CONCLUSIONS: Early Access Programmes (EAPs) provide the possibility of making medicines that address an unmet medical need available to patients before regulators approve access from the competent authorities. Market Access includes market development activities and patient access strategy. EAPs can positively impact both areas. The aim of this review is to consider, compile, and describe the main EAPs available in Non-European Countries. METHODS: We conducted a review and performed a mapping of EAPs systems that exists in Europe. We searched existing guidelines and selected appraisals. RESULTS: We described the practical implications surrounding the regulatory framework for EAPs, the key stakeholders involved in EAP decision-making, the timelines for EAP approval, and the key factors for success. Many countries do not have an EAP in place and compassionate use is the only route to market for unregistered or investigational products. This is the case for Russia, Turkey, South Korea, Israel, India, and Brazil. The markets where EAPs are most developed include those where there are possibilities to obtain an orphan designation in Africa, Canada and Australia CONCLUSIONS: This project made specific recommendations on the most favourable countries, based on the ease of setting up such a programme and the potential revenue that could result.

EA108 EARLY ACCESS PROGRAMMES (EAPs): REVIEW OF NON-EUROPEAN SYSTEMS

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OBJECTIVES: The national government is repositioning the Community Pharmaceutical Companies (CP) in the national health service, through definition of different mix of services, relation with other health care actors, and range of objectives to achieve. Considering the contextual factors, the paper aims at analyzing the managerial implication for CP. For this purpose the CP’s director strategic attitude and the structure of the information system are investigated. METHODS: The paper is based on literature review and on a survey conducted among a national sample of 695 community pharmacies (CP). Data were collected through a questionnaire organized in both open questions and closed questions (Likert scale 1-7). Data were analyzed according to descriptive statistics to support the qualitative study approach. The SPSS program was used. RESULTS: Respondents have limited awareness of the different actions that the national and regional contexts implement regarding CPs. Although, the mix of services provided is heterogeneous and not widely consistent with the aims of the government reform (2009 law decree), there is a positive willingness to extend the professional role. Increasing the mix of services provided is perceived a strategic action (m=5,09), services are delivered even if the contribution to the CP’s revenues is very low (m=2,62). The information system allows the monitoring of the overall financial results (m=5,53), while its relevance decreases with regard to the CP’s cost structure (m=4,59) and to the specific service/business area’s contribution to the general results (m=4,18). CONCLUSIONS: The study suggests that CP’s directors haven’t developed an effective strategic orientation yet. The actual information system is not able to support them to manage the changes. As long as CP’s director develop a strategic orientation, they could act as agent of change.

EA109 PRACTICE CHANGE IN ITALIAN COMMUNITY PHARMACY: AN ANALYSIS OF MANAGEMENTAL IMPLICATION

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I110 GAINING REIMBURSEMENT OF ORPHAN PRODUCTS IN EUROPE: CHALLENGES DUE TO WIDE VARIATIONS IN EVIDENCE REQUIREMENTS AND PROCESSES

Heron L1, Laurenson S1, Costello J1, Anderl C2, Knospe J2

1Heron L1, Laurenson S1, Costello J1, Anderl C2, Knospe J2

OBJECTIVES: Under country specific evidence requirements for the national reimbursement of orphan products (disease prevalence: 1/10,000) in the UK, 5,33), while its relevance decreases with regard to the CP’s cost structure (m=4,5) and to the specific service/business area’s contribution to the general results (m=4,18). CONCLUSIONS: The study suggests that CP’s directors haven’t developed an effective strategic orientation yet. The actual information system is not able to support them to manage the changes. As long as CP’s director develop a strategic orientation, they could act as agent of change.

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