Risk sharing and managed entry agreements: The context in which they arise

Stretched health care budgets, increasing availability of potentially life-saving high-cost drugs and increasing patient expectations, mean that manufacturers seeking inclusion in reimbursement lists need to demonstrate that their drugs can provide additional benefit in comparison with best available standards of care and value-for-money in order to obtain coverage.

Countries increasingly try to achieve this by using health technology assessment (HTA) as a tool to evaluate the clinical and cost-effectiveness of new drugs. However, data and the overall evidence base available at registration are increasingly inadequate to accurately estimate the clinical and cost-effectiveness of a drug in clinical practice or its budget impact in real life. Uncertainty, due to lack of information on (comparative) effectiveness, may delay coverage decisions and patient access.

Against this background, formal arrangements between payers and manufacturers with the aim of apportioning risk due to uncertainty surrounding the introduction of new technologies have been introduced to facilitate access to new medicines. These agreements can take different forms, including price-volume agreements (PVAs), outcome guarantee, coverage with evidence development (CED), and disease management programmes, to name but a few. A variety of names have been used to describe these schemes (e.g. risk-sharing agreements (RSAs), performance-based agreements (PBAs), patient access schemes (PAS), etc.), which have been recently summarised with the concept of “manage entry agreements (MEAs)” (Klemp, Frønsdal, Facey, and HTAi Policy Forum 2011; Ferrario and Kanavos, EMINet 2013)
Over time, there has been a proliferation of managed entry schemes focusing, among other things, on price, utilisation and health outcomes.

*The LSE Summit: 14 February 2014*

The Medical Technology Research Group (MTRG) at LSE Health is delighted to organise and host a one-day *summit on Risk Sharing and Managed Entry Agreements* (MEAs) on 14th February 2014. During the summit, leading experts from academia, policy-making, industry and the patient community will convey their experience with the implementation of MEAs in different settings, assess the emerging evidence on schemes such as coverage with evidence development and outcomes-based risk-sharing and reflect on policy options for the future.

Delegates can expect high calibre speakers from several countries implementing MEAs / risk-sharing agreements. Presentations will enable delegates to learn about the latest developments in the field, gain insights on implementing MEAs from different stakeholder perspectives, including a primer on collaborative approaches to coverage decisions, and debate the necessary conditions for the wider implementation of outcomes-based risk-sharing in the future. Delegates will also have the opportunity to network, exchange views and perspectives and become part of the LSE academic community.

Panellists will feature representatives from the Dutch Health Care Insurance Board, Myeloma UK, Oxford University, the Swedish Dental and Pharmaceutical Benefits Board (TLV), the Italian Medicines Agency (AIFA), the European Commission and the Organization for Economic Development and Cooperation (OECD).

The summit is sponsored by Ernst and Young, with The Financial Times being the media partner.

**Date:** 14 February 2014, 9am-5pm

**Venue:** The Royal College of Surgeons, Lecture Theatre Two, 35-43 Lincoln's Inn Fields, London WC2A 3PE, UK

**Programme and registration**

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Literature

Managed entry agreements for pharmaceuticals: The European experience, EMINet