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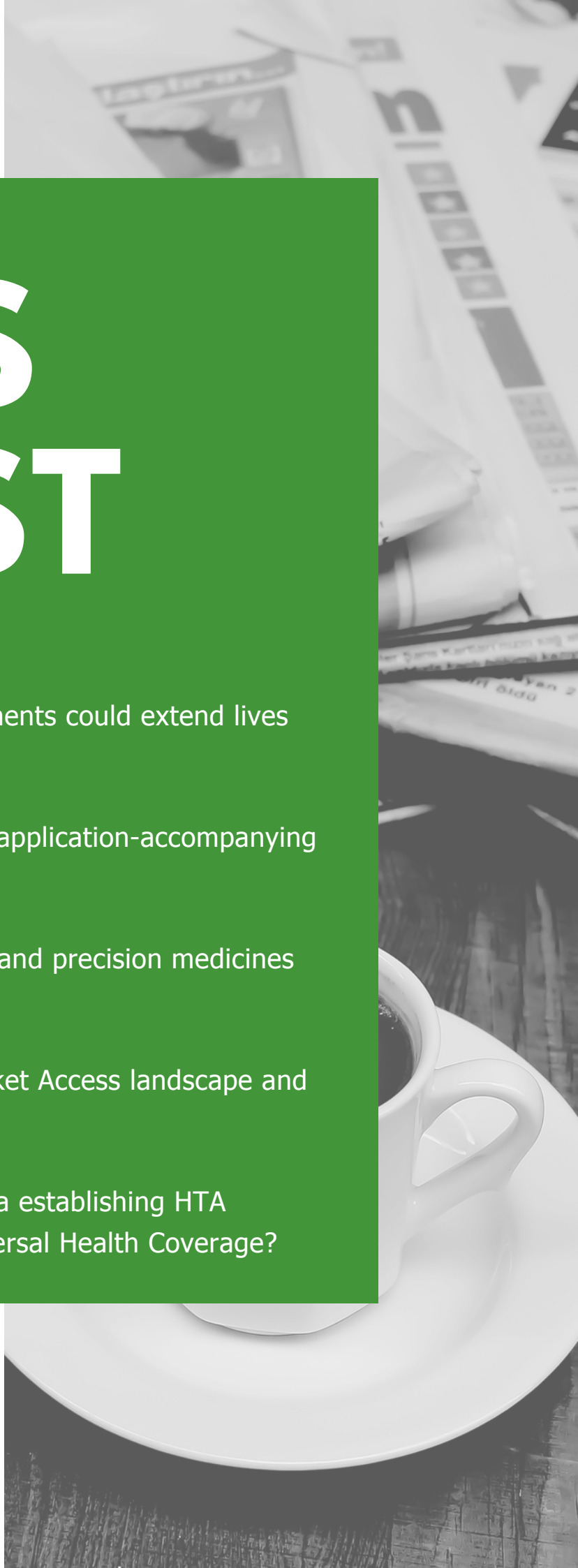

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UK: Improving access to new treatments could extend lives and boost economy – Report

According to research by PwC for the Association of the British Pharmaceutical Industry (ABPI), improving access to new treatments could transform patient outcomes and deliver a huge productivity boost for the economy. The research looks at the benefits for 13 medicines across four treatment areas – stroke prevention, severe asthma, type 2 diabetes and autosomal dominant polycystic kidney disease. Key findings include:

- An estimated 1.2 million additional NHS patients are eligible for, but are missing out on, these medicines
- In aggregate, extending the use of these medicines would provide patients with more than 429,000 additional years living in good health (QALYs)
- £17.9 billion in productivity gains would accrue to the UK economy
- £5.5 billion of which would be paid directly back to the exchequer through taxes from increased paid labour productivity.

According to the ABPI, these productivity gains "would more than offset the incremental costs of increased uptake". Indeed, increasing the use of medicines for severe asthma would bring the biggest gain to the economy, with an estimated £9.6 billion to be gained by the economy in productivity.

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Germany: G-BA determines against application-accompanying data collection for Tabelecleucel

The Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) at a meeting on 5th May 2022 determined against initiating an application-accompanying data collection for the ATMP Tabelecleucel. According to the G-BA, "the representatives of health insurance companies, doctors, patient representatives and the impartial members agreed that there is a need for further data on patient-relevant benefits when using Tabelecleucel, but the necessary national studies are difficult to implement".

This, states the G-BA, is because:

- the patient population in Germany is extremely small (between 6 and a maximum of 20 people affected) and heterogeneous.
- The treatment alternatives that could form the control group are "too ambiguous and unclear in terms of their importance for care".

Tabelecleucel is currently undergoing accelerated European Medicines Agency (EMA) approval for the treatment of patients with Epstein-Barr virus-positive post-transplant lymphoma (EBV+PTLD) who have received at least one previous therapy. After approval and market entry in Germany, the G-BA will assess the drug's additional benefit. According to the G-BA, "if the level of evidence is not sufficient at the time of market entry, the G-BA can request application-accompanying data collection in individual cases. Here, data from care is collected, for example as part of a comparative register study. The G-BA would then use these data to reassess the patient-relevant benefit later".

Sweden: TLV report on how ATMPs and precision medicines can be evaluated and paid for

In a report to the government, the Swedish Dental and Pharmaceutical Benefit Agency (TLV) has set out its proposals for increasing access to ATMPs and precision medicines, looking at both how these drugs can be evaluated and paid for. The key proposals include:

- The TLV, together with the regions and manufacturers, should jointly test outcome-based payment models. "Today, it is difficult for both payers and companies to see what the financial consequences will be in practice of implementing a certain payment model. We have therefore looked at how health economic calculations can be performed so that it is really visible how much risk reduction the payment model provides".
- In relation to uncertainty, the TLV states that it is reasonable to differentiate the degree of accepted uncertainty. "For two drugs aimed at two different but equally serious diseases where cost per health benefit is assessed to be the same, there may be reasons to make different decisions – accept greater (or less) uncertainty when the long-term consequences of waiting for treatment is large (or small)".
- A probability-weighted ICER may be particularly suitable for ATMPs, where the duration of effect is even more crucial for cost-effectiveness compared to drugs given continuously.
- The TLV should be given the legal authority to develop and draft proposals for payment models that can form the basis for agreements between regions and companies.
- Outcome-based payment models can reduce the risk of payment for one drug becoming too high in relation to the benefit that the treatment provides when it is used in everyday clinical practice. "By reducing the payer's risk, these payment models may therefore be part of the solution in making ATMPs available to patients", notes the TLV.
- The TLV will investigate how volume should be allowed to affect the price - both for drugs aimed at small and large patient groups. In some instances, the TLV notes that it has accepted a higher ICER than normal for treatments for rare diseases. The TLV will investigate whether this approach could potentially be expanded – it may, for instance, be particularly suitable for ATMPs and precision medicines due to their higher prices and limited patient populations.
- The TLV states that, in some situations, it may be justifiable to consider the effect of a new drug on relatives' quality of life. The "TLV believes that in certain situations it is reasonable to consider effects on relatives, when the impact is very large and when the company in its application to TLV can show that their drugs really improve the relatives' quality of life by giving the patient better health".

Brazil is a market of 210 million people.

As the largest country in South America, Brazil is a huge market to consider when launching a drug. However, as a country with significant organisational and budget constraints, not to mention massive wealth inequities, it can be a difficult market to navigate.

When launching, or considering launching, in Brazil you must consider both the public and private markets, how access may vary regionally, and all the key stakeholders involved.

Given the huge disparity that remains in patient access, patients are often a stakeholder themselves. Patient ability and willingness to pay often needs to be considered alongside the drivers for the price and HTA bodies

This article is an introduction to the Brazilian Market Access landscape and covers the below considerations in more detail:

1. Consider the public and private markets
2. Maximum drug price is set by the CMED
3. CONITEC carries out HTA appraisals
4. Further decisions could be made at a regional level
5. Patient access to high-cost drugs is a contentious issue

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How are countries in South-East Asia establishing HTA processes to progress towards Universal Health Coverage?

Health Technology Assessment (HTA) implementation has been historically slow in Asia compared to other areas around the world such as Europe, Australia and North America.

The ASEAN region consists of 10 countries: Brunei Darussalam, Myanmar, Cambodia, Indonesia, Laos, Malaysia, Philippines, Singapore, Thailand, and Vietnam.

While all of these nations have shown a commitment to implementing HTA process for healthcare priority setting, there are varying levels of integration. Brunei Darussalam, Malaysia, Singapore and Thailand provide UHC for their population which includes HTA as the basis for determining new healthcare; Indonesia, the Philippines and Vietnam have begun to provide UHC but their HTA processes remain at the early stage; and Cambodia, Laos and Myanmar have no formalised HTA processes and healthcare priority setting is conducted on an ad-hoc basis.

This varying level of adoption is dependent on different country-specific factors such as investment in public health and technological infrastructure, but also on general challenges faced across all of the nations.

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