1. INTRODUCTION

China is becoming a strategic player in the pharmaceutical market, both as a consumer country and as an R&D industrial platform (Spigarelli, Wei 2012).

The Government has been embracing a large reform in the healthcare system to upgrade the quality and coverage of healthcare assistance of Chinese people. Multiple strategies are promoted, both on the demand and on the offer side. The Twelfth Five-Year Plan for Health Sector Development is a milestone in this process. A key issue in the strategy towards a new healthcare system is related to the transformation of the Chinese pharmaceutical industry (Ministry of Health PRC, 2013, p. 130): the Government is planning to build an innovative system, led by research-based companies, where integration of local firms with international companies is encouraged and where a new – strong – role for Traditional Chinese Medicine is promoted. Foreign investments are supported, especially in high-end pharmaceutical products.
through the New Catalogue of Investments (CCCMHPIE, 2011), but at the same time, the development of national global players is encouraged (Mofcom, 2012).

To grasp knowledge, know how and best practices, China is attracting not only the manufacturing and marketing division of foreign firms, but it is also promoting the transfer in China of some of their critical business operations, core technologies and research development (Wilsdon, Fiz 2013).

The growth of the size of the «industry» is also due to an increased order in the market, to the exit of small and irregular competitors, to more stability in drug regulation and to an improved intellectual property (IP) protection. IP issues, in particular, play a fundamental role for the development of the market. In recent years, pharmaceutical is among the industrial sector which has applied the highest number of patents in China: domestic firms are actually the main actors, but patent applications and granted patents of foreign enterprises are increasing as well.

Despite the dramatic growth of the market, and the expected profitability deriving from a booming demand, there are also some evidence of how challenging and risky this market could become for foreign investors. Foreign firms must cope with some persistent problems in China’s healthcare system: under-compensated doctors, insufficient reimbursement to hospital administrators, unclear regulation for drug discovery and clinical trials, high level of bribery.

The aim of the paper is to give a general overview of the current characteristics of the Chinese pharmaceutical market, of its main trends, as well as of main changes and expected evolution of the demand and of the supply in the industry. We also look at the balance between foreign and national firms’ position in the market, in term of Western interests for Chinese traditional knowledge embedded in Traditional Chinese Medicine (TCM) as well. We try to build a general picture of the industry and of main competitors.

The paper is a first research output of a wide research project, founded by the European Commission, aiming at analysing cooperation opportunities and potential synergies for Europe and China in the healthcare sector 2. Using an interdisciplinary approach, researches in the project are focusing on policies issues (at national and local level), on legal issues, on medical practices, as well as on trade and FDI opportunities in the healthcare related businesses. Understanding the Chinese pharmaceutical market features is a starting point for the analysis of the extent, determinants and characteristics of trade and FDI flows between Europe and China.

2 The project title is China and Europe taking care of healthcare solutions – CHETCH. See www.chetch.eu.
The paper is structured as follows. Paragraph 2 is focused on main trends in the Chinese pharmaceutical market: consumptions, production, import and export flows. Features of the industry and main competitors are described in Paragraph 3, while Paragraph 4 is about TMC specific market. Paragraph 5 analyses the motivation of the increasing presence of global pharmaceutical players in China. Paragraph 6 is focused on IP trends and on the role of national firms vs foreign competitors.

Before starting the analysis, a clarification is fundamental. The Chinese pharmaceutical market is a comprehensive industry, for manufacturing and sale of: synthetic chemicals and drugs, the so-called Western drugs, including OTC – over the counter medicine and prescription medicine; traditional Chinese medicines (TCM); medical devices, apparatus and instruments; hygiene materials; and pharmaceutical machinery. In this paper we focus only on Western and TCM drugs, for which the patenting issues are more relevant and seem to fit best our research goals.

2. THE CHANGING INTERNAL DEMAND FOR PHARMACEUTICAL PRODUCTS

China is the world’s third-largest pharmaceutical market in term of sale (IMS, 2010; Economic Research Institute, 2012), but it should become the second by 2020, behind only the United States. Several data and trends can help understand the speed and scope of changes undergoing in China.

Expenditure on health care is expected to increase from 4.7 per cent of GDP to 6 per cent/7 per cent in the next few years. China should reach a total amount of healthcare expenditure of 705.74 dollar by 2015, while per capita expenditure should be set at a level of 437 dollars in 2016, compared to 109.5 dollars in 2007 (Deloitte, 2011, p. 10). Following latest projections, China’s health-care spending should triple to 1 trillion dollars by 2020 (Burkitt, Whalen 2013).

As a result of such facts and figures, the Chinese pharmaceutical market is becoming increasingly attractive to Western firms. It is considered one of the World’s most important emerging pharmaceutical areas (Business Monitor International Ltd, 2011).

At the moment, sales from generics dominate the market (61.4 per cent of the market share in 2009), but newly patented products are expected «to gain shares from a huge and rapidly growing absolute value market» (Jan-Willem, 2011, p. 2).

Data on imports of pharmaceutical products show a strong expansion (+195 per cent of the value of flows from 2006 to 2010), and in parallel, exports are accelerating (+135 per cent over the same period) (see fig. 1)

In 2013, exports (+6.8 percent) and imports (15.2 percent) in the industry totalled 89.7 billion dollars (Xinhua, 2014).
From a demand-side perspective, demographic factors can be considered as one of the most relevant drivers of the growth of China’s pharmaceutical market.

China is the most populous country in the World, thus resulting in a large size potential market. At the same time, the population is ageing, also as a consequence of the one-child policy. Many observers consider this issue the country’s Achille heel: the total fertility rate is well below the replacement rate\(^3\), and the share of young population is decreasing rapidly\(^4\). Elderly people require appropriate, specific and long-term health care assistance, whose costs are much higher compared to those absorbed by young country population. Estimated increase of drug prescription market as a result of ageing trends is between 23 per cent and 40 per cent, while the increase for the OTC market should be between 40 per cent and 50 per cent by 2016 compared to 2011 (Deloitte, 2012, p. 7).

The higher sensitivity of Chinese people on healthcare services and products can also be related to higher living standards (Yuanjia, 2007, p. 296). As

\(^3\) «Over the past 30 years, China’s total fertility rate - the number of children a woman can expect to have during her lifetime – has fallen from 2.6, well above the rate needed to hold a population steady, to 1.56, well below that rate. Because very low fertility can become self-reinforcing, with children of one-child families wanting only one child themselves, China now probably faces a long period of ultra-low fertility, regardless of what happens to its one-child policy» (The Economist, April 21\(^{st}\) 2012).

\(^4\) People above the age of 60 now represent 13.3 per cent of the total, up from 10.3 per cent in 2000. In the same period, those under the age of 14 declined from 23 per cent to 17 per cent» (The Economist, May 5\(^{th}\) 2011).
the income per capita heightens, people can put more money in taking care of their health needs, upgrading the typical expenditure structure of consumption from basic good to more sophisticated goods. More and more high quality healthcare services are going to be requested by healthier Chinese people.

Urbanization is another important aspect to take into account: mass migration to the cities, from the agricultural areas, is resulting in a growing demand for pharmaceuticals (Yuanjia, 2007, p. 296). People is becoming more used to new lifestyles and has an easy access to retail pharmacies. The strong commitment made by the Government towards the upgrading of rural infrastructure should supports this trend (Deloitte, 2011, p. 4).

Beside from the demographic perspective, the rising consumption of pharmaceuticals is also related to the evolution of the typical needs/requests of the Chinese healthcare consumer. High longevity, combined with environmental and pollution problems are increasing chronic diseases like respiratory illnesses, cancer, diabetes, as well as obesity (Jan-Willem, 2011). New lifestyles are considered the cause of those diseases, sometimes called «lifestyle disease» – for which the use of lifestyle drugs are booming. Consumption of OTC is increasing as well, as a result of a new attitude towards self-medication. As reported by several surveys (Yuanjia, 2007, pp. 297-298), self medication is becoming more and more popular among Chinese people (Deloitte, 2011, p. 15). Since without a medical prescription patients can only have access to OTC drugs, a relevant increase in this market is expected in the future.

Last sign of the evolving Chinese consumer habits is the booming sales of drugs on line, because of the increasing attitude towards online shopping and the diffusion of the internet (Cripps, 2013).5

The cultural and social revolution that is taking place in the healthcare habits of Chinese people has a lot to do with institutional factors. In 2009 the government launched new plans to reshape the National health-care system (Rein, 2009). According to the Guidelines on Deepening the Reform of Health-care System (Freeman, Lu Boynton, 2011), the first phase of the reform aims to: increase the Basic Medical Insurance (BMI) to reach a 90 per cent of population coverage by 2011; revise the reimbursable medicine under BMI, i.e. of the essential drugs list; set a more restrict regulation on prices

5 China has more online shoppers (193 million) than any other country in the world. US has 170 million online consumers (Jingting, 2012). «By 2015, China will add nearly 200 million users, reaching an Internet population of more than 700 million-almost double the combined number of Japan and the US» (Michael et al., 2012). As a result of the booming on line sales, the On 8 January 2013, the State Food and Drug Administration released a Report concerning the results of its investigations into online pharmaceutical trading activities conducted pursuant to the Notice to Further Enhance Supervision and Administration over Internet Drug Information Services and Internet Drug Trading Services to Severely Crack Down on the Illegal Release of False Drug Information and Drug Sales (SFDA, 2012, n. 62, 24th February 2012).
by the National Development and Reform Commission (Deloitte, 2011, p. 3). The second phase of the reform should bring into effectiveness a universal health care system, providing «safe, effective, convenient and affordable» health services to urban and rural residents (Freeman, Lu Boynton, 2011).

3. EMERGING TRENDS IN THE CHINESE PHARMACEUTICAL INDUSTRY

The 12th Five-Year Plan (2011-2016), released in 2011, has also put strong attention to pharmaceutical industries (Tung, 2011; Deloitte, 2010, 2011; WHO, 2012, Wong et al., 2014). To expand health coverage and to reduce inefficiency in healthcare delivery, the Government is tackling the drug market. Specific actions are carried out to cut drug prices, reduce hospital reliance on drug revenues, increase the quality of coverage and diversify the insurance scheme, strengthen local companies (Wong et al., 2014, pp. 4-7).

On Jan 18th 2012, the Ministry of Industry and Information Technology released «the Pharmaceutical Industry «12th Five-Year» Development Plan». Eight main objectives are targeted for the industry, ranging from reinforcement and concentration, improved managerial and quality standards, to enhance international competitiveness through export and international ventures (CCCMHPFIE, 2012).

Healthcare reforms, while affecting consumptions, habits, and behaviours of Chinese people are therefore having a significant impact on the industry, which is still highly fragmented (Yuanjia et al., 2007) and with strong rivalry. National firms compete and cooperate with foreign companies that have a direct presence in the market. The three major firms – one Chinese and two big Western multinationals – share only 10 per cent of the market. Yangtze River Pharmaceutical Group is the leading player (3.6 per cent of the market’s value), AstraZeneca PLC controls 3.4 per cent and Pfizer Inc. 3.0 per cent (Datamonitor, 2011, p. 8).

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6 On October 8th 2012, the Information Office of the State Council released the Twelfth Five-Year Plan for Health Sector Development. The five-year plan builds upon three previous documents, the Twelfth Five-Year Plan for the National Economic and Social Development of the People's Republic of China, Opinions of the CPC Central Committee and the State Council on Deepening the Health Care System Reform, and the Notice of the State Council on Printing and Distributing the Strategy and Implementation Plan of Deepening the Health Care System Reform during the 12th Five-Year Plan Period. See http://www.uschinahcp.org/twelfth-five-year-plan-health-sector-development#sthash.1NgeZZuH.dpuf.

7 From a geography perspective, most firms are located in the south-eastern zone, including two well developed areas (Zhejiang and Guandong provinces) and three underdeveloped areas (Hebei province, Heilongjiang province and Sichuan province). The motivation of this concentration can be found in the economic factors that draw the growth in last years. (Yuanjia et al., 2007, p. 19).
Distribution is fragmented, inefficient and with poor transparency. As a result of the 12th Five year plan actions, a considerable effort of concentration is in place. By promoting national mergers and acquisitions the government is trying to build an effective distribution system based on few leading national companies, and some regional drug distribution firms (Deloitte, 2012, p. 16).

Above this general picture, in recent years, Chinese pharmaceutical market has made remarkable development, and its scale has increased rapidly. In 2010, the gross output of Chinese pharmaceutical market was 183.57 billion dollars: 118.25 billion dollars more compared to 2005. The industrial added value was 69.25 billion dollars, with an annual growth rate of 15.4 per cent, larger than that of GDP and national industrial average growth. Total profit increased as well, at a rate higher than that of production value (Ministry of Industry and Information Technology, 2012). What’s more, from 2000 to 2010, the number of pharmaceutical enterprises above the «designated size» 8 increased from 3,301 to 7,039; the value added tax was $ 1.39 billion in 2000, and increased to 8.08 billion dollars in 2010. From 2000 to 2010, revenues from principal business changed from 19.66 billion dollars to 168.66 billion dollars (tab. 1).

The number of firms has quite doubled from 2000 to 2010 and their scale has been also increasing. State-owned enterprises, foreign enterprises and private enterprises compete in the market (see tab. 2). Even if the number of private firms has experienced a sharp increase, their average size is

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8 As stated by the National Bureau of Statistics of China, the relevant size is reached when revenue from principal business is more than 5 million yuan. 5 million yuan equal to 0.7386 million dollars in 2010.
<table>
<thead>
<tr>
<th>Year</th>
<th>Foreign pharmaceutical enterprises</th>
<th>State-owned pharmaceutical enterprises</th>
<th>Private pharmaceutical enterprises</th>
<th>Other kind of enterprises*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N. units</td>
<td>Gross industrial output value ($100 mil)</td>
<td>Average size ($100 mil)</td>
<td>N. units</td>
</tr>
<tr>
<td>2000</td>
<td>542</td>
<td>48.8</td>
<td>0.09</td>
<td>1496</td>
</tr>
<tr>
<td>2001</td>
<td>568</td>
<td>54.73</td>
<td>0.1</td>
<td>1341</td>
</tr>
<tr>
<td>2002</td>
<td>604</td>
<td>63.43</td>
<td>0.11</td>
<td>1180</td>
</tr>
<tr>
<td>2003</td>
<td>701</td>
<td>76.84</td>
<td>0.11</td>
<td>1001</td>
</tr>
<tr>
<td>2004</td>
<td>743</td>
<td>100.4</td>
<td>0.14</td>
<td>939</td>
</tr>
<tr>
<td>2005</td>
<td>890</td>
<td>127.93</td>
<td>0.14</td>
<td>676</td>
</tr>
<tr>
<td>2006</td>
<td>955</td>
<td>159.44</td>
<td>0.17</td>
<td>590</td>
</tr>
<tr>
<td>2007</td>
<td>1035</td>
<td>214.1</td>
<td>0.21</td>
<td>559</td>
</tr>
<tr>
<td>2008</td>
<td>1144</td>
<td>307.12</td>
<td>0.27</td>
<td>527</td>
</tr>
<tr>
<td>2009</td>
<td>1144</td>
<td>386.18</td>
<td>0.34</td>
<td>508</td>
</tr>
<tr>
<td>2010</td>
<td>1140</td>
<td>468.42</td>
<td>0.41</td>
<td>507</td>
</tr>
</tbody>
</table>

*Note:* Other kind of Enterprises includes: collective–owned enterprises, share-holding cooperative enterprises, share-holding enterprises.

*Source:* China Statistical Yearbook, several years (http://www.stats.gov.cn/).
much lower than SOEs and foreign firms. SOEs, on their side, have been experiencing a period of reorganization and rationalization: their number decreased from around 1,500 to around 500, but their average size grew significantly, as well as their gross domestic output.

Pushed by factors as market growth, technical progress, increased investment and mergers and reorganization initiatives, some large-scale enterprises are appearing in China and they are becoming leaders in basic drugs supply. There was only 1 pharmaceutical firm with more than 10 billion yuan (1.22 billion dollars) sale proceeds in 2005, while in 2010 they were 10. In 2010, 1,125 out of the 7,039 pharmaceutical firms in the market were large and medium-sized, controlling 694.8 billion yuan (102.64 billion dollars) of the pharmaceutical industrial output value (59.17 per cent of total value)⁹. Pharmaceutical enterprises with more than 5 billion yuan (0.61 billion dollars) sales were 17 in 2010, while only 3 in 2005 (Ministry of Industry and Information Technology, 2012). Among them, Yangtze River Pharmaceutical Group, Harbin pharmaceutical Group, China Shijiazhuang Pharmaceutical Company, TongRenTang, Guangzhou Pharmaceuticals Corporation, Weigao Holding Co. Ltd are gaining market shares.

At the same time, new enterprises, such as Jiangsu Hengrui Medicine Co., Zhejiang Hisun Pharmaceutical Co. Ltd., Tasly Group, Shineway Pharmaceutical Group, Mindray, are developing rapidly. Some backbone enterprises, such as China National Pharmaceutical Group Corporation, Shanghai Pharmaceutical Co., Ltd., Sino-Swed Pharmaceutical Corp.Ltd., are also growing rapidly by merger and acquisition, achieving integration of industry chain, enhancing their competitiveness.

Enterprises listed in table 3 were the top 20 firms in Chinese pharmacy market. Yangtze River Pharmaceutical Group is the first as for prime operating revenue, while Shanghai Pharmaceutical (group) Co. Ltd had most gross assets. Looking at total profit, China National Pharmaceutical Group Corporation ranked first.

The presence of foreign enterprises in China is increasing, as well as their size. From the absolute value of indicators, we can find that there were only 542 enterprises in 2000, while in 2010 they were 1,140. The total assets they hold moved from 6.4 to 44.34 billion dollars in 2010. In 2010, revenues from principal business reached 44.77 billion (ten times of that in 2000), while total profit was about 6 billion in 2010 (15 times of that in 2000) (tab. 4).

⁹ Large-sized industrial enterprises means that the number of employed persons is more than 2000, the sale revenue is more than 300 million yuan (44.31 million dollar in 2010), the total assets is more than 400 millions yuan (59.09 million dollars in 2010). Medium-sized Industrial Enterprises means that the number of employed persons is between 300 and 2000, the sale revenue is between 30 and 300 million yuan (4.43-44.31 million dollar in 2010), the total assets is between 40 and 400 million yuan (5.91-59.09 million dollars in 2010).
In 2010, firms from abroad produced 27.01 per cent of gross industrial output value, 26.55 per cent of prime operating revenue, 30.89 per cent of total profit, and 27.1 per cent of total assets (tab. 5). Anyway, despite the importance of foreign companies, their share in the market is not overtaking national firms, that are keeping their role and competitive position.
Competition and rivalry among foreign firms and local companies is strongly affected by the changing scenario for proprietary technology. While in the past foreign multinationals held patent protections of some of the world’s best-selling drugs 10, the situation is going to change rapidly as several drugs are going off patent within the next five years. This wave of patent-ed drug expirations will boost manufacturing and sales of the related generics. Chinese state-owned firms and private companies will probably lead this market (Deloitte, 2012, p. 13), while foreign enterprises are supposed to play a more important role in non-generic drug industry.

10 As an example, in the insulin market Novo Nordisk, Eli Lilly and Sanofi controlled more than 90 per cent of the sales in 2010. See China Medical Association, The Development of Insulin Market in China, at http://www.chinamsr.com/2011/0124/21748.shtml.
The pharmaceutical industry in China is peculiar also for the role played by TCM products and producers. Traditional Chinese medicines include proprietary Chinese medicines, raw materials and ingredients, as well as herbal extracts. Even though Chinese people are more and more addressing their health problems using Western medicine; the majority of them still use TCM (WHO, 2011, p. 69). TCM is considered part of the Chinese culture and tradition, to be preserved, protected and promoted also abroad.

The Government has been issuing several measures, in the past few years, to promote the development of a modern TCM industry, as well as the integration of TCM into the national health care system (WHO, 2011, p. 69). 2009 was launched as TCM Hospital Management Year and several specific actions were promoted by the State Administration of Traditional Chinese Medicine (SATCM) to disseminate the advantages of TCM among people and practitioners, as well as to improve quality, safety, and efficiency in the industry. In 2010, the Minister of Health identified some key priority actions for TCM development. Among them the need for «increasing policy support for TCM; strengthening research on key TCM issues and building capacity for TCM research; establishing well-known TCM hospitals and departments; promoting a culture of TCM; and strengthening international cooperation and communication on TCM» (WHO, 2011, p. 69).

The importance of TCM has been clearly recognized by The Twelfth Five-Year Plan for Health Sector Development. «Actively develop traditional Chinese medicine» is one of the key actions of the Plan.

TCM is important both to support the organization and management of the new Chinese healthcare systems, and to promote national industry competitiveness abroad. The Government aims to: improve legislation, information and standards, in the light of a strong integration with western medicine; increase research and innovation in the TCM; strengthen the organization of delivery of TCM services system, from primary health facilities, retail pharmacies, to diagnosis services.

Also, the development of a competitive TCM industry is considered a priority. Chinese firms are supposed to gain a competitive position at global level (The Twelfth Five-Year Plan for Health Sector Development, p. 12) and to expand their export propensity. The government is improving industrial standards to help companies deal with technology and patenting issues that arise in the international market, as well as to face trade barriers and other obstacles that Chinese firms encounter abroad. For China’s TCM exporters, the main challenges are technical standards, which are especially stringent for formulary TCMs, and registration in developed markets (Jie, 2012). Many overseas authorities, as a result of a poor knowledge of TCM, apply the stand-
ards relating to synthetic medicines to TCMs. This means that chemical indexing and data garnered from clinical trials are needed. However, scientific research into TCMs, especially into compound formulary medicines, only started in the mid-1980s and so no long-running databases are available.

In addition to those technical problems, new rules concerning market registration are also hindering Chinese companies’ strategies to enter international markets.

The Government is therefore supporting scientific research on many ingredients used in TCM, as well as the introduction of patent rights and modern applications for TCM-related products (PWC, 2009, p. 4). Several bodies, including Chambers of Commerce, government departments, research institutes and trading agencies are working to develop industry-supporting policies, such as the establishment of international trade guidance for traditional Chinese medicine (CCCMHPIE, 2012b). There is a lack of unified, systematic regulations to assess the safety, efficacy and the quality of TCM products. There are no national TCM standards or guidelines for TCM clinical trials: evidenced-based TCM product testing and research are still needed. Also the quality of TCM education needs to be strengthened, and the management and supervision of TCM institutions to improve the qualifications of TCM practitioners and the correct use of TCM within the new national healthcare system (WHO, 2011, p. 69) (tab. 6).

After the release of the 12th five year Plan, the value of traditional Chinese medicine exported from China is expected to increase by more than 10 percent a year. The demand for TCM in the international market increased from 600 million dollars in 1996 to 1.8 billion dollars in 2010. The value of China’s exports of the medicine reached 2.33 billion dollars in 2011, with an increase of 36.2 percent from the year before. Chinese companies are trying to make prices more stable and modify the composition of the exports. During the past few years, the proportion of raw materials and ingredients among exports has decreased and that of herbal extracts has risen. Herbal extracts can be more profitable, as they are semi-processed products with more intense added value.

\[\text{11 In Europe, the Herbal Directive ( Directive 2004/24/EC) was adopted to facilitate the placing on the EU market of traditional herbal medicinal products. The Directive introduces a simplified procedure to allow the registration of traditional herbal medicinal products without requiring safety tests and clinical trials. The Directive gave a long transitional period of 7 years to register traditional herbal medicinal products that were already on the market on the date of entry into force of the Directive. The transitional period ended on 30 April 2011 (see: http://ec.europa.eu/dgs/health_consumer/docs/traditional_herbal_medicinal_products_en.pdf). Despite the efforts of the European Commission, the Directive failed its goals, as it is particularly unsuitable for multi-herb products. As a result, only few herbal products associated with TCM has been registered (Alliance for Natural Health, 2010).} \]
As shown in the previous paragraphs, foreign firms play an increasing role in China. Most of them have made collaborative partnerships with Chinese companies to start manufacturing plants, business operations facilities, marketing divisions, and research facilities.

As a result of the Open Door Policy, China has been attracting huge flows of FDI and has become the first recipient of FDI among emerging market, the second after the US in absolute term (UNCTAD, WIR, 2011). The Chinese pharmaceutical industry has been one of the most interesting target for foreign investors. At the end of 1998, there were 1,500 pharmaceutical firms with foreign ownership (Jiang, 2005, p. 22). Since 2000, investments have nearly doubled (fig. 2). Large multinational groups from North America, Western Europe, and Asia were attracted to China, as a result of a more friendly and favourable business and institutional environment. Operating in the Chinese market is still considered high-risky, time-consuming and expensive compared to other emerging markets due to stringent regulations concerning safety and efficacy. Anyway, the interest...
for China is increasing and several factors can explain this trend. Based on the Dunning model (Dunning, Lundan 2008), key motivations can be highlighted.

5.1. Market seeking motivations

China is an important sales market for the internal, booming demand (Jiang, 2005)\textsuperscript{12}. As mentioned above, China is supposed to become the second world largest pharmaceutical market by 2020, as a result of demographic changes, improved life standards, government actions. Upgrading health care behaviours and consumptions, Chinese people are changing their attitude towards Traditional Chinese Medicine practices. Western medicines are considered more effective, especially as for life-saving drugs are concerned, antibiotics most of all.

China is also strategic for Western companies to reach other nearby Asian emerging markets: while operating in the country, China can offer a logistic and commercial platform to penetrate them.

\textsuperscript{12} In the study developed by Jiang (2005) on determinants of FDI into Chinese pharmaceutical market, the author found out that FDI\textsuperscript{s} were pushed mainly by China\textsuperscript{'}s specific location factors. China\textsuperscript{'}s market size and its potentials played the most important role. Other relevant motivations were: rapid economic development and growth, China\textsuperscript{'}s Open Door Policy and relatively stable political conditions.
5.2. Efficiency seeking motivations

China is a market for delocalizing the production of high quality and price competitive raw materials. In some specific market segment (antibiotics, cephalosporin or other high chemical substances), producing in China is a necessity. In the West, in fact, environmental and safety rules make it impossible to set up fermentation and chemical plants associated with pharmaceutical plants.

The delocalization phenomenon is not recent. Internationalization in China began in the middle Eighties, when important pharmaceutical groups settled fermentation plants in the North of the country to produce basic products for antibiotics. During the Nineties, production in China evolved, including more sophisticated products/materials. Nowadays, China is the world leader in the production of pharmaceutical base materials, that are then re-imported in the Western markets to produce finished goods (medicines). This phenomenon could justify the huge increase in imports and exports volumes, as well.

5.3. Strategic asset seeking motivations: R&D providers

China is the frontier to develop applied research programs. Big players such as Novartis, Pfizer, Merck Serono, AstraZeneca, Roche have established research centres in China (Choi et al., 2011). The strategic idea is to leave good R&D departments in the country of origin to develop basic programs. The implementation phases and applied research activities are carried out in China, to reduce time for drug improvement and to cut costs. The core phases related to market entry of a new drug are left in the West, partly because of stringent rules of trials required by the US and European agencies. All other, subsequent, trials and market extension activities are developed in China, where skilled labour workforce, talented scientists and leading University research centres are available (Tung, 2011).

China is more and more considered as a platform to develop innovative drugs (Choi et al., 2011, p. 6). Chinese Contract Research Organizations (CROS) are considered the backbone of Chinese R&D. They support the pharmaceutical and biotechnology industries on a contract basis, providing spe-

13 «The globalisation process of industry-sponsored clinical trials is growing. More and more study sites are located outside North America and Europe, especially phase III trials. From the latest analysis, there are now more phase II-III trial sites in the rest of the world (ROW) than Europe; 27.0 per cent versus 24.6 per cent, respectively. [...] The major emerging regions are still Eastern Europe, Asia and Latin America» (Karlberg, Speers 2010, p. 58).
specific services: biopharmaceutical development, preclinical research, clinical research, as well as clinical trials management 14.

Chinese CROs are expanding the activity of the value chain that they can serve, from early stage phases (genetic research, functional genomics, etc.), lead discovery (compound generation, screening, lead optimization), preclinical trials, pharmaceutical development, to clinical trials (Choi et al., 2011). Large and global organizations as well as niche specialty groups are offering reduced costs, high flexibility, high level research premises and high quality services. CROs are considered as a valuable source of innovation for Western pharmaceutical companies to develop strategic alliances to boost both research and development of new products. At the same time, CROs are economic and effective way to buy «on demand» innovation.

5.4. Strategic asset seeking motivations: exploiting TCM products and practices

Part of the interest of key Western pharmaceutical companies into the Chinese market can also be related to the potentials of TCM (Shen, 2008, p. 22). Many Western countries have set up TCM institutions, including the United States, Europe, Japan and South Korea which are investing heavily in related research and medication development and industry (Shan, 2013).

Despite the increase popularity of alternative medicines in recent years around the world (Datamonitor, 2010, p. 15), Chinese companies do not have a primary role at world level. Local companies dominate the internal market (PWC, 2009, p. 4) and most of them have a low internationalization profile (Zhang, 2009; 2011): only about 3 percent of the global TCM market is in the Chinese’s hands. There is therefore huge space for partnership and alliances by Western companies that could help pushing the Chinese firm in the international arena. One of the key problems in expanding abroad is related to intellectual property rights, trademark registration and patent applications. Chinese companies are still weak in promoting their products on the global market (Zhang, 2011).

5.5. Challenges and obstacles

Despite the great opportunities offered by the Chinese market, compared to weak sales growth in developed markets and revenue reduction because of competition from generics multinational firms, Western firms are encountering several problems in China.

14 At the end of 2007 the value of R&D outsourced to China, mostly through CROs, was worth 550 million dollars (Shen, 2008).
As a result of slowdown in the Chinese economy and corruption scandals, the market is still growing but at weaker rate (Armstrong, 2013) than in the past. In 2013, main revenues in the industry amounted to 355.4 billion dollars (+17.9 percent increase on a year basis) and pharmaceutical profits rose 17.6 percent (Xinhua, 2014).

The recent case of corruption against GlaxoSmithKline Plc is considered emblematic of the some new dynamics within the industry (Jourdan, Ruwitch 2014). Foreign firms might have violated anti-corruption laws or artificially inflated drug prices, to be able to smooth business ties between sales representatives and doctors. The State Administration for Industry and Commerce (SAIC), the country’s public security bureau (PSB) and other local authorities, are increasing their visits to foreign drug firms in search for evidence of crime (Jourdan, Ruwitch 2014). At the same time, the political pressure on policy makers is strong to address inequities and high costs of healthcare. This will probably bring additional public pressure on multinational firms to lower prices (Shobert, 2014).

Western drugmakers are also facing more intense competition from Chinese firms. Foreign companies are more and more held to different standards than their domestic Chinese competitors (Shober, 2014). The government wants to transform low-cost manufacturers of generics into companies capable of turning out branded medicines (Armstrong, 2013). The level of competition is getting more and more intense.

6. INNOVATION AND PATENTING TRENDS

To better understand industry dynamics, it is important to focus on innovation and IP trends. Technological innovation achievements in the Chinese pharmaceutical market are remarkable. The Government has launched an investment campaign on innovation medicine, to support projects on «significant new drug». Several state-level technical centers were opened as a result of some «Industry-University-Institute» cooperation programs. Innovative medicines (such as antofloxacin hydrochloride and recombinant helicobacter pylori vaccine) were approved. Some monoclonal antibody agents (such as recombinant human tumor necrosis factor) had achieved industrialization. Breakthrough was made in cells culture in a large scale. The production technology of some products (such as amoxicillin and vitamin E) was enhanced. Achievements were made in the area of product and technology development (Ministry of Industry and Information Technology, 2012).

In such a flourishing environment, China has been very active in patent applications. According to the statistics from WIPO in 2011, the quantity of Chinese patent applications was increasing rapidly compared with other leading
countries. China applied 10,894 patents in 2010, which was 7 times of that in 2000. China became the second largest patent application country in the pharmaceutical domain after US exceeding Japan and German in 2005 (see tab. 7). Chinese enterprises have accelerated product registration also in developed markets. In 2013, Chinese medical companies submitted 150 files to the US Food and Drug Administration and 172 similar applications were submitted to the European Directorate for Quality Medicines reached (cccmhpie, 2014).

Considering the industrial sectors involved in patenting in China, from 2000 to 2009, pharmaceutical has been one of the leading industrial sector for number of applications applied (tab. 8).

Domestic firms lead the patent application ranking (see tab. 9). Taking medicine manufacturing industry as an example, there were only 273 patent applications in 1995, and this number increased to 8,601 in 2009. There were only 183 patents granted in 1995, and this number increased to 6,017 in 2009. In the meantime, the patent applications and granted patents of foreign enterprises were also increasing. From 23 patent applications made by foreign enterprises in 1995, the number increased to 923 in 2009, while granted patents increased from 19 in 1995 to 986 in 2009.

**Tab. 7. The pharmaceutical patent application by leading countries (2000-2009)**

<table>
<thead>
<tr>
<th>Year</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>The United States of America</td>
<td>9,989</td>
<td>11,386</td>
<td>15,069</td>
<td>16,877</td>
<td>18,584</td>
<td>21,872</td>
<td>22,155</td>
<td>21,884</td>
<td>20,957</td>
<td>19,497</td>
</tr>
<tr>
<td>China</td>
<td>1,347</td>
<td>2,509</td>
<td>3,445</td>
<td>4,178</td>
<td>4,689</td>
<td>8,385</td>
<td>9,578</td>
<td>11,157</td>
<td>10,962</td>
<td>10,894</td>
</tr>
<tr>
<td>Japan</td>
<td>2,949</td>
<td>3,240</td>
<td>3,814</td>
<td>4,514</td>
<td>5,112</td>
<td>5,528</td>
<td>5,694</td>
<td>5,358</td>
<td>5,165</td>
<td>5,297</td>
</tr>
<tr>
<td>Germany</td>
<td>2,708</td>
<td>2,990</td>
<td>3,965</td>
<td>4,428</td>
<td>4,727</td>
<td>5,236</td>
<td>4,814</td>
<td>4,229</td>
<td>3,899</td>
<td>3,649</td>
</tr>
<tr>
<td>Switzerland</td>
<td>854</td>
<td>1,129</td>
<td>1,504</td>
<td>1,993</td>
<td>2,598</td>
<td>2,991</td>
<td>2,839</td>
<td>3,098</td>
<td>3,332</td>
<td>2,992</td>
</tr>
<tr>
<td>France</td>
<td>1,647</td>
<td>1,667</td>
<td>1,875</td>
<td>1,881</td>
<td>2,134</td>
<td>2,159</td>
<td>2,174</td>
<td>2,234</td>
<td>2,326</td>
<td>2,488</td>
</tr>
<tr>
<td>Britain</td>
<td>1,933</td>
<td>1,866</td>
<td>1,944</td>
<td>2,122</td>
<td>2,306</td>
<td>2,268</td>
<td>2,203</td>
<td>2,215</td>
<td>2,184</td>
<td>2,103</td>
</tr>
<tr>
<td>The Republic of Korea</td>
<td>518</td>
<td>648</td>
<td>880</td>
<td>1,089</td>
<td>1,140</td>
<td>1,295</td>
<td>1,186</td>
<td>1,149</td>
<td>1,342</td>
<td>1,842</td>
</tr>
</tbody>
</table>


**Tab. 8. Patent applications published by field of Technology from 2000 to 2009, in China**

<table>
<thead>
<tr>
<th>Field of Technology</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals</td>
<td>1,347</td>
<td>2,509</td>
<td>3,445</td>
<td>4,178</td>
<td>4,689</td>
<td>8,385</td>
<td>9,578</td>
<td>11,157</td>
<td>10,962</td>
<td>10,894</td>
</tr>
<tr>
<td>Telecommunications</td>
<td>270</td>
<td>534</td>
<td>933</td>
<td>1,697</td>
<td>2,376</td>
<td>3,560</td>
<td>5,679</td>
<td>7,190</td>
<td>10,055</td>
<td>6,782</td>
</tr>
<tr>
<td>Computer technology</td>
<td>778</td>
<td>1,156</td>
<td>1,740</td>
<td>2,683</td>
<td>3,346</td>
<td>4,710</td>
<td>5,226</td>
<td>7,336</td>
<td>9,645</td>
<td>11,818</td>
</tr>
<tr>
<td>Biotechnology</td>
<td>428</td>
<td>2,570</td>
<td>2,198</td>
<td>1,343</td>
<td>1,561</td>
<td>2,329</td>
<td>2,472</td>
<td>2,787</td>
<td>3,873</td>
<td>4,574</td>
</tr>
<tr>
<td>Chemical engineering</td>
<td>428</td>
<td>578</td>
<td>692</td>
<td>1,053</td>
<td>1,131</td>
<td>1,877</td>
<td>2,191</td>
<td>2,884</td>
<td>4,061</td>
<td>4,785</td>
</tr>
<tr>
<td>Environmental technology</td>
<td>344</td>
<td>477</td>
<td>656</td>
<td>862</td>
<td>1,030</td>
<td>1,688</td>
<td>1,967</td>
<td>2,308</td>
<td>3,232</td>
<td>4,020</td>
</tr>
</tbody>
</table>

Patents are becoming more and more popular also for TCM. The Chinese State Intellectual Property reported that since 1985, more than 68,000 TCM patents were registered. Over 66,000 of them were from domestic applicants (Jingjing, 2010). At the same time, China has applied for 3,000 TCM patents in foreign countries, but foreign countries applied for more than 10,000 TCM patents in China. Western firms do not appear to have a significant role in the database of Traditional Chinese Medicine patents (Spigarelli, Wei, 2012).

The increasing role of foreign enterprises in patent applications and granted patents can be considered a combined consequence of improved IP protection made by the Government and of the booming pharmaceutical demand in China (Xu, Shao 2013).

The Government has adopted industrial and regulatory policies, such as preferential drug pricing and hospital drug procurement policies. The aim is to support research-based multinational firms and large domestic enterprises. At the same time, market access for foreign companies has been improved, also to strengthen intellectual property protection. A huge effort has been made also to regulate and approve active pharmaceutical ingredients and audit drug production facilities (Shen, 2008, p. 21). Anyway, there are also some evidence of growing protection of national interest, as in the case of the recently amended Chinese patent law. On May 1st 2012, a revised version of the Measures for the Compulsory Licensing for Patent Implementation came into effect. The amendment allows China to “issue compulsory licenses to eli-

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Patent application</th>
<th>Total Patent granted</th>
<th>Foreign enterprises Patent application</th>
<th>Foreign enterprises Patent granted</th>
<th>Foreign enterprises Patent application (proportion, %)</th>
<th>Foreign enterprises Patent granted (proportion, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995</td>
<td>273</td>
<td>183</td>
<td>23</td>
<td>19</td>
<td>8.42</td>
<td>10.38</td>
</tr>
<tr>
<td>1996</td>
<td>168</td>
<td>113</td>
<td>67</td>
<td>54</td>
<td>39.88</td>
<td>47.79</td>
</tr>
<tr>
<td>1997</td>
<td>257</td>
<td>134</td>
<td>38</td>
<td>25</td>
<td>14.79</td>
<td>18.66</td>
</tr>
<tr>
<td>1998</td>
<td>275</td>
<td>224</td>
<td>95</td>
<td>62</td>
<td>34.55</td>
<td>27.68</td>
</tr>
<tr>
<td>1999</td>
<td>283</td>
<td>232</td>
<td>30</td>
<td>16</td>
<td>10.60</td>
<td>6.90</td>
</tr>
<tr>
<td>2000</td>
<td>547</td>
<td>414</td>
<td>87</td>
<td>168</td>
<td>15.90</td>
<td>40.58</td>
</tr>
<tr>
<td>2001</td>
<td>735</td>
<td>308</td>
<td>139</td>
<td>62</td>
<td>18.91</td>
<td>20.13</td>
</tr>
<tr>
<td>2002</td>
<td>999</td>
<td>484</td>
<td>70</td>
<td>64</td>
<td>7.01</td>
<td>13.22</td>
</tr>
<tr>
<td>2003</td>
<td>1,305</td>
<td>459</td>
<td>208</td>
<td>91</td>
<td>15.94</td>
<td>19.83</td>
</tr>
<tr>
<td>2004</td>
<td>1,696</td>
<td>902</td>
<td>354</td>
<td>145</td>
<td>20.87</td>
<td>16.08</td>
</tr>
<tr>
<td>2005</td>
<td>2,708</td>
<td>1,134</td>
<td>594</td>
<td>273</td>
<td>21.94</td>
<td>24.07</td>
</tr>
<tr>
<td>2006</td>
<td>2,383</td>
<td>1,965</td>
<td>575</td>
<td>495</td>
<td>24.13</td>
<td>25.19</td>
</tr>
<tr>
<td>2007</td>
<td>3,056</td>
<td>2,482</td>
<td>589</td>
<td>747</td>
<td>19.27</td>
<td>30.10</td>
</tr>
<tr>
<td>2008</td>
<td>3,917</td>
<td>3,170</td>
<td>863</td>
<td>853</td>
<td>22.03</td>
<td>26.91</td>
</tr>
<tr>
<td>2009</td>
<td>8,601</td>
<td>6,017</td>
<td>923</td>
<td>766</td>
<td>10.73</td>
<td>12.73</td>
</tr>
<tr>
<td>2010</td>
<td>5,767</td>
<td>5,672</td>
<td>841</td>
<td>986</td>
<td>14.58</td>
<td>17.38</td>
</tr>
</tbody>
</table>

Source: China Statistical Yearbook On High Technology Industry, several years.
gible companies to produce generic versions of patented drugs during state emergencies, or unusual circumstances, or in the interests of the public. For «reasons of public health», eligible drug makers can also ask to export these medicines to other countries, including members of the World Trade Organisation (Lyn, 2012). This legislation is considered a further proof that China is shaping its legal framework, to make use of legal space to produce generic drug.

7. CONCLUSIONS

As the first research output of a wide European funded project on Europe-China cooperation in the healthcare sector, this paper assessed demand and supply-driven dynamics within the Chinese pharmaceutical industry.

The Chinese pharmaceutical market is booming a result of several forces that have to do with demographic changes, improved living standards, and public policies. In particular, the Government has been embracing a large reform of the healthcare system to upgrade the quality and coverage of healthcare assistance by 2020.

Chinese middle and upper classes are changing their attitude towards healthcare consumptions. Western medicines are now considered more effective than traditional Chinese medicine practices, especially as for life-saving drugs are concerned, antibiotics most of all.

From an industry perspective, the Chinese market seems to be evolving into a highly competitive marketplace, where Chinese firms are acting not only to keep market shares compared to Western firms, but also to conquer an active and strategic position in the global value chain. An R&D driven re-evolution of the market is taking place, thanks to the Government’s policies aiming at building a friendly environment for Western firms, attracted in China not only to be partners of local actors and grasp knowledge from them, but also to become customers of a more and more qualified R&D oriented supply. At the same time, the Government is supporting the growth of global-national champions, reorganizing SOEs and pushing new private pharmaceutical firms. The rise of Chinese innovative and large multinationals is promoted (Shen, 2008, p. 21).

Easier market access, revenue growth potentials, booming demand have been attracting in the last few years multinational pharmaceutical firms in China, looking for market opportunities to offset maturing patents and price pressures in their home markets (Shobert, 2014). Despite the potentials of the market, some relevant emerging pitfalls should be taken into consideration by Western firms while assessing opportunities in China:

– the Government is building a new Chinese life science sector, increasing the level of innovation and promoting global competitiveness of the na-
tional industry. The conditions of access and competition in the market for Western companies will be inevitably affected, in a pejorative sense;

– while China intends to develop a domestic life science sector, the government is promoting technology transfer programs between multinational firms, Chinese research institutions, local industry partners. Strategic alliance to promote spillover effects are involving Western firms (Di Tommaso, Huang 2010; Barbieri et al., 2013). The question is whether the empowerment of Chinese competitors will be adequately offset for Western firms – in terms of revenues - and will allow them to safeguards global R&D investments;

– while a universal coverage is promoted, there is a growing public resentment over inadequate healthcare. To face this situation, the Government is trying and re-direct public frustrations away from policy makers and towards private, for-profit entities. Bribery cases and inspection campaigns for Western firms is considered a proof of this trend.

As a result of the industry analysis performed in the paper, further steps in the European-funded project will be developed. Researchers will: define the level of integration reached so far in the healthcare industries in Europe and China considering both trade, cooperation initiatives and investment flows; map European investments in the healthcare related industries; clarify obstacles, barriers and difficulties faced in initiating, maintaining and consolidating business initiatives in China.

Some key implications can be highlighted for scholars involved in this research field. Government policies (ie. institutional factors) have a huge influence on composition, competition and evolution of industrial sectors in China, as they produce huge social, economic and industry shifts. In the case of the pharmaceutical sector, major impacts of government policy range from support to local firms towards new specialization (to upgrade their role in the value chain) and competitiveness (more effectiveness of patenting strategies and encouraged globalization), to increased attractiveness of the local market to foreign investors. As Government policy vary consistently across sectors, assessing FDI or trade trends would require to consider the impact of such institutional voids. Very detailed sectoral level analysis is required including in-depth focus on pharmaceuticals, TCM products, and medical devices and equipment. General trends of trade and FDI in the healthcare sector might not be significant in the light of specific measures of intervention that affect sectoral dynamics.

Entrepreneurs and policy makers should be aware of the highlighted trends in the Chinese market as well. The analysis has confirmed the tremendous changes that China is experiencing in the approach to healthcare needs of the population. China is shifting towards a new universal healthcare system. Among key changes to be promoted, there is the need to upgrade industry capabilities to produce healthcare products and to play an active role
in supplying solutions to the market. Western industries have reached a scale of efficiency, global competitiveness and sophisticated approaches to innovation in the pharmaceutical sector (including medical devices, apparatus and instruments; hygiene materials; pharmaceutical machinery). China can therefore offer huge opportunities to «export» solutions, best practices and to create business opportunities. Specific policy (at country level) and business strategy could therefore tackle the Chinese request/eager in the healthcare sector. At the same time, pitfalls of the market, as described above, make the Chinese marketplace more and more challenging.

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China Statistical Yearbook On High Technology Industry, several years.

China Statistical Yearbook, several years (http://www.stats.gov.cn/)


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