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Health care payers and the European Medicines Agency discussed cooperation on evidence generation along the product life-cycle in a joint virtual meeting on 12 March 2021

On 12 March, representatives from the International Association of Mutual Benefit Societies (AIM), the European Social Insurance Platform (ESIP), the payer platform Medicines Evaluation Committee (MEDEV) and the European Medicines Agency (EMA) met for the third time to further explore synergies and foster mutual understanding and cooperation on evidence generation, with the aim of better aligning evidence requirements for the different decision-making processes. On this occasion the focus was on evidence generation along the life-cycle of medicinal products /therapies.

Addressing gaps in evidence generation

Today an increasing number of therapies entering the market represent novel technologies which have the potential to significantly improve the life of patients but which come with a higher level of uncertainty regarding effectiveness and safety at the point of market entry, and also sometimes with very high prices. This leads to the need for reassessment by regulatory, HTA and payer bodies post-market authorisation based on post licensing evidence generation. Especially in this area, collaboration and alignment of requirements are becoming increasingly more important.

During the meeting payers and EMA presented and discussed their experiences and perspectives on evidence generation, identifying evidence gaps to feed into early evidence generation, and the challenges of using registries and routine data as sources of real-world data for evidence-based decision-making post-market authorisation at EU and national level. Looking to the future and in line with plans for a European Health Data Space (EHDS), EMA presented its new EU-level initiative for a Data Analytics and Real-World Interrogation Network (DARWIN) that should play an important role in the future in the use of real-world data both for regulatory and payer decisions.

Continuing the good cooperation between payers and EMA

Payers are co-generators of data, co-financers as well as key decision-makers in the healthcare systems. Preparedness and good cooperation with the regulators is key to achieving better outcomes for patients. The meeting served to highlight the common challenges facing the Payer organisations and EMA related to the collection and use of real-world data for decision making and identify key areas which EU payers and EMA will take forward as part of their continued collaboration in the future. The results of the meeting will be summarised in a highlight report that will be published on the EMA website.

Press contact: christine.dawson@esip.eu