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3. Market Access in the UK

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3.1 Introduction

The UK healthcare system is primarily governed by the National Health Service (NHS), a body that commissions services such as general practitioners (GPs), pharmacists and medicines as per the needs of the UK population, for effective healthcare provision. NHS successfully provides good healthcare services in the UK, assisting all stakeholders in meeting their goals. Due to lack of regulation, until 2009 the pharmaceutical companies would negotiate with the government on a particular price, and provided medicines to the patients at that price. However, after the Pharmaceutical Price Regulation Scheme (PPRS) of 2009, healthcare delivery in the UK changed drastically. Currently, the NHS has divided the decision-making power as well as healthcare budgets of the United Kingdom into regional and local levels, to take care of the unique unmet medical needs of the different regions. Therefore, the healthcare market has changed, leading to differentiated markets for every drug, forcing companies to come up with differentiated market access strategies for their drugs. Thus, the price regulation and reimbursement landscape of a medicine after its approval is segmented, and pharmaceutical companies face several challenges in negotiating with different payers, healthcare organizations and decision makers in order for the value of their product at a given price to be recognized. The scenario of pricing and market access in the UK is discussed in the following sections.

3.2 General Outlook of Healthcare System and Health Policies

The United Kingdom consists of England, Wales, Scotland and Ireland, and all regions have different healthcare policies in terms of value decision-making, as well as medicine reimbursement schemes. In 2015, the government financed £ 147.1 billion of healthcare expenditure, with a total healthcare expenditure in the UK accounting for 9.9% of the total GDP. However, the extension of therapeutic networks and hospital formularies remain the same. The UK healthcare budget is spread across 211 Clinical Commissioning Groups (CCGs), which are NHS organizations responsible for planning and commissioning of healthcare services for the needs of patients in a particular geographical area. The healthcare system in the UK is publicly funded. The NHS has a well-

established constitution, published in 2011 by the Department of Health. Besides the constitution, the Health and Social Care Act of 2012, under which the Clinically Commissioning Groups were established, regulates the NHS budget. The NHS provides assistance to these CCGs through Commissioning Support Units (CSUs), in addition to providing clinicians, as well as payers, an outlook on which practices are good for a particular therapeutic area.

The Act also brought about significant legal changes, such as the implementation of the Healthwatch network, to reinforce the voice of the consumer, and the Public Health England, to protect and improve the nation's health and wellbeing, and reduce health inequalities. This act also oriented the competition in the healthcare market towards the interest of the patients, by establishing Monitor, which issues licenses to regulate providers of NHS services. Now in the UK pharmaceutical companies have to operate alongside many local groups, each with different unmet needs and value definitions. Thus, companies need to first understand the needs of the stakeholders and deliver healthcare solutions to the population of that area accordingly.

The NHS is not only concerned with price regulation, but also with the health insurance system of the region. Healthcare is covered by the NHS for the majority of the population, entirely funded by taxes. Besides the government-funded public healthcare insurance, certain private companies, which hold minor sectors, also cover residents, offering additional benefits. In order to involve local health councils and authorities to join the NHS and contribute to the enhancement of social welfare and healthcare, in 2015 the UK government allocated £ 2.7 billion and £ 200 million, respectively, to these bodies. The government also established Integrated Care and Support Exchange (ICASE), which is aimed at bringing expertise from different parts of the nation to contribute to the goal of developing integrated models of care and support in different places, to enhance the degree of public healthcare in the respective locations.

3.3 Pathways of Market Access

As seen above, the UK government exercises control over healthcare, insurance, and pharmaceuticals to a great extent, ensuring and safeguarding the interest of consumers and patients alike. The market access of pharmaceutical companies in the UK involves several processes, but it is mainly related to government regulations, pricing and reimbursement strategies. Figure 1 shows the common steps involved in enabling market access on the part of any pharmaceutical company within the UK.

Pharmaceutical Regulation

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health. The MHRA has three centres: 1) the Clinical Practice Research Datalink (CPRD), which is a data research service that provide anonymized

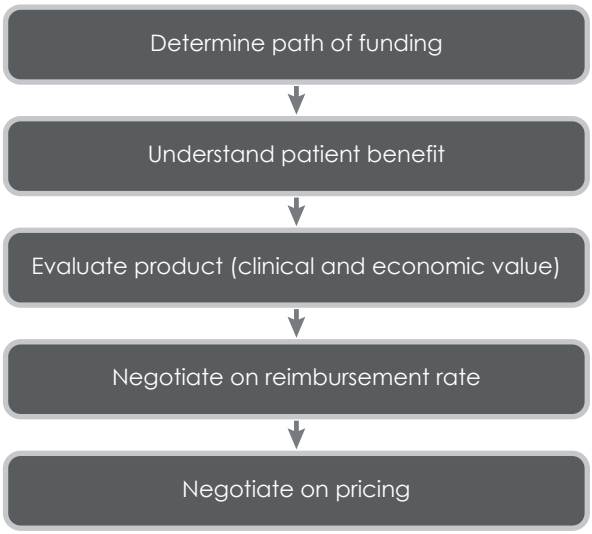

Figure 1. Market Access Process within the UK pharmaceutical sector

NHS clinical data, 2) the National Institute for Biological Standards and Control (NIBSC), which has been established to standardize and control biological medicines, and 3) the MHAR, which regulates medicines, medical devices and blood components for transfusion, according to the standards set to ensure their safety, efficacy and quality. The degree of control to be exercised over the supply of a medicinal product depends on the legal classification the latter falls into. There are three such categories, namely: 1) Prescription, which includes the drugs that must be dispensed only by a licensed facility, and upon a prescription written by a health professional, 2) Pharmacy, which includes the drugs that can be bought under the supervision of a pharmacist, and 3) General sales list, which includes the drugs available at retail stores.

Besides the need of an appropriate license for the distribution of medicines, drugs must meet the minimum production standards, as determined by the Good Manufacturing Practices (GMP). The MHRA is responsible for carrying out the inspection in the manufacturing and distribution sites, to ensure the adherence to GMP guidelines, and for issuing GMP ratings, depending upon the compliance report, the information regarding the previous inspection history, and any changes in the organization. MHRA works alongside the EMA (European Medicine Agency) to provide recommendations for the various medicines that are submitted for approval. However, Brexit has changed the dynamics between EMA and MHRA, and this might lead to a different process of drug approval and access in the UK. Furthermore, the agency aims at ensuring that the applicable standards are met. The regulatory dilemma arisen post-Brexit poses implications of serious nature on the UK pharmaceutical industry, since UK lost EMA, and the influence of MHRA is also perceived as decreasing.

Pharmaceutical Pricing

Pharmaceutical pricing has changed since 2009, after the Pharmaceutical Price Regulation Scheme (PPRS) was enforced by the NHS. In the UK, the NHS is the main buyer of pharmaceutical products, either branded, innovative drugs/biologics or generic drugs/biosimilars. To finalize the price of these prescription drugs, the manufacturers discuss matters with the government, and these discussions are different for innovative and generic drugs. The price of branded drugs is controlled by PRRS, which was brought into effect by an agreement between the pharmaceutical industry and the government. The payment percentage of PPRS is also set by an agreement between the pharmaceutical industry and the government, to bring stability to the stakeholders – to plan investment strategies – and to support NHS funding, in order to provide health services, respectively. The PPRS for 2017 has been revised and set at 4.75%. The scheme regulates the profits pharmaceutical companies can make on the sales of their drugs to the NHS, and includes a clause for a renegotiation to be implemented every 5 years. NICE assesses the clinical efficacy and cost-effectiveness of each drug on behalf of the NHS for England, Wales, and Ireland, and then recommends a fair price to the NHS. Since the budget allocation with the NHS for healthcare is fixed, the price of new treatments comes at the expense of other treatments. Thus, the NHS is always looking for effective and safe generics and biosimilars for the treatment of various diseases.

Pharmaceutical Reimbursement

The healthcare system in the UK is largely public, with around 80% of funds sourced from taxes, 12% from insurance, and the rest from miscellaneous charges and sources as depicted in Figure 2.

In terms of reimbursement, the process in the UK is quite different from the other European countries. The country has little direct pricing control, since the originator drug price is set by the PPRS and the drug price is reimbursed by the NHS to the contractors under the Community Pharmacy Contractual Framework. However, the reimbursement prices to be dispensed by the NHS are determined by the Secretary of the State, with the reimbursements being issued in the form of a combinations of allowances, medicine margins, and fees. The medicine margin, as achieved by a contractor, is assessed by the Department of Health and Pharmaceutical Services Negotiating Committee. Apart from the price set, there is a matter of spending through patient co-payment as a form of prescription charges, which is a claw-back system operated by the UK government for government hospitals and community pharmacies [15].

3.4 Mapping and Structure of Decision Makers

The Code of Practice for Pharmaceutical Industry was laid out by the Association of the British Pharmaceutical Industry (ABPI), to ensure the appropriate promotion of drugs to

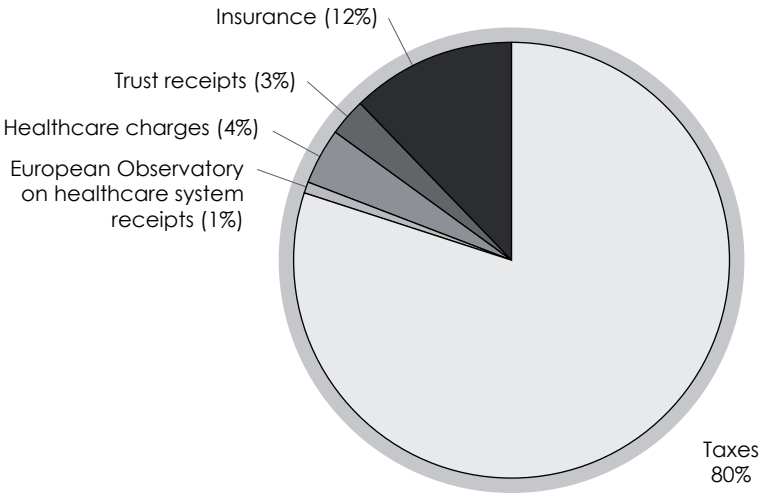

Figure 2. NHS healthcare funding

health professionals and other decision makers. The code incorporates the principles set out in the codes of different organizations around the world (i.e., IFPMA – International Federation of Pharmaceutical Manufacturers and Associations, EFPIA – European Federation of Pharmaceutical Industries and Associations, WHO, etc.). The code of practice is administered by the Prescription Medicines Code of Practice Authority (PMCPA), which monitors the activities and provides guidance.

In terms of assessing value through Health Technology Assessment (HTA), The National Institute of Health Research (NIHR) in the UK runs various programs. The most

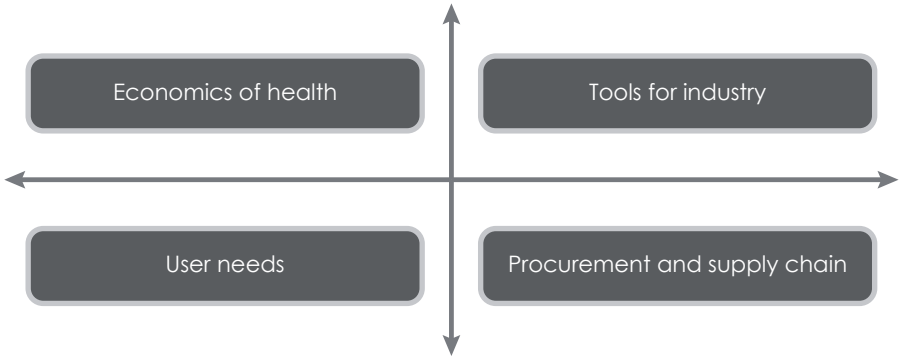

Figure 3. The four themes assessed by the MATCH

prominent is NIHR Health Technology Assessment Programme, which assesses drugs through conventional HTAs through evidence synthesis and modeling, and generates evidence of effectiveness through cohort studies. Apart from this organization, the Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH) also plays a HTA role, in collaboration with the NHS, to assess various industrial partners. The main four themes that MATCH organizes for assessment are shown in Figure 3.

The PPRS is a voluntary agreement between the Government and the pharmaceutical industry. The current scheme runs for five years from January 2014. Companies that choose not to join the PPRS are covered by the Statutory Scheme for Pricing of Branded Medicines. In this scheme, a 15% cut is applied on the NICE list price, and is subject to revision. The scheme does not include the companies that have sales lower than € 5 million and the products which have been launched after December 2013 are not allowed for discounts.

3.5 Challenges and Catalyzers for Market Access

Challenges

Marketing consultant PharmaBase surveyed 27 European pharmaceutical companies (while the UK was still a part of the Community), which included 5 top Pharma companies of the region, and the results suggested that the greatest challenge for an effective market access strategy was local decision making, something that would change with changing territory. Another challenge revealed by the survey concerned the NHS's constant drive to increase cost-savings in the healthcare sector, driving up negotiations on discounts and reimbursement. QALY was also seen as a hurdle, since it was considered a blunt tool to measure the value of a drug. Even though QALY measures cost-effectiveness through clinical benefit for the patient, it fails to look into the impact the drug might have on caregivers and family members, as well as on the wider social costs and benefits for the general population or the NHS. For example, four of AstraZeneca's drugs were voted as being cost-effective for moderate to severe Alzheimer, but not so effective for mild Alzheimer. However, many argue that providing drugs in a mild setting helps slow the progression to a moderate and severe condition, and helps increase the quality of life of the patient, as well as being beneficial from the caregiver's perspective.

Catalysts

The main processes that prove to be a driving force for an effective market access strategy include an effective pricing strategy, accurate health outcomes/health technology assessments (HTAs), as well as an efficient milestone management of drug candidates by the companies. Additionally, stakeholder mapping, the issues regarding the preparation for market access and patient advocacy are also factors that help create a successful market strategy in the pharmaceutical sector.

Successful Market Access Strategies

AstraZeneca developed an innovative drug – osimertinib – to treat patients suffering from a type of lung cancer characterized by high unmet medical needs. Using the Early Access to Medicine Scheme (EAMS), AstraZeneca could enter the market sooner. The scheme directly helped 22 UK patients benefit from this decision, and the marketing approval was granted to the drug only eight months after its submission to EMA for authorization. The drug, thus, reached the patients only 3 years after it was first tested on humans, providing a great example of an effective development and marketing strategy by AstraZeneca.

Similarly, Abbvie's drug glecaprevir/pibrentasvir (G/P), was the first treatment for HCV to be approved through EAMS. The approval was granted in May 2017, and UK patients would have early access to the drug while it is being reviewed by EMA for potential authorizations in other countries of the European Union and the European Economic Area.

Another non-cancer drug to be approved through EAMS is dupixent by Sanofi, for the treatment of atopic dermatitis. Through EAMS, Sanofi received the NICE recommendation and MHRA approval in 30 days, instead of the standard 3-month procedure. These are two examples of successful strategies to gain pre-authorization approval and accelerated pricing and reimbursement approval. These were possible because the company had decided to develop therapies that had a high unmet medical need in the UK.

3.6 Advances in the Near Future

The challenges and drivers, along with the processes and organizational policies in the UK pharmaceutical industry, suggested that there is no 'one-size-fits-all' process that a company can undertake to implement price and reimbursement schemes for their different products. The highly localized and customizable processes for any drug in different setting urged the companies to develop their market access strategies in order to examine every process in detail beforehand, and be ready for any consequences from any stakeholder. The market access management has become a great need for the future, and the companies need to implement market access strategies, in order to create better prospects. Moreover, they have to increase their engagement with government bodies as well as patient organizations, GPs, chief pharmacists and patients. Companies also need to create robust methodologies, have transparent testing systems, implement post-launch trials and improve their patient-awareness processes, to promote their products among each stakeholder, in order to increase sales and profit, keeping in mind the fact that drug development and manufacturing require huge R&D expenses.

3.7 Bibliography

- AbbVie Press Release. Early Access to Medicines Scheme (EAMS) Granted to AbbVie's Investigational Pan- genotypic Regimen for Chronic Hepatitis C – the First EAMS in HCV. May 2017
- Accelerated Access Review: Final Report. Review of innovative medicines and medical technologies. An independently chaired report, supported by the Wellcome Trust. October 2016. Available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/565072/AAR_final.pdf (last accessed July 2017)
- Ainge D, Aitken S, Corbett M, et al. Global Access Programs: A Collaborative Approach for Effective Implementation and Management. *Pharmaceut Med* 2015; 29: 79-85
- Carlson JJ, Gries KS, Yeung K, et al. Current status and trends in performance-based risk-sharing arrangements between healthcare payers and medical product manufacturers. *Appl Health Econ Health Policy* 2014; 12: 231-8
- Castle G, Bogaert P. Impact of Brexit on Pharmaceutical Regulations and Structures. Covington, June 2016
- Ciani O, Jommi C. The role of health technology assessment bodies in shaping drug development. *Drug Des Devel Ther* 2014; 8: 2273-81
- Chang J, Peysakhovich F, Wang W. The UK Health Care System. New York: Columbia University, 2015. Available at http://assets.ce.columbia.edu/pdf/actu/actu-uk.pdf (last accessed July 2017)
- Danzon P, Keuffel E. Regulation of the pharmaceutical-biotechnology industry. In: Economic Regulation and Its Reform: What Have We Learned? Chicago: University of Chicago Press, 2014
- Dawson S, Rosen E. Market Access in practice: do you have a strategy? PharmaField 2008
- Department of Health. Integrated Care: Our Shared Commitment. Gov.UK, May 2013. Available at https://www.gov.uk/government/publications/integrated-care (last accessed July 2017)
- Department of Health. PPRS: payment percentage 2017. December 2016. Available at https://www.gov.uk/government/publications/pprs-payment-percentage-2017 (last accessed July 2017)
- Devlin N, Dakin H, Rice N, et al. NICE's cost effectiveness threshold revisited: new evidence on the influence of cost effectiveness and other factors on NICE decisions. European Conference on Health Economics. Helsinki, July 2010
- Garattini L, Curto A, Freemantle N. Pharmaceutical Price Schemes in Europe: Time for a 'Continental' One? *Pharmacoeconomics* 2016; 34: 423-6
- Gautam A, Pan X. The changing model of big pharma: impact of key trends. *Drug Discov Today* 2016; 21: 379-84
- Hannah L, Phillips J. Is the Current UK System of Pharmaceutical Price Regulation Working? Lexology, February 2017

- Hill CA, Harries M. The Uk Pharmaceutical Price Regulation Scheme (Pprs) - Considerations of Voluntary Versus Statutory Regulations and How to Negotiate Pricing. *Value Health* 2015; 18: A520
- Macaulay R. The Future Of Uk Drug Pricing: The 2014 Pprs (An Interim Review). *Value Health* 2016; 19: A447
- Medicines and Healthcare products Regulatory Agency. Medicines: reclassify your product. Gov.uk, December 2014. Available at https://www.gov.uk/guidance/medicines-reclassify-your-product (last accessed July 2017)
- Medicines and Healthcare products Regulatory Agency and Department of Health. Good manufacturing practice and good distribution practice. Gov.uk, December 2014. Available at https://www.gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice (last accessed July 2017)
- Murteira S, Millier A, Ghezaiel Z, et al. Drug reformulations and repositioning in the pharmaceutical industry and their impact on market access: regulatory implications. *J Mark Access Health Policy* 2014: 2
- NHS England. Medicines reimbursement prices. Available at https://www.england.nhs.uk/commissioning/primary-care/pharmacy/meds-reimbursement/ (last accessed July 2017)
- NHS England. Understanding the new NHS. A guide for everyone working and training within the NHS. NHS England, 2014
- Prescription Medicines Code of Practice Authority. Code of practice for the pharmaceutical industry. 2016. Available at http://www.pmcpa.org.uk/thecode/Documents/Code%20of%20Practice%202016%20.pdf (last accessed July 2017)
- Owen L, Morgan A, Fischer A, et al. The cost-effectiveness of public health interventions. *J Public Health* 2012; 34: 37-45
- Rowland B. UK: Pricing and Reimbursement- The Basics. Lexology, December 2015
- Shkopiak T, Epping M, Schultes R. To what extent are pharmaceuticals prices controlled? TaylorWessing 2015. Available at https://united-kingdom.taylorwessing.com/synapse/regulatory_pricecontrol.html (last accessed July 2017)
- Song C. Understanding the aftermath of Brexit: implications for the pharmaceutical industry. *Pharmaceutical Medicine* 2016; 30: 253-6