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Germany: Experts criticise the GKV's financial stabilisation Act

On 28th September there was a two-hour public hearing on the GKV Financial Stabilisation Act. There was much criticism of the federal government's plans. Parliamentary groups were subjected to questions from experts on the proposed Act.

A primary concern was the two-year increase in health insurance deduction which the general manager of ABDA (Federal Union of German Associations of Pharmacists), Sebastian Schmitz, explained that this would lead to huge financial burdens on pharmacies and may negatively impact their operation. The remuneration for pharmacies has been fixed for several years and Schmitz argues that measures to increase remuneration and not decrease it were needed. Especially in the wake of inflation, increased wages and rising energy costs.

Another topic covered was the interchangeability of biosimilar. Current draft law says that the G-BA should be given one more year to develop information about the interchangeability of biosimilars. This was agreed by those at the hearing stating that it is important for clear conditions to be agreed upon.
The planned lowering of the orphan drug threshold from 50 million euros to 20 million euros was also criticised with a spokesperson from the association of research-based pharmaceutical companies claiming that it would be dangerous as the care of patients with rare disease is jeopardised. But the G-BA took a different view saying that it would curb drug expenditure without endangering patient care by impeding access to innovative drugs.

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France: An update on the transitional reimbursement mechanism for medical devices

The aim of the transitional reimbursement mechanism (PECT) launched in February 2021, was to allow reimbursement of medical devices for a period of one year, the time required to collect results of clinical studies necessary for conventional reimbursement, whilst enabling rapid access to innovations for patients with a rare or serious disease.

To be eligible medical devices obtaining transitional coverage are presumed to be innovative, falling within the scope of the List of reimbursable Products and Services (LPPR) and must meet the following prerequisites:

1. CE marked
2. Not already covered by LPPR
3. Manufacturer must undertake an application for registration with the LPPR for the respective medical device within 12 months of its application to PECT

The submitted application to Ministry of Health is assessed by the National Commission for the Assessment of Medical Devices and Health Technologies (CNEDiMTS), which determines whether the medical device meets the five eligibility criteria (outlined in our full article).

Since February 2021, the French National Authority for Health (HAS) has recommended four medical devices are covered by the PECT, which are indicated in stable angina pectoris, uncontrolled arterial hypertension, intestinal insufficiency and symptomatic heart failure. On the other hand, an inability to demonstrate criteria 3 and 5 of the above list, has seen the refusal of transitional coverage to other devices.

Currently, two applications for transitional reimbursement are under assessment by CNEDiMTS, highlighting the impact this new method of reimbursement is having in the field of medical devices.

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UK: DEKRA becomes the first new body for certifying medical devices in the UK

In the UK, manufacturers of a medical device must have their products certified to demonstrate it meets certain regulatory requirements and quality standards. Historically, this has been the CE mark (European conformity mark), but a new UKCA mark (UK Conformity Assessed) has now been introduced.

Certification marks can only be granted by Approved Bodies. The Medicines and Healthcare products Regulatory Agency (MHRA) has appointed DEKRA as the first new Approved Body since the introduction of the UKCA mark. This means that DEKRA joins BSI Assurance UK, SGS United Kingdom and UL International in being qualified to grant medical devices with the UKCA certification, potentially increasing the capacity of the UK to process necessary assessments.

Dr Laura Squire, MHRA Chief Healthcare Quality and Access Officer said:

- "This is a major milestone in our mission to ensure patients across the UK have access to the high-quality medical devices they need to protect their health"
- "Approved Bodies play a critical role in the supply of medical devices and expanding capacity is vital to the successful development of the UK's medical device regulatory regime. This has been a significant piece of work and our teams have worked extremely hard to get to this stage"

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Germany: Pros and cons of register-based randomised trials, as defined by IQWiG

Study designs that combine explanatory and pragmatic aspects have recently been weighted up by authors at IQWiG with a particular focus on register-based randomised control trials.

Randomised control trials are often required for the approval of new drugs and are often seen to be the gold standard for comparing new treatments to pre-existing ones. However, they often come under criticism as they can be too complex, too lengthy and the heavily controlled conditions may not be transferable to everyday clinical care. These disadvantages has caused pragmatic studies such are real world evidence studies to gain traction and are favoured by some randomised control trials critics.

In an article in the journal Prevention and Health Promotion , Stefan Lange, deputy head of the Institute for Quality and Efficiency in Health Care (IQWiG), and his colleague Jörg Lauterberg present the spectrum that lies between these two study designs. If a trial is overly pragmatic then the data can loose its meaning as there are not a sufficient amount of control parameters and so some differences may no longer be able to observed. However, they do facilitate the large number of patients that may be required for differences to become apparent.

Register- based randomised control trials may facilitate the combining the best of both worlds. i.e. provide reliable knowledge that can be transferred to routine care and be less complex to carry out, since they use existing structures from patient registers. Lange and Lauterberg point out the potential of such a design but had concerns that the data quality of the basic variables and outcomes in many registries is not yet sufficient for good Register- based randomised control.

In their article, Lange and Lauterberg propose a modification of the legislation in Germany of the application-accompanying data collection for medicinal products with very limited evidence. In it, randomised comparisons are currently excluded. However, in Lange and Lauterberg's opinion, further research into such new active substances with relatively uncomplicated and but meaningful register - based RCTs should definitely be made possible.

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Paul Craddy

MANAGING DIRECTOR
& FOUNDER

Graham Foxon

MANAGING DIRECTOR
& FOUNDER

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