts become over time accepted by members as norms and re-iterated uncritically.

In the specific case of Japan's MHLW, one approach towards 'maintaining' the institution's status through 'on-going interactions' and furthermore purposively 'restrict actions' – for example, in terms of regulating against new entrants into Japanese markets – is their close relationship to another key institution or 'force' relevant to the Five

Forces model: the Japan Pharmaceutical Manufacturers Association (JPMA). The JPMA is the leading association for R&D-based pharmaceuticals companies in Japan. Recognising the substantial contribution that these companies make to the nation's economic performance (ca. 2.5% of GDP), the JPMA interprets their role in both corporate and patriotic terms: "One of the missions of the pharmaceutical industry is to contribute to the growth of the Japanese economy as a highly value-added industry. The Japanese government expects the pharmaceutical industry to achieve this mission and clearly mentions it in the government recommendations and other official documents" (JPMA, 2017).

When assessing the coherence and reliability of such announcements from high-profile institutions in Japan, it is advisable for outsiders to understand something of the political-cultural background to policy making (Kingston, 2014). To illustrate, it is widely known and expected – among government insiders, at least – that high-ranking officials in institutions such as JPMA – the major lobbying agency on behalf the industry - tend to be recruited after their formal retirement as bureaucrats at the MHLW – the major regulatory body governing Japan's pharmaceuticals industry. A bureaucrat's move from Ministry to private or 'non-profit' company or institution through process of preferred appointment is known in Japanese as *amakudari* or 'descent from heaven' (Sugimoto, 2014: 230-1). By extension, generational interests are likely to play a role in policy making at the highest political and institutional levels: elderly (mostly male) bureaucrats in Japan tend to become leaders of policy-influencing institutions that are likely to communicating encouraging rather than discouraging signals to owners of care and nursing homes than to providers of (for example) nursery education (Sugimoto, 2014:243). For now, at least, much of what might become public in terms of health care policies impacting on business developments in the pharmaceutical industry in Japan night first have been rehearsed by "people [men] who play golf together" (Jackson and Tomioka, 2004).

Box #9: Regulatory systems in Japan

According to Hara (2008:27): "The pharmaceutical industry is strictly regulated by social institutions. [and, furthermore] the extent of regulations is greater than it is other industries because drugs have a critical influence of human life. Although drugs often save lives, they are potentially harmful, and sometimes lethal." The Ministry of Health, Labour and Welfare (MHLW) is the highest regulating agency in the Japanese pharmaceuticals industry: as such, it is the most significant barrier for any non-Japanese companies seeking to introduce pharmaceutical products or services into Japanese markets. The MHLW monitors and intervenes to regulate every stage of the R&D, production, distribution and sales activities of pharmaceutical manufacturers, including setting list prices for the sales of their drugs and the licensing of outlets where these drugs might be bought or prescribed. In short, the MHLW plays a vital regulatory role at every stage of value creation in pharmaceuticals companies, as depicted in **Figure #1** (page 12).

The Japan Pharmaceutical Manufacturers Association (JPMA) is the most powerful advocate for pharmaceuticals manufacturers in Japan. As a non-governmental organisation (NGO), their mission is to promote the commercial interests of their member companies. This includes influencing government trade polices that serve to open or close Japanese markets for pharmaceutical products and services to new entrants and to threats to their member companies' profits. However, and given that senior members of the JPMA are ex-government officials and lawmakers in Japan, boundaries between JPMA members' for-profit and not-for-profit roles fare likely to be 'ambiguous' – and not least from the perspective of non-Japanese and industry outsiders.

4.3 Major barriers to market entry: medical practitioner networks

Professional networks can be interpreted as self-regulating and self-preserving interactions between an exclusive set of social actors and technological / knowledge experts, who gain membership through investments in study, training and on-going interaction with influential others. Medical doctors (physicians) belong to one of the most enduing, politically independent and – over time – most socially respected professions in Japan as elsewhere in the world (Jackson, *forthcoming*).

Several illustrations have been given in this Report regarding the vital role that medical doctors play in shaping the Japanese pharmaceuticals industry, and not least as distribution points for prescription medicines and as a largely unchallenged source of knowledge and advice about which treatments might be more or less efficacious for their patients, for whom doctors tend to be so busy that there little time anyway to question the treatments being offered (Hara, 2008). Until recently the packaging of drugs in Japan tended to be more focussed on image attraction than information provision (Thomas, 2001). One consequence of this lack of transparency has meant that drug stores that sell certain listed drugs are required to employer trained and qualified pharmacists to advise about a particular OTC drug or combination of drugs before a customer can buy these. In this sense, qualified pharmacists can achieve the status of 'sensei' in the perception and experience of customers and patients in Japanese society.

To illustrate, adopting a broader socio-culturally and economical perspective on the role of doctors in the contexts created by the aforementioned demographic trends in Japan leads companies to recognise how many of the burdens related to caring for the elderly and the very young members of Japanese society fall to families (Thang, 2013; Kohsaka, 2013). Within whatever defines a 'family' in modern Japanese society, these burdens continue to fall especially to women of working age – women who, anyway, may be missing out on accumulating health care and other social benefits as a result of them being in insecure employment (White, 2013 Sugimoto, 2014). Linking to demographic and ecological (human geographical and infrastructure) factors outlined above, in Japan as elsewhere in the world families turn to local doctors and community health advisers when caring for the very young and the

very old (Thang, 2013).

Consequently, medical doctors and other professionals routinely act as an influential and – in strategic terms - pivotal feature of the market and, by extension, the product and service distribution structure in Japan is the role played by medical practitioners or doctors. As such, much of the investment made by Japanese pharmaceutical manufacturers into marketing (promotion, distribution) and sales are targeted at developing business and supply relationships with doctors (Roehl, 2014). The perceived strategic need for companies to invest in and secure the 'support' of individual doctors entails a huge expenditure of time, money, knowledge and other key strategic resources – resources that, as highlighted in our introductory discussion, SMEs in Japan and from outside Japan seldom have at their disposal. Where the relevant resources are available, SMEs can perceive them as being under threat of rival companies and products (see **Figure #2**, page 45).

Box #10: Roles of medical doctors in the promotion and distribution of drugs

As mentioned earlier in this Report, Japan's hierarchical social system accords medical practitioners and medical doctors (MDs) a high status. Around 80% of all hospitals (regulated by government license) and 94% of all clinics (often unregulated) in Japan are privately owned. Physicians are currently allowed to proclaim expertise and open a clinic anywhere in Japan as a private business and without central government authorisation. In effect, these clinics act like family businesses, whereby the reputation of a practice can be transferred from mother / father to their children and so on – a network of reputation and public service that impacts especially in less urbanized regions in Japan.

Generally speaking, all hospitals and clinics – and whether state-, Prefecturally- or privately-owned - can procure medical equipment and many medicines without formal authorization. From a public welfare perspective, the whole system continues to operate on the basis of public trust in health care institutions. Within this system, and as explained in **Box #5** (page 33), all revenue from the distribution and sale of pharmaceutical products is regulated by a government-authorised 'fee schedule' or retail price list ('list prices') determined by the national government and the MHLW, taking advice from institutions such as JPMA. The current system allows individual MDs and their hospitals / clinics to make a surplus from prescribing drugs they receive from selected manufacturers. The selling price of these recommended (sponsored) drugs exceeds what would be the usual market price for these drugs, hence the common reference across the industry to "doctors' margins", estimated to amount (on average) to 25% above an expected market price for drugs (Odagiri and Goto, 1996).

Tax laws in Japan regard this doctor's margin as a 'surplus', meaning that MDs and clinics must re-invest the surplus as capital back into the business. This has consequences for the relationships negotiated between individual pharmaceuticals

companies and doctors. Firstly, companies recognise that MDs in Japan represent their most influential and effective channel of distribution. Secondly, MDs and their clinics provide their most reliable and immediate source of data from clinical (human) trials of new drugs and treatments.

Of immediate relevance to this Report is the insight that EU-based SMEs attempting to enter t Japanese markets for pharmaceutical products will at some point need to connect with and establish a sustainable position and positive reputation among MD networks in Japan if the products they offer are to be distributed and, over time, be perceived by Japanese consumers as trustworthy: for example, as effective, timely, and credible towards satisfying a market and / or lifestyle need.

It is worth re-iterating here the role that qualified pharmacist s play in the distribution of sale of OTC drugs and treatments. The aforementioned government 'list' not only specifies retail prices for all licensed drugs: it also stipulates which drugs must be dispensed (sold) in the presence of a qualified pharmacist. Consequently, many OTC drugs that would require a doctor's prescription in European countries can be bought OTC at pharmacies and drugstores in Japan (see **Appendix B**). However, the customer cannot actually receive and pay for these drugs without first taking and accepting spoken advice (in Japanese) from a qualified pharmacist hired by the drugstore retailer. Consequently, certain OTC drugs can only be bought at times and places where a qualified pharmacist is available and physically on site. Note: there is early talk about making it possible for this on-site advisory role to be played be new generations of robots (Jackson, *forthcoming*).

5 Section 5: Interviews

The following summaries represent extracts from several interviews conducted specifically towards giving practitioner perspectives on some of the key themes presented in this Report. It is hoped that the insights offered here could prompt SMEs in Europe to make their own contacts and research among business practitioners working in or with the pharmaceuticals industry in Japan. Given the sensitive and (in parts) frank nature of the information and advice offered by these interviewees, it was decided that all summaries should be treated equally in terms of granting anonymity to all those who volunteered the information and insights that follow.

Interviewee #1: (Japanese). Project lead for clinical development at a major pharmaceuticals manufacturer in Japan.

One thing that SMEs in Europe might recognise as familiar is how the pharmaceuticals industry in Japan – by law and tradition – is oriented towards offering health care as a welfare service. My experience with business partners from the USA is that they arrive here with the experience and expectation of health care provision as a business;

they gear their R&D investments towards making profit. They appear to accept that 20% of the American population being without health insurance is prices that society needs to pay. This attitude is quite shocking for most Japanese people, I think. And what I saw recently on the streets in California as a result of opiate abuse really scared me and the Japanese colleagues I was travelling with.

In my area (oncology) there is great competition for discovering and developing new drugs. This is important. But as a professional, I sometimes ask myself whether we should all be doing more to research into drugs for even greater killer diseases in society, and especially in Japan – diseases such as dementia.

If there are SMEs in Europe with drugs or treatments in development that can help Japanese companies target these major and distressing diseases in society, then they should be able to find suitable business partners in Japan, including interest from the Japanese government and the increasing number of private care homes for the elderly.

Interviewee #2: (Japanese). Sales manager for a medium-sized pharmaceuticals manufacturer**.**

Most of my time travelling around the country is spent visiting hospitals and medical practices meeting and often entertaining medical doctors (MDs). Our company knows that these MDs and clinic owners are very influential in deciding what drugs are promoted and prescribed; and, if I'm honest, these decisions do not always seem to be mainly with the patients' interests in mind; in addition genuinely to helping patients, MDs expect to make good 'margins'.

Our company is not so big and relatively new compare to several big rivals, so we feel we have to work that much harder to form and maintain good relations with MDs. I'm not sure, as my international experience is not so good, but I think perhaps foreign companies – and particular companies of similar size to our company – would really struggle to make contacts among doctor networks in Japan that would work. SMEs in Europe might have to partner with a bigger Japanese company, or if there's a possibility of synergy, with a company like ours. What I'd suggest to SMEs in Europe is to visit the various trade fairs in Japan, get noticed, network, and communicate in Japanese. Find the most relevant trade fairs to your particular products and plan to visit and re-connect with people you first meet and meet them again and, if possible, regularly over at least three years. When the time is right, invite them over to Europe; if they accept, there's a good chance you could later do business together. In my experience, that how business relationships are made in Japan.

Interviewee #3: (Swedish). Advisor on drug regulatory systems in Japan.

I found the time I worked in Japan to be – personally and professionally – some of the most wonderful but also some of the most frustrating years of my life. People are wonderful, and young people generally so courteous and hardworking – in my experience, particularly the younger women I met working in local restaurants and who were studying pharmacy: idealistic, dedicated, chasing their individual dreams. Many of them, I remember, were motivated to study pharmacy, become a midwife or a nurse as a result of something they had experienced in their family when they were younger, often a sad story involving a grandparent or other relative or close friend.

Of course, language is a major obstacle: mainly for me being a foreigner who at the beginning spoke little Japanese. But a bigger obstacle is the inefficiency of business and management communication. So many very well qualified and experienced Japanese colleagues appeared too nervous to speak at meetings. Even now, when I have TCs and VCs [telephone and video conferences] with people back in Japan that I've known and worked with for years. I sometimes get frustrated that they either seem not to understand my questions, or that they are too shy to share the information we need and that they have in order to make progress. A lot of time is spent checking and double-checking after the conferences with Japanese colleagues who were at the same meeting, but who I know will be more open about communicating outside of the formal meeting or conference.

What advice can I give to European SMEs trying to enter the Japanese markets? As a priority you need to get expert and reliable advice about the regulatory systems in Japan. And I mean not just find out what laws and regulations apply to your particular products: for example, in terms of pricing, packaging, patient safety, and so on. It took me a long time to recognise that 'what it says on the packet' – a law, a regulation or set of ethical guidelines – is not precisely how people in Japan expect it to be interpreted in practice. You need to keep talking about and around the regulations: discover the context, the history, whose interests are being promoted – and protected – by the regulations. There is a lot of trust - even naivety, I think: most people expect other people to act is a professional and ethical manner: 'do no harm'. Trying to make strategic sense of all this takes time: we can't take anything 'at face value': the values lies deep and are seldom made explicit, and especially not to people or companies who are still regarded as 'outsiders'. This system won't be changing any time soon. Consequently, in my view and experience SMEs in Europe face strategic choices that lead i) to becoming recognised and accepted as a foreign 'insider' to existing networks or ii) can make being a foreign 'outsider' a key and decisive feature of their USP [unique sales proposition]. Good luck!

Interviewee #4: (Japanese-American). Patent lawyer.

A general view among Americans is that Japanese companies generally – and Japanese pharma companies especially – are not very innovative when compared to American rivals. However, I would say there is a different

tradition of 'innovation' in Japan that doesn't fit what I call the American 'MBA mind-set'. Japanese companies are ingenious, thinking long and hard about a problem, examining details of a potential opportunity precisely before investing in working towards prototypes and trialling products. They [Japanese manufacturers] listen a lot to their customers – in Japan, that means doctors and former politicians and ministry bureaucrats working in organisations such as the JPMA. They talk a lot among themselves at various 'club' meetings – including (in my experience) the local golf club, that that model is becoming a little dated now, I think.

How does all this bring us to my work in patent law in Japan? Well, I get asked by many Japanese SMEs to help identify and explain what patent laws in the USA actually 'mean'; more especially, what can be found 'between the lines' that gives strategic scope for these SMEs Japanese to compete – in Japan, primarily, but also where possible learning from solutions and opportunities found by SMEs and smaller ventures in America. When it turns out I can help them do this, our business relationship becomes very strong. I have customers who remain loyal to our legal partnership over many years.

What practical advice can I give to SMEs in Europe trying to get into markets in Japan? Get advice from comparative (international) lawyers like me in Europe. Look at existing patent laws in the EU and try to identify what is *not* covered explicitly in those laws: what, specifically, is *not illegal*? What gaps can be found in the specifications describing and distinguishing existing laws and patents that impact on your own product development and investment decisions and those of your main rivals? Become more skilled in ingenuity, in precision, in examining current patents and patent laws by 'reading between the lines'. And then hire or work with an expert in Japanese law who you trust and know and get his or her feedback on guidance on you and your company can do the same in Japan.

Interviewee #5: (Swedish). CEO of successful non-Japanese SME in Japan.

For non-Japanese who want to see in the Japanese health care market, you probably need to start small and extremely focussed. We started as a subsidiary to our parent company in Sweden: our initial presence in Japan was a desk at the Embassy in Tokyo. We then hired a Japanese scientist with expertise directly relevant to the one main product we wanted to develop and sell in Japan. Having hired a product specialist locally, we relied on bringing in our own marketing and sales expertise. We visited relevant trade & technology fairs over years and became known. I can speak Japanese; we could form business relationships; we came to be perceived as reliable and committed to helping solve specific health problems in Japanese society. We have shown that we are here for the long-term.

Now we are registered as K.K. and employ 35 people (all Japanese) in Tokyo. Our product is respected and we are growing in terms of sales, and learning all the time as we do this: we invest in training and developing our

employees; our team is close-knit, egalitarian in the Swedish manner; we are strongly committed and loyal to each other in the Japanese manner. In short, we work consistently to our strengths, and work to develop these all the time.

Practical advice for SMEs in the EU? Well, every company is different; every product or service will and should be 'unique' in what it can and should bring towards improving health care in Japan and as a result help improve Japanese society. So, let me say something about practicalities I didn't' expect to be confronted with. Our relationships to banks in Japan have taken time to develop. There is mutual trust, but nonetheless so much of our financial management still work in book, folder or paper document form. On reflection, we could have got more information about administrative details like this from organisations such as JETRO [Japan External Trade Relations Organisation], who have offices in most of the main cities in Japan. Travelling city to city and return is possible as a one-day business trip all across Japan, with the exception of Okinawa in the far south: the *shinkansen* and dense domestic airline systems allow this. Oh, and make sure you bring a working fax machine when you set up business in Japan: most of our orders, invoices and specification documents still arrive by than as an Email attachment!

Interviewee #6: (Japanese). Expatriate working in a French pharmaceuticals company.

My former boss [in the Tokyo office of multi-national America pharma manufacturer] worked in business development. He knew of a small molecule compound owned by a German company that could be developed and used to treat viral infections. Our American employer had other strategic priorities for investment at that time, so my former boss set up his own small specialty pharma company in Japan and negotiated IP [intellectual property] rights with the German company. The agreement they negotiated meant that the company set up by my former boss acquired IPR for the development and worldwide sales of the compound. In return, the German company received an upfront payment, milestone payments during the drug's development in Germany, and a share of any worldwide sales.

Interestingly - for Japan, at least – my former boss hired myself and nine other colleagues at the American company to become his project team. We each quit and joined his venture. Because I'd worked in Europe previously [for a Japanese company in the UK] and subsequently gained an MBA degree in London, I was sent to run a Europe office. My primary roles were to liaise with the German company and consult about regulatory matters from a European perspective.

Our business plan succeeded. When the drug had received worldwide recognition in the industry, my boss sold it to an American manufacturer. He was then invited to re-join our former American employer, who [he later told me] had admired his 'entrepreneurial spirit'. After the sale of the drug and disbandment of our team's venture, I

stayed on in Europe and work now in clinical development for a French company on a drug destined to find a market in Japan.

Interview #7: (Japanese) Business consultant specialising in foreign start-ups.

My company offers a tailored service advising foreign entrepreneurs about how to set up in Japan. On the legal side, setting up a company in Japan is not particularly difficult. However, for entrepreneurs who want to establish themselves developing and selling health care products, including cosmetics, food, beverages and pharmaceutical products – that is, anything with a clear and potential risk to people's health – the regulations can be very strict. How strictly they are enforced depends very much on the particular type of product, and the current state of the Japanese market for that product.

Let me give you one example. One of my clients wanted advice about brining a herbal medicine to the Japanese market. In addition to working with us, we advised the client to test the market for the product with major on-line retailers such as Rakuten (Japan) and Alibaba (China). They each saw potential in our client's product and helped the client develop business and marketing plans relevant to the Japanese and Chinese markets – sharing information the client alone could not have accessed.

Another of my clients had developed a compound for which they had a patent pending. Our market research found that there was potential in Japan to find business partners to develop this compound. We advised the client to set up in Japan as a research organisation. We introduced the client to people involved in developing a biotech cluster in Kobe, a city west of Japan. We assessed that setting up in Tokyo and carrying the much higher living costs while at the same time negotiating the more crowded spaces for start-ups would have brought much greater risks.

Interview #8: (Japanese) Leader (clinical development) British-Swedish pharmaceuticals manufacturer in Japan.

In my view, the two main market-entry barriers to non-Japanese pharmaceuticals companies – and especially for European SMEs - are the tight and closed networks of MDs and the lack of brand familiarity. If their brand is perceived as 'foreign', they need to ensure that customers - and especially MDs - recognise that the quality of their product is clearly superior to Japanese brand products. The cost-quality ration must also be right, leaving sufficient profit or surplus margin for MDs and hospitals. For this reason, I see little prospect for foreign generics making headway in Japanese markets.

Having said this, I notice in my own company that, slowly, the influence of MDs might be getting less. The

MDs we hire know their patients and trends in market demand in Japan very well, but tend to know little about global business developments. In my view we are hiring more specialised business experts to work with MDs in targeting investments in drug development and – especially – marketing.

The regulatory questions remain a barrier to non-Japanese companies. It's still probably best that they work with Japanese partners to understand and negotiate the regulatory. However, as companies become more global, and more people at the strategic level become used to negotiating with the FDA [Food and Drug Agency in the USA] for approval, I think the standards and procedures are becoming more similar. However, how the regulatory works in Japan is still difficult for outsiders to fully understand: for example, understanding the relationships between MDs, hospitals, drug manufacturer lobbies like JPMA, and the [Japanese] government.

You mentioned this EPA between Japan and the EU. In my area [clinical development], I haven't heard much discussion about this. My impression is that it will affect mainly the OTC market. Perhaps that's where European SMEs might concentrate their efforts: for example, targeting life-style treatments that might interest certain well-off segments in Japan. Otherwise, I think they should look top offer very specific technologies and expertise and form partnerships: e.g. in my area [oncology] we are investing heavily in immuno- treatments. To do this effectively we need we specialist support with procedures such as ALT [automated laboratory testing] linked to processes of clinical trials.

6 Case studies of successful entry to Japanese markets

Despite the actual and perceived barriers to market entry to Japan, EU countries can boast a number of success stories, running from start-up ventures and established SMEs who have managed top attract customers and develop positions in Japanese markets for pharmaceutical products and services. Several of these will be illustrated in detail during the Webinar and podcast that accompany this Report. Re-invoking the Value Chain presented as **Figure #1** (page 12), the success stories to be discussed in the Webinar include the three following examples.

6.1 Early-stage entry as a specialist R&D company

EirGen Pharma was set up in 2005 by two MBA graduates in Waterford, Ireland. After pitching their business plan at a number of competitive fairs, they attracted sufficient investment to set up a company specialising in clinical trials for oncology treatments using a high containment process they had developed. The company has gained access to a number of world markets, including Japan.

6.2 Mid-stage entry as partner to another European SME already established in Japan

Hertart Aps is a Danish R&D company located in Greve, near Roskilde in Denmark. They produced a form of disposable plastic (Labware) that proved suitable for use as medical device for fertility treatments. The company first entered a collaborative arrangement with a by a Swedish company (Vitrolife) as Vitrolife expanded its operations into East Asia. As a business, Hertart Aps gained access to Japanese markets after being bought out by Vitrolife. Vitrolife, founded in 1994 in Gothenburg, Sweden specialises in offering fertility treatments and is now well established in Japan.

6.3 Entering Japanese markets with help of the EU-Japan Centre for Industrial Cooperation.

Sphere Fluidics is a UK-based SME founded in 2010, emerging out of a group of scientists affiliated to the University of Cambridge. Sphere Fluidics originally specialised in the development of biochip systems and in providing R&D support to other companies. They subsequently developed and patented expertise in the production of platforms for single-cell analysis. Through the EU Japan-Centre, Sphere Fluidics attended the BioJapan Expo in 2016, where they met four potential distributors. Sphere Fluidics subsequently signed a distribution contract for two of their products in Japanese markets with a Japanese company.

7 Conclusions and practical recommendations to EU-based SMEs seeking to enter Japanese markets for pharmaceutical products and services

This Report has given detailed context of the historical development and current structure of the pharmaceuticals industry in Japan. Taking the strategic perspective of EU-based SMEs that are seeking to enter and / or developing exiting positions in markets for pharmaceutical products and services in Japan, this Report has detailed several embedded barriers to market entry for EU-based SMEs, noting that for non-Japanese companies the Japanese market remains a relatively 'tough nut to crack'. Before, however, indicating spaces for business opportunity I respect of EU-Based SMEs seeking to enter or develop positions in Japanese markets for pharmaceutical products and services, it is worth expanding the context of this discussion by highlighting some relevant trends impacting and driving developments in the Japanese pharmaceuticals industry.

7.1 Trends impacting the global pharmaceuticals industry

It is beyond of the scope of this Report to outline a full and comprehensive catalogue of trends impacting the global pharmaceuticals industry: for example, in terms of emerging technologies, treatments and market demands. Readers of this Report can find in-depth information in publications by global business consultancies and science and research networks. However, and specifically in relation to the information and examples given in this Report, relevant global trends include:

- The continuing lack of breakthrough treatments for Alzheimer's and similar degenerative diseases (Hall, 2018)
- The increasing application of Information technology (IT) and Artificial Intelligence (AI) in the search for cancer treatments (Vella, 2017; McKinsey, 2018)
- As patents for leading branded drugs expire, the increasing penetration of generic drugs and treatments available for OTC distribution and sale into emerging economies and markets: for example, in Southeast Asia and South Asia (ITA, 2017)
- An emerging wave of mergers and other forms of strategic alliance between large manufacturers, and especially of acquisitions made by larger manufacturers of smaller, specialised manufacturers and research-led companies and start-up ventures across national boundaries (Jackson and Matsumoto, 2017)

The struggle of national health systems to cope with the increasing demands of health care treatments and of health care itself: for example, in relation to ageing populations and the increasingly uneven distribution of clean water and nutritious food across both developed and emerging economies. One related development and threat to social health and happiness is the emergence of new types of allergies on account of polluted air, food and water, especially among younger people.

7.2 Trends impacting the Japanese pharmaceuticals industry

In addition to remaining a relatively closed market for new entrants, Japan remains one of the most productive sources of exported pharmaceutical products: for example, to the USA (ITA, 2017). The Japanese market remains distinctive in relation to high levels of social access and affordability – both features supported by the still generally robust national insurance system (GlobalData, 2017). The main focus areas for investment are anticancer and enhanced immune class drugs, which tend to allow high margins at distribution and sale – a business performance expectation that makes markets in the USA and (for certain high quality products) China and South Korea appear most attractive (Pharmtec, 2017).

The markets for pharmaceutical products and related services is predicted to grow from around €75 billion currently to around €80 billion by 2021. Within the parameters described in this Report, growth in Japanese markets for pharmaceuticals products is becoming increasingly driven by investments in biologics, including products such as vaccines, therapeutic proteins, blood, blood components and tissues (ITA, 2017). Following on from these investments are an early generation of investment returns in the form of so-called biosimilars, which comprise biologics that have gained regulatory approval after successful clinical trials, notably passing FDA requirements in the USA (Dalzell, 2013).

As the Japanese government struggles to meet the health care demands of an ageing population, it is expected that there will be increasing penetration of generics entering the Japanese domestic markets, notably from India. As a result, increasing numbers of Japanese pharmaceuticals manufacturers are switching production to generics and / or seeking partnering arrangements with original brand producers (Pharmtech, 2017).

Furthermore, these partnering s will seek to improve current knowledge and technologies in japan in relation to the application of AI and IT procedures to drug research, development and production in Japan: for example, in processes of automated laboratory testing (ALT) and computer modelling in the search for targets suitable to host endogenous proteins (*Nikkei,* 2016; ITA, 2017). A general strategic assessment is that the Japanese pharmaceuticals industry is engaged in a gradual and still (largely) closed process of 'consolidation' of its traditionally gained and worked assets (Shimura, Masuda and Kimura, 2015).

7.3 Practical recommendations for EU-based SMEs

Against the background of this brief outline of current and emerging global and Japan-specific trends in markets for pharmaceutical products and services, and drawing in conclusion on the practical examples, insights and advice presented across ections of this Report overall, it is possible to make five practical recommendations to European SMEs seeking to enter and develop positions in Japanese markets:

Firstly, investigate how to research, develop and introduce to Japanese consumers pharmaceutical products and services that are perceived as being so scarce and specific to market needs and expectations that consumers, medical doctors, regulators and other key stakeholders defining the Japanese market can be persuaded to import and distribute these.

Secondly, consider partnering with large pharmaceuticals manufacturers in Europe that already have established positions in Japanese markets for pharmaceutical products and services.

Thirdly, consider partnering with EU-based SMEs that already have established positions in Japanese markets: for example, by making research, development and clinical trial agreements with these SMEs.

Fourthly, consider attracting the attention in Europe of Japanese pharmaceuticals manufacturers such that they invest in a strategic alliance and thereby offer access to Japanese markets for pharmaceutical products and services.

Fifthly, if EU-based SMEs do not already own or control distribution of a pharmaceutical product or service that does not offer proven vaue added in terms of scarcity and / or specificity relevant to current and emerging Japanese markets, they should calculate carefully the risk of investing in entering Japanese markets and perhaps instead invest vital resources in other more accessible markets: for example, emerging markets across South and Southeast Asia.

This Report has detailed the rationale behind each of these recommendations for strategic thinking and action: for example, by identifying and highlighting distinctive features in the structure, development and trajectory of the pharmaceuticals industry in Japan that might over time be perceived as market entry barriers that EU-based SMEs might currently experience and / or perceive.

Finally for now, readers should note that the **Webinar** accompanying this Report and otherwise available as a **podcast** goes into deeper practical detail by relating the stories of EU-based business ventures and SMEs that through early, mid- and late-stages of business investment have managed successfully to establish themselves in Japanese markets.

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8 Appendices

Appendix A: Leading drugs manufacturers in Japan (JPMA, 2018)

A1: Major pharmaceuticals manufacturers (Japanese and non-Japanese) registered in Japan

Abbreviated Name	**Full Name & Country of Origin / Ownership** (if not Japan)
AbbVie	ABBVIE G.K. (USA)
Alcon	ALCON JAPAN LTD. (Switzerland)
Asahi Kasei Pharma	ASAHI KASEI PHARMA CORPORATION
ASKA	ASKA PHARMACEUTICAL CO., LTD.
Astellas	ASTELLAS PHARMA INC.
AstraZeneca	ASTRA-ZENECA K.K. (UK-Sweden)
Ayumi	AYUMI PHARMACEUTICAL CORP.
Baxalta	BAZALTA JAPAN LTD.
Bayer	BAYER YAKUHIN, LTD. (Germany)
Boehringer Ingelheim	NIPPON BOEHRINGER INGELHEIM CO., LTD. (Germany)
Bristol-Myers Squibb	BRISTOL-MYERS SQUIBB K.K. (USA)
Celgene	CELGENE K.K. (USA)
Chugai	CHUGAI PHARMACEUTICAL CO., LTD.
Daiichi Sankyo	DAIICHI SANKYO CO., LTD.
Dainippon Sumitomo	DAINIPPON SUMITOMO PHARMA CO., LTD.

EA Pharma	EA PHARMA CO., LTD.
Eisai	EISAI CO., LTD.
Eli Lilly	ELI LILLY JAPAN K.K. (USA)
Fujimoto	FUJIMOTO PHARMACEUTICAL CORP.
Fuso	FUSO PHARMACEUTICAL INDUSTRIES, LTD.
Genzyme	GENZYME JAPAN K.K.
GlaxoSmithKline	GLAXSMITHKLINE K.K. (UK)
Hisamitsu	HISAMITSU PHARMACEUTICAL CO., INC.
Janssen	JANSSEN PHARMACEUTICAL K.K.
Japan Tobacco	JAPAN TOBACCO INC.
Kaken	KAKEN PHARMACEUTICAL CO., LTD.
Kissei	KISSEI PHARMACEUTICAL CO., LTD.
Kowa	KOWA COMPANY, Ltd.
Kracie Pharma	KRACIE PHARMA, LTD.
Kyorin Pharma.	KYORIN PHARMACEUTICAL CO., LTD.
Kyoto	KYOTO PHARMACEUTICAL INDUSTRIES, LTD.
Kyowa Hakko Kirin	KYOWA HAKKO KIRIN CO., LTD.
Maruho	MARUHO CO., LTD.
Maruishi	MARUISHI PHARMACEUTICAL CO., LTD.
Meiji Seika Pharma	MEIJI SEIKA PHARMA CO., LTD.

Merck Serono	MERCK SERONO CO., LTD. (USA)
Minophagen	MINOPHAGEN PHARMACEUTICAL CO., LTD.
Mitsubishi Tanabe	MITSUBISHI TANABE PHARMA CORPORATION
Mochida	MOCHIDA PHARMACEUTICAL CO., LTD.
MSD	MSD K.K.
Mylan	MYLAN EPD G.K.
Nihon Pharma.	NIHON PHARMACEUTICAL CO., LTD.
Nippon Chemiphar	NIPPON CHEMIPHAR CO., LTD.
Nippon Kayaku	NIPPON KAYAKU CO., LTD.
Nippon Shinyaku	NIPPON SHINYAKU Co., Ltd.
Nippon Zoki	NIPPON ZOKI PHARMACEUTICAL CO., LTD.
Novartis	NOVARTIS PHARMA K.K. (Switzerland)
Novo Nordisk	NOVO NORDISK PHARMA LTD.
Ono	ONO PHARMACEUTICAL CO., LTD.
Otsuka	OTSUKA PHARMACEUTICAL Co., Ltd.
Pfizer	PFIZER JAPAN INC. (USA)
Pola Pharama	POLA PHARMA INC.
Sanofi	SANOFI K.K. (France)
Santen	SANTEN PHARMACEUTICAL CO., LTD.
Sanwa Kagaku	SANWA KAGAKU KENKYUSHO CO., LTD.

Seikagaku	SEIKAGAKU CORPORATION
Senju	SENJU PHARMACEUTICAL CO., LTD.
Shionogi	SHIONOGI & CO., LTD.
Taiho	TAIHO PHARMACEUTICAL CO., LTD.
Taisho	TAISHO PHARMACEUTICAL CO., LTD.
Takeda	TAKEDA PHARMACEUTICAL COMPANY LIMITED
Teijin Pharma	TEIJIN PHARMA LIMITED
Teikoku Seiyaku	TEIKOKU SEIYAKU CO., LTD.
Terumo	TERUMO CORPORATION
Toa Eiyo	TOA EIYO LTD.
Toray	TORAY INDUSTRIES, INC.
Torii	TORII PHARMACEUTICAL CO., LTD.
Toyama Chemical	TOYAMA CHEMICAL CO., LTD.
Tsumura	TSUMURA CO.
UCB	UCB JAPAN CO., LTD. (Belgium)
Wakamoto	WAKAMOTO PHARMACEUTICAL CO., LTD.
Yakult	YAKULT HONSHA CO., LTD.
Zeria	ZERIA PHARMACEUTICAL CO., LTD.

Note: 'K.K.' refers to *Kabushiki Kaisha* in Japanese, variously translated into English as "Co., Ltd.", " Corporation" or "Incorporated" or as "joint stock corporation". The K.K. is the most widely utilized form of legal incorporation in Japan.

A2: Global sales of prescription drugs

In terms of global ranking for sales of prescription drugs (STATISTA, 2018), the companies from the list above would fall into the following ranking:

1. Pfizer
2. Novartis (owner of Alcon)
3. Roche (through strategic alliance with Chugai)
4. Merck & Co.
5. Sanofi
6. GSK
7. AbbVie
8. Astra-Zeneca
9. Bristol-Myers Squibb
10. Eli Lilly
11. Bayer
12. Boehringer Ingelheim
13. **Takeda**
14. Celgene
15. **Astellas**
16. **Dai'ichi-Sankyo**

As the only all-**Japanese** companies on this global sales list, Takeda (13), Astellas (15) and Dai'ichi-Sankyo (16) record sales of prescription drugs at a *fifth* to a *sixth* of Pfizer's global sales.

A3: Spending on Research and Development (R&D)

In terms of global ranking for investments in 'in-house' R&D (STATISTA, 2018), the companies listed in **A2** (above) would fall into the following ranking:

1. Merck & Co.
2. Roche (through strategic alliance with Chugai)
3. Novartis (owner of Alcon)
4. Pfizer
5. Astra-Zeneca

6. Eli Lilly
7. Bristol-Myers Squibb
8. Sanofi
9. GSK
10. AbbVie
11. Bayer
12. Boehringer Ingelheim
13. Celgene
14. **Takeda**
15. **Astellas**
16. **Dai'ichi-Sankyo**

As the only all-**Japanese** companies listed here, Takeda, Astellas and Dai'ichi-Sankyo currently invest proportionately a *quarter* of the amount in R&D when compared to R&D investments made by Merck.

Appendix B: Major drugstore chains in Japan.

Apart from drugs that are or can only be sold via prescription directly from doctors' practices or in hospitals or clinics, most 'over-the counter' (OTC) drugs can be bought at chains of pharmacies ('drugstores') that - like convenience stores (*konbini*) - are ubiquitous across Japan.

According to figures published by the Japan Association of Chain Drugstores (JACD, 2018), total retail sales through the registered 19,654 drugstores in Japan amounted to **JPY 65,348 Billion**.

By measure of retail sales, the largest single drugstore group is Matsumoto **Kiyoshi**, followed by **Cawachi Yakuhin** (including **Sun Drug**), and **CFS Corporation**, affiliated to Japan's largest shopping mall name, **Aeon**.

Note: In tourist areas, retail sales of many pharmaceutical and cosmetic products from these drugstores are currently exempt from Consumption Tax: currently 8%, with a debate in Japan's parliament (Diet) to raise this to 10% in the autumn of 2019.Conusption tax is levied on all Business-to-Consumer (B2C) and Business-to-Business (B2B) transactions.

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