RELATIVE EFFECTIVENESS ASSESSMENT IN THE EUROPEAN UNION, DATA AND METHODOLOGY

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In the context of the EMEA Pharmaceutical Forum, the Working Group on Relative Effectiveness (RE) has developed a draft report on data and methodology of RE assessment in the European Union. The objective of the Working Group is to support Member States in developing and applying RE in order to avoid excessive expenditure, maintaining a fair reward for innovation.
The first report focuses on three issues: 1 - How to gather and use the data available at the time of reimbursement decision, which usually are those already submitted by the companies to obtain marketing authorisation; 2 – How to gather and use data available after the drug commercialization to reassess reimbursement conditions; 3 – Develop tools to help Member States in performing RE assessment and harmonising requirements.
The Working Group, after analysing the different practices among Member States in assessing RE, concludes that the first need is to clearly define what a RE assessment is and who conducts these assessments. Secondly, it must be identified the best practice in terms of process and methodology when transforming inferior data into possible RE information and this should be done by developing guidelines. Thirdly, it is advisable to establish a system of reimbursement advice, similar to scientific MAA, to help both Member States and Companies to design appropriate studies to collect RE data.