STORY - 19/05/2020

'Useful clarifications' in G-BA's rules of procedure – expert

Country : **Germany**

Keywords : #gba #legislation #rare diseases

INTERVIEW

HTA

BERLIN, 19 May (APM) - A set of updates in the rules of procedure of Germany's higher health technology assessment (HTA) body G-BA are "useful clarifications" to avoid conflicts in assessments, a pharma consultant has told APM.

"The amendments are details in G-BA's rules of procedure that clarify and substantiate certain points that had left room for interpretations and had caused conflicts in the past," Matthias Schönermark, managing director of consultant firm SKC Beratung, told APM in a phone interview late last week.

Under the amendments, which come into effect once published in the Federal Gazette, pharma companies must file an HTA dossier for fixed combination drugs composed of older compounds in a new indication.

"These combination drugs are common in ophthalmology, such as an antibiotic in combination with a glucocorticoid," Schönermark said.

This new obligation seems reasonable as only a few drugs under patent protection have not undergone HTA procedures under the AMNOG law since 2011. Also, this gives pharma companies "planning reliability", Schönermark added.

COMPARATIVE THERAPY

Under the amendments, G-BA will ask medical societies and the drug commission of the German Medical Association AkdÄ for a written statement on the designated comparative therapy for assessments, a provision introduced under the law on "better safety in drug supply" (GSAV) in 2019 (APMHE 64066).

This provision "makes sense" when medical guidelines - based on which G-BA usually sets the comparative therapy - have not been updated for some time and do not reflect standard of care "and there is a range of such 'inactive' guidelines", Schönermark said.

This is particularly pertinent in oncology, where "guidelines updated in 2016 already seem outdated today". Experts from oncologists' association DGHO have already been active to provide their views in consultation phases of G-BA assessments, he added.

"I think that G-BA assessments will benefit when clinical reality is considered - this has been an issue in lower HTA body IQWiG's recommendations, as these only accepted data from highly-standardised settings" and it is positive when "clinicians calibrate" this choice, Schönermark said.

However, Schönermark is sceptical about how such medical expertise will be brought into the assessments.

Another issue is that medical experts could increase physicians' influence within G-BA, which could raise "general suspicions" by payers that pharma industry's influence would also grow.

From his perspective, this is a "very old and unjustified prejudice", as clinicians usually judge "the standards of patient care very realistically", Schönermark said.

"Today, it is hard for the pharma industry to find medical experts who do not get nervous about seeming compromised when they are asked to think about industry matters," he added.

ORPHAN DRUGS

Changes also include provisions on orphan drugs, which were mainly introduced under the GSAV law.

For example, G-BA cannot freely qualify "unquantifiable added benefit" ratings but will specify whether a rating was given based on limited scientific evidence or because the assessment file was incomplete (APMHE 63310). The comments G-BA had made in some assessments were "tendencious", Schönermark said.

Also, under the GSAV law, hospital and pharmacy sales count for the threshold of €50 million in annual sales for orphan drugs, after which a full assessment is triggered (APMHE 60657) - a provision that "was lobbied into the GSAV law" by umbrella payer group GKV-Spitzenverband (GKV-SV), Schönermark said.

Pharma companies must supply sales figures to G-BA upon request from drugs received by hospitalised insurees of statutory health insurance GKV, according to the amendment to G-BA's rules of procedure.

"However, it is really hard to tell for pharma companies which proportion of sales comes from hospitals and when the drug was used, as logistic chains are not easy to follow," he added.

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