NEWS DIGEST

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DACH EDITION

- The VFA put forward a concept for an AMNOG reform
- Insurance companies reject industry demands of lowering drug prices
- Austria kicks off the national process for the European pharmaceutical package
- G-BA confirm that in exceptional cases off-label therapies can be considered comparators

Remap

The VFA put forward a concept for an AMNOG reform

The AMNOG introduced benefit-based pricing in Germany in 2011, however, since then medical progress advances mean that the benefit assessment and reimbursement rules may need modernization, in the view of the VFA. To address this, the vfa proposes the "AMNOG 2025" reform concept.

The main points are:

- Gene and cell therapies, targeting small patient groups, and mRNA technology represent a new era in precision medicine. Traditional verification methods for assessing additional benefits have limitations. Therefore, Germany needs to adapt the AMNOG rules to accommodate advancements in medicine. These novel therapies require a more flexible and open AMNOG.
- Starting January 12, 2025, the European benefit assessment will include advanced therapy medicinal products (ATMP) and oncology medicinal products. The vfa suggests integrating the common European work results into the national process. This avoids duplication of efforts and enhances the quality of clinical assessments.
- The vfa also suggests strengthening the negotiation principle of AMNOG. Negotiating partners should have the necessary flexibility to recognize therapeutic improvements and consider the market situation. External elements introduced by the GKV Financial Stabilization Act should be eliminated. Strict "guard rails" or additional deductions for combined drugs restrict negotiation options and are not aligned with AMNOG.

Source

Insurance companies reject industry demands of lowering drug prices

The AOK Federal Association (of health insurers) in Germany have rejected demands from the pharmaceutical industry to strengthen Germany's position as a pharmaceutical location. This was following the VFA (pharmaceutical industry association) published a report on the ways in which Germany could “improve” AMNOG, which included ways to increase their attractiveness to the pharmaceutical market such as the removal of the GKV financial stabilisation act.

The VFA called for better coordination between politics and industry to refrain from falling behind to other markets that may offer more favourable conditions for industry. They argue that this would allow German patients to continue to have early access to drugs. The VFA ask for discussions on how to improve this going forward.

However, Reimann, the chairwoman for the AOK, rejects these arguments and says that "There was already a pharmaceutical dialogue in the past but with questionable added value.If a new start is now required in the form of a round table, then the astronomical entry-level prices for new drugs should be openly discussed here.". Suggesting that talks should really be held to discuss fair price models and ethical profit margins and going on to ask “Is it not enough to have free pricing for six months?”. The AOK argue that greater transparency is needed about the actual costs of research and development.

Source

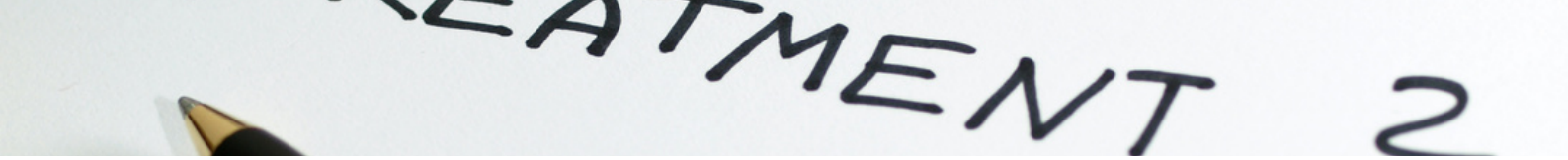
Austria kicks off the national process for the European pharmaceutical package

The national process for the European pharmaceutical package began this week with a kick-off at the Ministry of Health and involved all important Austrian stakeholders.

The European pharmaceutical package aims to ensure long-term medicine supply with a coordinated approach involving all stakeholders. In the meeting, it was discussed how Austria supports strengthening pharmaceutical locations through research, innovation, and supply security. It was highlighted that the package addresses challenges like medicine shortage and promotes bringing production back to Europe. Stakeholder participation and expertise are considered crucial for the package to work but Austria hopes that it will emphasise safe, effective, and affordable medicines for all, combating shortages, and increasing reserves.

Minister of Labor and Economic Affairs, Martin Kocher, said at the meeting “An excellent healthcare system is a central concern of the federal government. Austria is a very strong pharmaceutical location in the EU. It is important for the federal government to further strengthen the pharmaceutical location. Research and production play a central role here because companies can only develop innovative solutions and at the same time ensure a reliable supply if the two areas are closely interlinked. By investing in research and by protecting innovation, we not only secure the location in the long term, but also the security of supply, competitiveness, and high-quality jobs. Innovation in the form of better and new medicines benefits all patients,”

Source



G-BA confirm that in exceptional cases off-label therapies can be considered comparators

When the G-BA assesses “soloists”, products where no other therapy is approved for that indication, it can be challenging to determine the comparator. In the recent Medicines Supply Bottleneck Combating and Supply Improvement Act (ALBVVG) which came into force in late July the assessment of soloists was clarified.

It states that in exceptional cases, the G-BA can also determine the off-label products as an appropriate comparator therapy. This is possible if it has been the standard therapy in an area of application according to general medical knowledge. In addition, an appropriate comparator therapy can also be a non-drug therapy, the best possible supportive therapy, or watchful waiting.

This has come about following products being unlawfully accessed in the spring of this year as they were compared to products which were non-approved in the indication under question.

Source

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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