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EVOLVING BUSINESS UNITS

Market Access thus becoming "transversal"

The pharmaceutical market, in regards to the price component covered by the NHS, has been, until today, characterised by the presence of drugs of high therapeutic value, such as cancer-drugs, rheumatologic drugs, anti-infection drugs and drugs for the treatment of chronic illnesses, the vast majority of which have either seen their patent expire recently or will see it expire in the next two years.

We are now very close to a generation of innovative drugs (for example for the treatment of Hepatitis C, Alzheimer and Parkinson's disease), which will presumably change not only the history of patients and the illnesses themselves, but also of the social welfare models, of the logic behind healthcare strategy and the way scientific research is aimed and conducted.

In parallel, the drug manufacturers – according to our Companies observatory, at Executive Search, which has been operating in this sector for years – are showing a tendency to structure themselves according to a concept of "submarket", i.e. with Sales and Marketing business units, dedicated to innovative products, products with a high therapeutic value and those whose patent has either expired or is close to its expiry date.

If, in the past, these business units were mirroring the treatment areas exactly, today they appear more inclined towards commercial and promotional logic, closely linked with patent coverage. "Market Access", which is transversal to the business units, is destined to have an increasing importance in this process of transformation of the market and Companies. By "Market Access" we mean the function which, within a pharmaceutical manufacturing organisation, deals with drugs in terms of patenting, price, NHS-covered cost and inclusion into the clinical handbooks of local practices and hospitals.

The professionalism and competencies demanded by these Companies in recent years, especially those with bigger structures, are in line with this vision of access and reflect its history; consider, on the one hand, the profile of the Regional Access Manager, who has different professional characteristics to those of the traditional field roles (centred on the provision of information about a drug to each GP) and is able to understand the peripheral processes of decision-making and to interface with the needs of their counterparts in regional institutions created by the devolution, which has progressively widened the areas of competence of Regions when it comes to public healthcare. [Laura's note: the "regional institutions" referred to are the Local Healthcare Authorities. Regions are the Italian equivalents of Counties in the UK; in recent years, successive Italian governments have promoted a decentralisation of many powers, out of central government and into the Regions, such as the administration of funds from local taxes, provision of healthcare and other services].

On the other hand, healthcare policy choices, constrained by the importance of the economic and financial component, by introducing central and regional measures of containment of healthcare expenditure, have caused a growing need, within the Companies, of both pharmacological and economic competencies in the Market Access scenario (thus creating the position of Pricing & Health Economics Manager and his/her reports), to create models which are able to highlight the value of the drugs and develop pricing strategies which are in line with the resources available to the NHS.

The importance of Market Access must, however, be sought in the role that it can play in the promotion of both innovative drugs and those whose patent has expired or is about to expire. Many drugs, which are past their patent validity, are still producing scientific evidence and new health outcomes. Think, for instance, of statins, drugs for a chronic condition which have largely lost their patent: to this day, adherence to their therapeutic scheme is under 60%. Which means that 40% of these drugs are used inappropriately, resulting in a low probability of therapeutic success (i.e. the avoidance of myocardial infarctions ["heart attacks" to the layperson – Laura's note] in most patients) and a waste of resources. If the loss of patent of most statins has meant lower costs for the NHS, continuing to seek their appropriate use could contribute to both the attainment of their therapeutic objective and an optimisation of [NHS] resources.

To play this role, in our opinion, Market Access should be equipped with new professional competences (alongside the established ones of outcome research) in the research and use of Real World Data, i.e. data collected outside of clinical trials.

The sources of these data are largely with the public sector (for example the administration databases and the Aifa monitoring registers) and their collection, in the scope of public/private collaborations and projects, represents an opportunity for pharmaceutical manufacturers to generate "evidence of Real Life" which contribute to the understanding of real costs of a pathology, to the evaluation of the appropriateness of use of the drugs and the real effectiveness in clinical practice, managing the entire life-cycle of the drugs. By directing Real World Evidence to its own internal practice (in a logic which is inter-functional with medicine), market Access will be able to play a role which is increasingly strategic for pharmaceutical Companies, contributing to the process of evolution of the NHS.

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