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Remap

Germany: Additional rules added surrounding ATMPs

Following a meeting on the 20th October, the G-BA in Germany has added an additional chapter of rules surrounding advanced therapy medicinal products (ATMPs). The new 9th chapter of rules.

The new chapter set out the following key points:

- Consultation on a new AMTP can begin as soon as the pharmaceutical company submits an application for marketing authorisation to the European Medicines Agency (EMA). This aims to allow for regulations on quality requirements for the AMPTs use to already be in place when the AMTP is approved
- Criteria have been set out to access the AMTPs which includes complexity of the indication, preparation, implementation and aftercare, comparison to the applicable therapy standards in the area of application of the ATMP
- Additional fact-finding abilities. Expert discussions will be conducted and ad hoc requests for information about the relevant ATMP can be sent to the pharmaceutical company

Further to this there will be additional requirements for an AMTPs usage to be based on a recognised state of medical knowledge as well as how it can be implemented into care within Germany.

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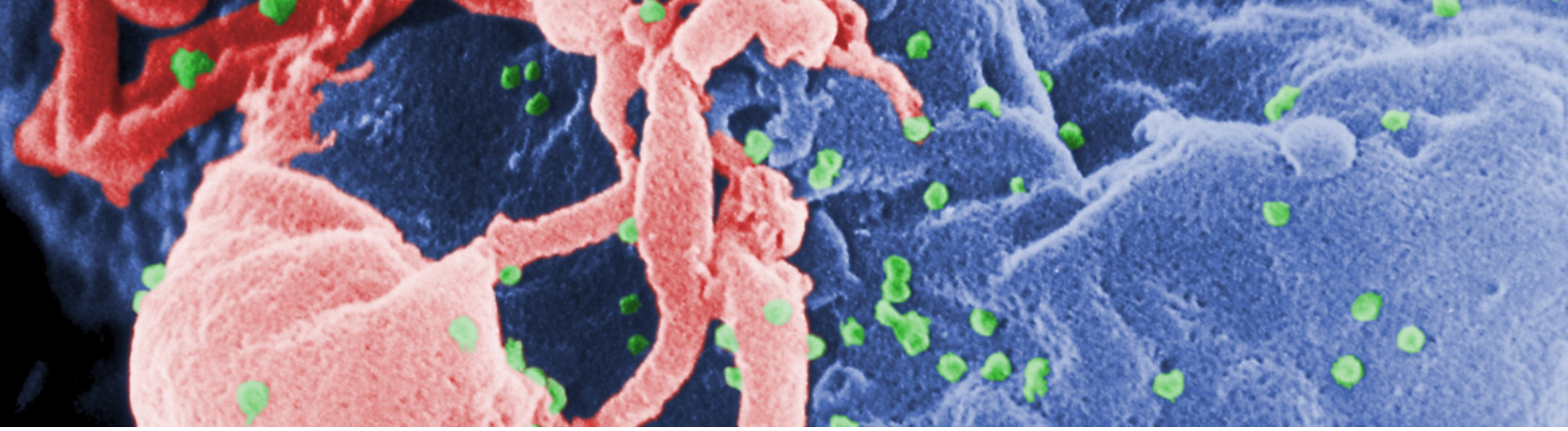

NHS England makes key deals for HIV drugs

The National Health Service (NHS) have made a number of deals to ensure patients can access the latest and greatest HIV drugs anywhere in England. The deals mean 87,000 people currently receiving HIV treatments and 61,000 people receiving HIV preventative medicine will benefit, and the end of regional disparities in HIV commissioning.

Products available via the deals include:

- Cabotegravir and rilpivirine, the first long-acting injectable (replacing daily tablets)
- Fostemsavir for multi-drug resistant infections
- Pre-exposure prophylaxis (PrEP) medicines

Successful HIV treatment keeps the number of virus particles in the blood (viral load) low enough to prevent transmission to another person, while PrEP can prevent HIV negative people from becoming infected if exposed. With the current products now available across England, the NHS hope they can become the first country to defeat the virus, aiming for no new HIV infections by 2030.

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Germany: Significant interest has been aroused by the G-BA with 200+ applications for the innovation fund

From 2016, the Innovation Fund has served as an instrument of central health policy to promote new forms of healthcare research in Germany.

The latest funding announcements have evidently garnered great interest, as following the application deadline, 231 applications for financial support from the innovation fund were received for funding in health services research for the further development of care in statutory health insurance – the second highest quantity of applications in this area of funding. Moreover, there were 31 applications for funding in the development or further development of selected medical guidelines. In the next step of the process, the G-BA Innovation Committee will now evaluate which projects in the two areas will receive funding, with advice being considered from volunteer members from the pool of experts in science and healthcare. New funding announcements are to be published next summer.

The €200 million fund provided for by statutory health insurance (GKV) is split amongst different areas of research according to the G-BA Innovation Committee who determine the qualifying criteria. Criteria for submissions this year were determined and outlined in a funding announcement from the G-BA.

The topics outlined are projects in the field of health services research or projects in the development or further development of medical guidelines.

Read in full here.

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Germany – Is digitisation the gateway to better treatment of rare diseases?

Knowledge generation in the field of drug development for individuals suffering from rare diseases faces difficulties that must be overcome.

Digitisation is believed to contribute significant improvements in knowledge generation in this field, and here, the expected improvement from increasing digitalisation is outlined from the perspective of three healthcare institutions: the Federal Institute for Drugs and Medical Devices, the Institute for Quality and Efficiency in Health Care, and the Federal Joint Committee.

The three healthcare institutions argue that:

- Digitisation has a high potential to increase the efficiency of clinical development and regulatory decision making
- Digitisation can be a tool to reduce barriers to the implementation of care-associated, register-based, randomised controlled trials
- High-quality registry studies should start within the approval process to ensure the evidence necessary for therapy decisions is available immediately following approval

The final point emphasised that the improvement of the evidence base through the qualitative improvement of data sources will result in direct benefits to patients, with effective drug provision being ensured by usable evidence that can be generated over longer periods of time. The institutions concur that high-quality indication registers should be developed as independent infrastructures to facilitate the access of high-quality data early in the medicinal development for rare diseases.

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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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