波蘭生物科技及醫藥產業概況[1]

2018.10.12駐波蘭經濟組整理

一、波蘭生物技術及醫藥之發展方向

應用分子生物學和基因工程之醫療技術在現代醫學中越來越重要。生命醫學相關科技之發展，促進新一代生物科技製藥和個人化用藥(personalized medicine)之蓬勃發展。全球之生物技術和製藥公司，其成功越來越取決於如何將研究成果快速上市，以及開發全球市場為導向之產品，而不能再侷限於國內市場。這個事實已扭轉並開始引導波蘭生物科技業者之發展方向。

儘管醫療使用之生物科技藥物越來越普遍，但在波蘭開始推動創新經濟行動計畫(the Operational Programme Innovative Economy, OPIE[2])前，除Bioton公司所生產的重組胰島素(recombinant insulin)，尚無任何其他生物科技製藥。這種情況已逐漸改變，波蘭之生物技術公司（例如MABION，是該行業領導者）和大型製藥廠（例如ZF POLPHARMA公司）已開始運用biosimilars技術生產藥品。基於波蘭藥品市場的規模（估計銷售價值每年約為300億波幣），以及該產業發展所需的人才充沛及歐盟資金之支援，biosimilars將成為波蘭生技製藥行業發展重點之一。此外，越來越多的生物科技製藥專利保護即將到期，而生物科技製藥比生產傳統學名藥之技術門檻更高，波蘭業者必須先掌握此技術，才有能力達到終極目標－成功地將生物技術應用於新藥開發及上市。

波蘭業者有揚棄生產學名藥等傳統商業模式，而朝研發新藥發展之趨勢。這種趨勢在Adamed Group、Celon Pharma等生產傳統學名藥公司，以及後來才設立的公司中都很明顯，例如：Selvita、Blirt、Celther POLSKA、Stem Cells Spin、Proteon Pharmaceuticals等，該等業者將生物技術應用在製藥上，並致力於以全球市場為目標開發新藥。越來

[1] 資料來源：” Report on Polish Biotech and Pharma”, 該報告係由波蘭經濟部(Ministry of Economy，2015 年 10 月 PiS 黨勝選並執政後進行組織改造，將經濟部更名為經濟發展部(Ministry of Economic Development),新增歐盟補助款之分配權, 2018 年 1 月再改為 Ministry of Investment and Development, 另新設 Ministry of Enterprise and Technology)及歐盟區域發展基金(European Reginal Development Fund)結合若干生技醫藥研發顧問公司於 2013 年共同發布。

[2] OPIE 為波蘭申請歐盟補助款之國家型計畫(2007-2013)”The Promotion of Polish Ecoomy in International Markets”項下之子計畫。2014-2020 之 Operational Programme 之優先目標 Smart Growth 項下, 亦針對企業之創新、研發、國際化提供補助。

越多年輕有活力的生物技術和製藥業者將「波蘭生物技術和製藥走向全球(Polish biotech and pharma go global)」列為策略發展目標。

波蘭的生物技術公司雖然很少（約70家[3]），但該行業正在蓬勃發展，且生物技術新創企業(startup)的發展榮景仍然可期。大量的科學團隊投入生物技術研發、有利startup發展的基礎設施（育成機制，技術園區）、合格人才、對應用研究的興趣提升（包括提升對研究成果的專利保護）等，上述因素共同形塑有利創新型startup發展的有利環境。

生物技術和製藥行業的發展，使得相關新創企業有機會從歐盟基金(European Union Fund)和波蘭政府主導之基金（例如the National Center for Research and Development, Polish Agency for Enterprise Development, National Capital Fund）獲得補助。然而，能否成功吸引私人投資－包括個人和機構（例如風險投資基金），對startup同樣重要。許多投資人已經注意到該行業的潛力，例如，從華沙NewConnect證券交易所上市的生物技術公司的市值就可看出。波蘭生物技術和製藥行業已經吸引越來越多地金融業者之投資，預期此趨勢在未來幾年會持續，並將成為該部門發展和潛力的客觀指標。

二、波蘭生技及醫藥企業

目前波蘭約有70家生物技術公司和140多家製藥公司；其中屬「核心生物技術(core biotech)」者特別值得關注。該等業者主要開發創新的生物技術產品。研發佔其營運資金至少50%。這些公司使用DNA重組技術、現代分子生物學技術、細胞生物學和組織工程(tissue engineering)等開發新技術。儘管它們占波蘭生物技術公司總數的比例仍然很小（15%），但卻極活躍且具有巨大發展潛力。

絕大多數波蘭生物技術公司致力於開發創新產品，這些產品處於不同發展階段。前述創新產品[4]中以創新藥物(innovative drugs)為主，包括biosimilars和新生物技術藥物。許多公司（例如Adamed或Celon Pharma）同時進行生物技術和傳統藥學研究。他們生產傳統學名藥，並對原創生物技術新藥進行研究。

[3] 引述相關報告發布時間 2013 年。嗣依 ICEC European Center 於 2014 年委託研究報告「Biotechindustry in Poland」公布資料，波蘭廣義之生技業者有 129 家，包括傳統典型之生技業者 90 家。

[4] 波蘭生技公司在 2012-2017 年所開發之創新產品，依次分類如下：New cosmetics(23%)、Drugs for metabolic dis.(21%)、Oncology drugs(16%)、Food supplements(12%)、immunology drugs(8%)、API(5%)、Neurodegenerative dis. drugs(5%)、Molecular biology tools(3%)、其他(7%)。

波蘭學名藥商也意識到生物技術對於發展現代創新生物製藥的重要性。例如波蘭最大學名藥廠ZF Polpharma公司即創設了一個專門的研發部門，Polpharma Biologics則主要開發生物技術新藥和biosimilars，生產並將其引入市場。

開發創新藥品、經授權對現有藥品研發新療效(new generations of already existing drugs with market authorization)，促使波蘭業者運用新科技進行大規模生產(production on an industrial scale)。例如生物技術公司Mabion以生物技術生產藥品－humanized monoclonal antibodies，用於治療腫瘤。該公司使用modern orbital shake bioreactors重組蛋白生產技術。該技術主要用於現代R&D實驗室。Mabion將成為世界上最早將這種技術運用在工業生產的公司之一。

波蘭生物技術公司和學名藥廠均對與外國廠商合作持開放態度。波蘭公司積極參與國際活動（CPhI，BioConvention），並共同參與創設中歐生物技術和製藥公司的合作平台BioForum（www.cebioforum.com）。

三、生物科技在波蘭經濟中之表現

波蘭之生技業者所創造之附加價值，較一般科技研發業者低。其出口尚不活躍，約有10家業者出口其服務或解決方案(solutions)。依據波蘭中央統計局(GUS)2012年公布資料，生技業者之營業額僅有5.1%來自出口，但仍有若干以出口為導向的業者。例如Bioton公司2013年之營業額，波蘭市場僅占35%，其主要出口市場包括俄羅斯(9%)、澳大利亞(9%)、義大利(8%)、中國大陸(7%)。該公司基於與德國拜耳公司(Buyer Healthcare)之協議，可將該公司所生產之胰島素銷往中國大陸。另波蘭生技業者之R&D支出比例僅2%，亦低於其他歐美國家。

波蘭生技業者主要仍仰賴自有資金。2012年9,680萬歐元之研發支出，83.3%係自籌；惟仍有若干個案主要由外部資金支持。另歐盟補助款對波蘭生技業者相當重要，在創新經濟行動計畫(OPIE)項下，業者提出65件申請案，共計獲得5,000萬歐元之補助。其中Mabion公司為最大受益者，該公司從2010-2015之OPIE計畫獲得1,560萬歐元之補

助，主要用於開發治療癌症藥物(mabionCD20)[5]。

絕大多數的生技公司是從各大學、研究機構之研究成果獨立出來(spin-offs)。波蘭市場已有相當多之國內外業者，提供生技公司所需之實驗室解決方案或相關輔助服務，進而形成產業聚落。波蘭主要之生技產業聚落如下：

產業聚落／園區	城市	研發領域	企業家數 life science	企業家數 biotechnology
Klaster LifeScience	Krakow	Life science	20	6
Life Science Park	Krakow	Life science	14	6
Pomeranian Science and Technology Park	Gdynia	Diversified	7	4
Wroclaw Technology Park	Wroclaw	Diversified	9	4
Bioregion Wielkopolska (cluster)	Poznan	Life Science	8	3
Nutribiomed Cluster	Wroclaw	Food-biotech-biomedicine	17	3
Nickel Technology Park Poznan	Poznan	Diversified	6	2
BioTechMed Advanced Technology Centre (cluster)	Lodz	Life Science	4	2
Pomeranian BioEcoChem Cluster	Gdansk	Bio-eco-chem	2	1
BioPark – Biotechnology Cluster	Gdansk	Life Science	4	1
Cluster BIOCEW	Warszawa	Life Science	3	0

四、結論：

生物科技產業對波蘭而言，尚屬起步階段。基於國家鼓勵高教及科研發展之傳統，越來越多的生技研發spin-offs業者形成聚落或園區並且快速發展。但成功商品化之案件仍有限。顯示波蘭生技產業潛力尚待開發。

[5] 同註 3，第 12 頁。

1. The direction of development of Polish biotechnology and pharmacy

Therapies based on the achievements of molecular biology and genetic engineering technology are playing an increasing role in modern medicine. The dynamic development of a new generation of biotechnological drugs and personalized medicine is possible only due to the success of life and medical sciences. The economic success of biotech and pharmaceutical companies, including those from Poland, is increasingly determined by the ability to quickly implement the results of research and by the creation of innovative products with a view, primarily, to the global market, not – as previously – the local one. This fact has already caused deep changes both to the mindset and functioning of the Polish scientific and (bio)business environment.

Despite the fact that therapies based on biotechnological drugs are increasingly implemented in practice, apart from recombinant insulin produced by the Bioto n company, no modern biotechnological drug is produced in Poland. This situation is slowly changing and, gradually, both biotech companies (MABION S.A. is the leader in this group) and large pharmaceutical companies (e.g. ZF POLPHARMA S.A.) are beginning to implement technology for biosimilars production. It is to be expected that, because of the size of the Polish drug market (sale value is estimated at about 30 billion PLN a year) and the availability of resources necessary for the development of this drug sector (see: chapters 5 and 6), biosimilars are one of the main focuses for development of the Polish biotech and pharma industry. Moreover, there are an increasing number of biotechnological drugs whose patent protection is expiring. Technology for the production of biotechnological drugs is much more advanced and requires more qualifications than the technology for the production of classic generic drugs. Mastering this technology is one of the first and most important steps to be taken before undertaking the more ambitious task facing the Polish biotech and pharma industry – developing new innovative biotechnological drugs and introducing them into the market.

There is a clear tendency to leave behind the previous business model, consisting of the production of generic drugs, and to start working on new innovative drugs. This tendency is visible both in the case of companies producing traditional generic drugs (Adamed Group , Celo n Pharma Sp. z o.o.) and also when it comes to the newly-established companies whose work combines some elements of biotechnology and pharmacy (Sel vita S.A., Blirt S.A., Celther POLSKA Sp. z o.o., Stem Cells Spi n S.A., Proteo n Pharmaceuticals S.A.). These companies work on producing new drugs with a view to the global market. The motto “Polish biotech and pharma go global” is the strategic direction for an increasing group of young dynamic companies from the biotech and pharma industry.

Despite the fact that the number of biotechnological companies in Poland is still low (about 70), the sector is growing dynamically. Over half of the companies have been established in the last 5 years. Nevertheless, the real boom for biotech startup companies is still ahead. A high number of

scientific teams conducting biotechnological R&D projects, systematically developed infrastructure necessary for the functioning of such companies (incubators, technology parks), qualified personnel (see chapter 5), increased interest in application research, including raised awareness of the importance of proper patent protection for research results among Polish scientists – all of these create good conditions for establishing innovative startup companies. The development of the biotech and pharma sector stimulates the possibility of obtaining funds for innovative products, both from European Union funds and financial instruments created by the Polish government (e.g. by such institutions as the National Center for Research and Development, Polish Agency for Enterprise Development, National Capital Fund). Nevertheless, the influence of private investors, both individual and institutional (e.g. venture capital funds) is equally important for its success and dynamics. Investors have already noticed the potential of the industry, which is indicated, for example, by the valuation of biotech companies listed on the Warsaw NewConnect stock exchange market. The increasing engagement of financial circles in the development of the Polish biotech and pharma sector is a tendency, which will certainly intensify in the future years. This tendency will be the most objective indicator of the sector's development and potential.

2. Polish biotech and pharm companies

Currently there are about 70 biotechnology companies (figure 2.1) and over 140 pharmaceutical companies (figure 2.2) in Poland.

An interesting group of biotechnology companies are the so-called “core biotech” companies. These companies focus their activity mainly on developing new innovative biotechnology products. R&D represents at least 50% of their total activity. These companies use recombinant DNA technology, modern technologies of molecular biology, cell biology and tissue engineering in developing new technologies. They constitute still a small (15% of the total number of biotech companies in Poland), but very dynamic group with great development potential.

The vast majority of Polish biotech companies work on new innovative products, which are at different implementation stages. Innovative drugs constitute the majority of these products (figure 2.3), both biosimilars and new original biotechnology drugs. A significant number of companies from this sector operate through combining some elements of biotechnology and traditional pharmacy (e.g. Adamed or Celo n Pharma). They produce traditional generic drugs and conduct research on new original biotechnology drugs.

Polish producers of generic drugs also realize the importance of biotechnology for the development of modern innovative biopharmacy. ZF Polpharma S.A., the largest Polish company producing generic drugs can serve as a good example. It has created a special research and development department, Polpharma Biologic S, whose main task is to develop both original biotechnology drugs and biosimilars, implement their production and introduce them into the market.

Work on innovative drugs and/or new generations of already existing drugs with market authorization stimulate Polish companies to implement new technologies for production on an industrial scale. Mabio n S.A. is an example of a biotechnology company implementing the production of biotechnology drugs – humanized monoclonal antibodies used in tumor treatment. The company implements technology of production of recombinant proteins using modern orbital shake bioreactors. The technology has been used mainly in modern research and development laboratories. Mabio n will be one of the first companies
in the world to use it in industrial production.

What is characteristic of both Polish biotech companies and generic drug producers is their openness towards cooperation with foreign partners. Polish companies actively participate in international events (CPhI, BioConvention) and co-created BioForum (www.cebioforum.com) – a Central European cooperation platform for biotech and pharma companies.