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Brexit Concerns: Industry Structure, Regulation and Supply of Medicines

Brexit is coming closer and while industry associations are playing for time in order to enable smooth transition, companies face hundreds of issues, many of which may translate into business development opportunities.

European Industry Organisations have voiced concerns over securing ongoing cooperation between the UK and EU on medicines, fearing „an unorderly withdrawal" of the UK from the EU which could result in medical goods being „held either at border checks, in warehouses or manufacturing and/or subject to extensive retesting requirements."

The eight associations representing the European and British pharmaceutical and life science industry, namely the Association of the British Pharmaceutical Industry (ABPI), the Association of the European Self-Medication Industry (AESGP), the European Federation of Pharmaceutical Industries and Associations (EFPIA), EuropaBio, Medicines for Europe, British Generic Manufacturers Association (BGMA), BioIndustry Association (BIA), and the Proprietary Association of Great Britain (PAGB) are afraid that „this would lead to a severe disruption of most companies' supply chains, which would lead to potential supply disruptions of life-saving medicines."

The current structure of the European pharmaceutical and biotechnology industries can be described as highly integrated and interdependent in all aspects of R&D, manufacture, trade, supplies, and collaborative arrangements. It is regulated under EU law, whereby the EU institutions and the national authorities of the Member States have set up a complex system of legal and regulatory arrangements which in their entirety constitute the European regulatory environment for health products.

Brexit will mean that the UK and EU-27 part of the European industry integration will have to be re-designed which will affect the development, manufacture, and supply of products. Implementing the re-design will take time during which the supply of medicines to the patient could be adversely affected. While this will be a task of the individual companies involved, disentangling the complex regulatory framework which up to the present spans 28 Member States while at the same time ensuring a smoothly ongoing regulatory process in the UK and the remaining 27 Member States will be a formidable task. Nobody seems to have a clear idea how this can be achieved, which is not really surprising.

Fearing unintended consequences, the mentioned eight industry associations have asked the Brexit negotiators to allow an implementation period that reflects the time needed by pharmaceutical and biotech companies to transition to a new framework: „For example, pharmaceutical and biotech companies may need to submit applications for the transfer of marketing authorisation for specific products, move batch release for products or move personnel into the EU-27 from the UK, all of which would take a significant amount of time."

The Brexit negotiations will determine the new arrangements but the time that will be allowed for the transition will determine the consequences and the impact on the industry.

The resulting needs in adjusting clinical trials, moving production or warehousing, transferring marketing authorisation, bringing distribution into line, just to name a few, will spell challenges and business development opportunities for non-EU and EU companies alike. Direct communication with companies concerned is required and euroPLX 65 London will provide and excellent opportunity for that on 27 and 28 November in the Sofitel London Heathrow Airport Hotel.

BD People on the Move

* Appili Therapeutics Inc.: Sean McBride, who served most recently as head of an entrepreneurial business unit of GSK has been appointed as Vice President, Business Development. (Press Release 6 Jul 2017)

* Concordia International: Blanca Esteban, who has been Head of

Alliance Management, left the company. (Pers Comm 27 Jun 2017)

* Ethypharm SA: Friederike Elissalt, who has been Licensing Manager, left the company. (Pers Comm 18 Jul 2017)

* iTeos Therapeutics SA: Mohamed Ragab, M.D. most recently the Vice President, Search and Evaluation, Oncology at Bristol-Myers Squibb. has been appointed as Vice President of Corporate Development. (Press Release 29 Jun 2017)

* Lanxess: Dr. Jens-Christian Blad, until recently with McKinsey & Company, has been appointed as new head of Corporate Development as per September 1, 2017. (Press Release 5 May 2017)

* Merrimack Pharmaceuticals, Inc.: Thomas E. Needham, Jr., M.B.A., who most recently served as Senior Vice President of Business Development at C4 Therapeutics, where he was responsible for executing business development strategy and establishing corporate partnerships, has been appointed to the position of Chief Business Officer with responsibilities in in- and out-licensing, co-development and R&D collaborations. (Press Release 24 Jul 2017)

* Perrigo Company: Mark Vallance, who has been International Sales Development Manager for Rosemont Pharma left the company. (Pers Comm 27 Jun 2017)

* Relay Therapeutics: Deborah Palestrant, Ph.D., MBA, who led the business development team at Editas Medicine has been appointed to Vice President of Corporate Development and Strategy. (Press Release 24 Jul 2017)

* Strathos Pharma Group: Dr. Petra Lange, who has been Product and Business Development Manager, left the company on 24 May 2017. (Pers Comm 27 Jun 2017)

* Teva Pharmaceutical Industries Ltd.: Elisabet Thorgeirsdottir, who has been Director Portfolio Management International for Teva/Actavis, left the company. (Pers Comm 27 Jun 2017)

* Teva ratiopharm: Dr. Renata Stegmann, who has been Associate Director Licensing for the Business Development & Alliance Management, Europe & Growth Markets, left the company. (Pers Comm 29 Jun 2017)

Company News

* Acquisistion: Acino has acquired South Africa's Litha Healthcare. Litha's existing product portfolio comprises nearly 100 molecules focusing on primary care, largely through originator products, and specialty care, partly through generic products. 3 Jul 2017 (www.acino-pharma.com)

* Licensing and Distribution: BioDelivery Sciences International, Inc., a specialty pharmaceutical company with a focus in pain management and addiction medicine, and Purdue Pharma (Canada) announce that they have signed an exclusive agreement for the licensing, distribution, marketing and sale of BELBUCA® (buprenorphine buccal film) in Canada. It was recently approved by Health Canada for the management of pain severe enough to require daily, continuous, long-term treatment and that is opioid-responsive and for which alternative options are inadequate. 12 Jul 2017 (www.bdsi.com)

* Acquisition: Bioverativ Inc., a biotechnology company focused on the discovery, development and commercialization of innovative therapies for hemophilia and other rare blood disorders, has successfully completed its acquisition of True North Therapeutics, a privately-held, clinical-stage rare disease biotechnology company. 28 Jun 2017 (www.bioverativ.com)

* Share exchange: BriaCell Therapeutics Corp., an immuno-oncology focused biotechnology company with a proprietary vaccine technology, has entered into a definitive share exchange agreement with its wholly-owned subsidiary, BriaCell Therapeutics Corp., Sapientia Pharmaceuticals, Inc. and all the shareholders of Sapientia. Sapientia is a biotechnology company, that is developing novel targeted therapeutics for multiple indications including several cancers and fibrotic diseases. 24 Jul 2017 (briacell.com)

* Acquisition: Dendreon Pharmaceuticals LLC has been acquired by Sanpower Group, a private Chinese conglomerate, from an affiliate of Valeant Pharmaceuticals International, Inc. for $819.9 million in cash. 29 Jun 2017 (www.dendreon.com)

* Alliance: Eli Lilly and Company and Nektar Therapeutics have announced a strategic collaboration to co-develop NKTR-358, a novel immunological therapy discovered by Nektar. NKTR-358, which achieved first human dose in Phase 1 clinical development in March of 2017, has the potential to treat a number of autoimmune and other chronic inflammatory conditions. Under the terms of the agreement, Nektar will receive an initial payment of $150 million and is eligible for up to $250 million in additional development and regulatory milestones. 24 Jul 2017 (www.lilly.com)

* Divestiture: Endo International plc (NASDAQ: ENDP) today announced that it has completed the previously announced divestiture of its South African based operations, Litha Healthcare Group, to Acino Pharma AG. Endo received approximately $100 million in cash (after giving effect to cash and net working capital purchase price adjustments) and may receive up to an additional $11 million in contingent consideration. 3 Jul 2017 (www.endo.com)

* Name change: Lion Biotechnologies, Inc. has changed its name to Iovance Biotherapeutics, Inc. (www.iovance.com)

* Co-promotion: Ipsen's US affiliate has entered into an exclusive, three-year agreement with Saol Therapeutics Inc. to promote Dysport® (abobotulinumtoxinA) for injection for approved therapeutic indications in adult spasticity and pediatric lower limb spasticity in the United States. 30 Jun 2017 (www.ipsen.com)

* Acquisition: Lonza has completed the acquisition of Capsugel S.A. from KKR for USD 5.5 billion in cash, including refinancing of existing Capsugel debt of approximately USD 2 billion. 6 Jul 2017 (www.lonzagroup.com)

* Acquisition: Medicure Inc has closed the acquisition of additional interests in Apicore Inc. and Apicore LLC from Apicore's founding shareholders. The acquisition, for US$24.5 million, represents approximately 32% of the fully diluted ownership of Apicore and brings Medicure's ownership in Apicore Inc. to approximately 98%. 12 Jul 2917 (www.medicure.com)

* Acquisition: NeuroDerm Ltd., an Israeli clinical stage pharmaceutical company developing drug-device combinations for central nervous system (CNS) disorders, has signed a definitive agreement under which Mitsubishi Tanabe Pharma Corporation will acquire NeuroDerm for US$39 per share in cash. The transaction implies an equity value of approximately US$1.1 billion. 24 Jul 2017 (neuroderm.com/)

* Acquisition: Norgine B.V. and Merus Labs International Inc. have arranged for Norgine to acquire a product portfolio of 12 established products which are sold across Europe and in other selected markets. Merus, which has approximately 22 employees, becomes a wholly-owned subsidi-

ary of Norgine. 17 Jul 2017 (www.norgine.com)

* Distribution: Noventure has allied with Pierre Fabre Pharma Italy for the distribution of Aprotecol in Italy, an oily suspension administered via medical device, designed to prevent and treat intestinal colic, meteorism and aerophagy – ailments that frequently occur in infants and children. Pierre Fabre Pharma Italy anticipates launching Aprotecol in January 2018. 17 Jul 2017 (noventure.com)

* Name change: Novo A/S , the holding company for the companies in the Novo Group, has changed its name to Novo Holdings A/S. 23 Jun 2017 (www.novoholdings.dk)

* Acquisition: The takeover of Stada Arzneimittel AG by Bain Capital and Cinven failed owing to an acceptance rate of 65.52 percent falling short of the minimum acceptance threshold of 67.5 percent. 27 Jun 2017 (www.stada.de)