

HMPC's view on utilization of RWD for herbal medicinal products

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The use of Real World Data (RWD) as a source of valuable information for regulatory activities for Herbal Medicinal Products (HMP) represents nowadays an increasingly valuable, highly strategic tool. The HMPC has actively embedded RWD into its regulatory roadmap and work plans for the upcoming years with the objective of updating, establishing or revising the EU herbal monographs for both Well-Established Use (WEU) and Traditional Use (TU) products. Nevertheless, there are still challenges limiting the potential of RWD in the regulatory field, such as the lack of adequate description of the herbal ingredient and herbal medicinal product or the existing regulatory category fragmentation across the European Union states. Thus, it is of paramount importance to have access not only to the information regarding the HMP quality, but also its regulatory classification and prescription status, among other, this leading to a better integration of these products into electronic records.