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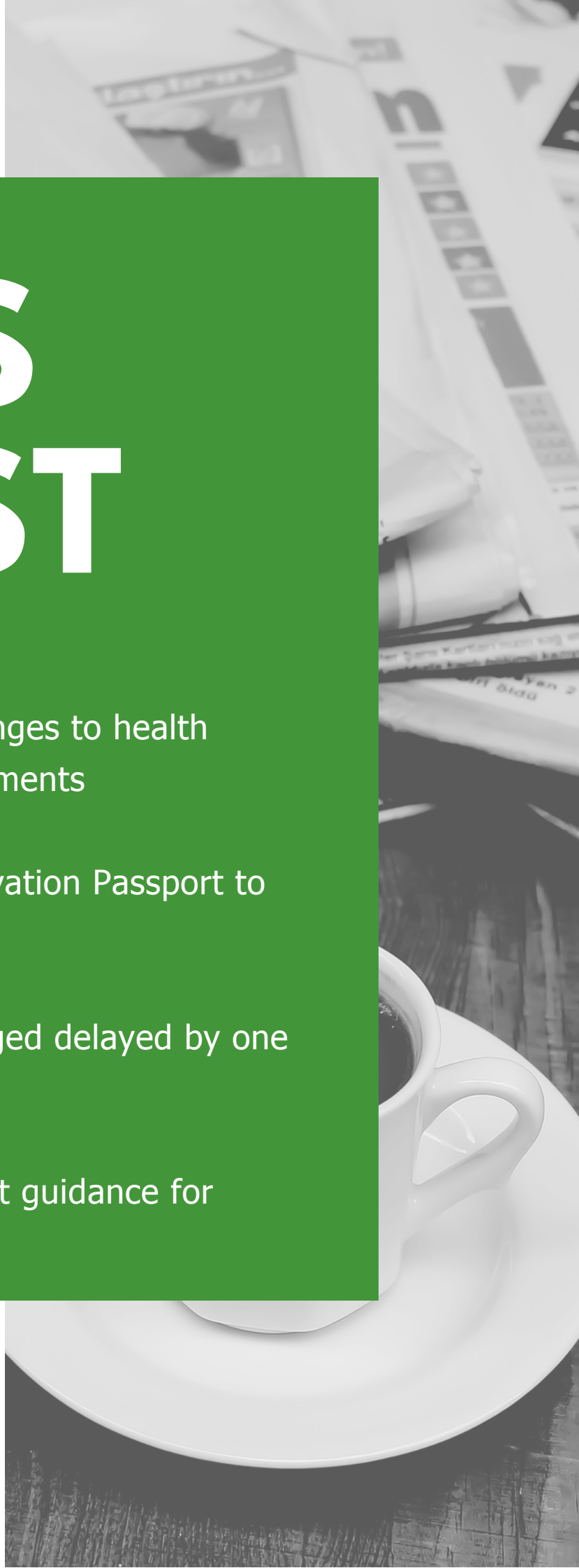
- UK: The MHRA awards Innovation Passport to a new product
- Germany: Biosimilar exchanged delayed by one year
- UK: NICE publishes first draft guidance for Early Value Assessment pilot



REMAP CONSULTING

France: HAS announces changes to health economic evaluation requirements

The Haute Autorité de Santé (HAS), recently announced changes to the conditions in which a drug with an ASMR rating I-III is required to undergo health economic evaluation. The changes set out will come into force on January 1st, 2023.

To determine whether a product has, or is likely to have a significant impact on health insurance expenditure HAS assesses the company's claims of the turnover of the product in its stated indication. In the event of first registration of the indication, this is understood as the forecast pre-tax turnover for the second year of marketing and for renewal of the registration of the indication as the turnover pre-tax recorded during the preceding 12 months of the company's application.

The company must cover in its application for submission to HAS:

- Its claims in terms of impact on the organisation of care, professional practices or the conditions of care for patients
- An estimate of the forecast turnover per year over three years, in the stated indication, in the event of initial registration, or in the event of renewal of registration the turnover recorded, in the stated indication
- An estimate of the projected population per year over three years, in the stated indication, in the event of initial registration or in the event of renewal of registration the population reached observed per year over three years, for the indication stated

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UK: The MHRA awards Innovation Passport to a new product

Spanish pharmaceutical company, PharmaMar, announced on the 5th of August that their product Zepzelca® (lurbinectedin) was awarded an Innovation Passport by the UK'S Medicines and Healthcare Products Regulatory Agency (MHRA).

The MHRA awards Innovation Passports to those products it deems innovative, in order for them to be assessed via the Innovative Licensing and Access Pathway (ILAP). The ILAP aims to accelerate time to market for these products, allowing patients faster access to life-saving or life-changing medicines.

The criteria for an Innovation Passport include targeting a life-threatening or seriously debilitating condition where there is significant unmet need, and where the product can offer benefit to patients in terms of improved efficacy, safety or quality of life compared to the current alternative treatments.

Zepzelca® inhibits active transcription of protein-coding genes, triggering DNA breaks and apoptosis. It is an analogue of trabectedin, which was originally isolated from the marine organism ecteinascidia turbinate. In May 2022, a conditional marketing authorisation assessment was submitted to the MHRA for the treatment of metastatic small cell lung cancer in adult patients who have progressed on chemotherapy.

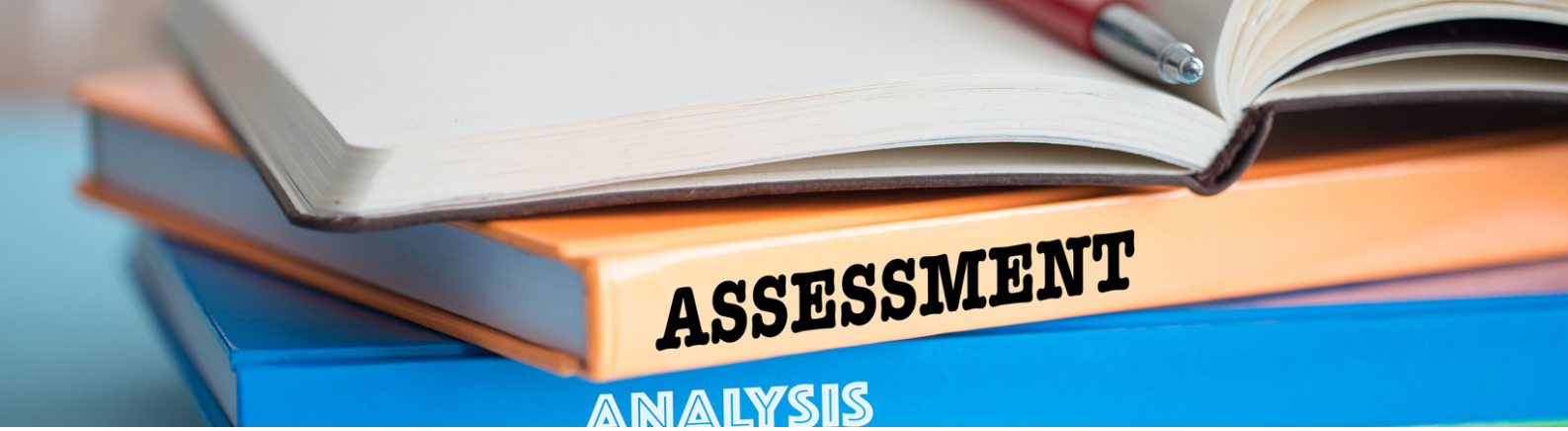
Source > https://bit.ly/3PrF4Pf

Germany: Biosimilar exchanged delayed by one year

Currently in Germany, biosimilars cannot be exchanged by pharmacists as current rules state that only preparations with the same raw materials and the same manufacturing process can be exchanged. As biosimilars differ in the manufacturing process from the original biologic they are not interchangeable in the pharmacy.

However, last year a law came into effect in Germany that amongst other initiatives should have seen pharmacies exchanging biosimilars in the same way as generics from 16th August 2022. For this to occur the G-BA would have to create an interchangeability note for each biosimilar.

The exchange has received large amounts of criticism because of its short time frame, and many have warned that setting up this process in just one year would leave the system in turmoil and negatively impact the delivery of care to patients. The G-BA has now been given an additional year to develop the criteria for change, relieving pressure from pharmacies.



UK: NICE publishes first draft guidance for Early Value Assessment pilot

On Friday 12th August, the National Institute for Health and Care Excellence (NICE) issued draft guidance recommending a smartphone-linked heart rhythm monitor for patients taking antipsychotic medication. AliveKOR's KardiaMobile 6L is a device that allows users to record an electrocardiogram (ECG) using their thumbs, with the data sent to an app that can detect heart rhythm abnormalities.

The technology was included in the pilot of NICE's Early Value Assessment (EVA) project, which offers timely advice on the value of medical devices and digital health technologies. The draft guidance recommended the use of KardiaMobile 6L to measure cardiac QT interval in patients taking antipsychotic medication, who require regular testing for heart problems before and during treatment. The technology allows this monitoring to occur in a more accessible way, with its use allowed in any psychiatric setting, including home visits.

The EVA pilot will review ten medical devices in total, including at least six digital health technologies – this guidance is the first to be published. More guidance is expected to be published in the coming months. For more information on the EVA, check out our insider insights piece from last month.

We always welcome your thoughts and opinions on the topics raised here.

If you'd like to share anything or hear how we can support you in getting your product to market email Paul and Graham, managing directors, today at: contact@remapconsulting.com.

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