Introduction. Within early benefit assessment of pharmaceuticals in Germany, addenda can be commissioned by the Federal Joint Committee (FJC) to the health technology assessment (HTA) agency, mainly as a result of a hearing. Our aim was to analyze the issues for and impact of commissioned addenda, as well as the agreement between HTA agency recommendations and FJC decisions.

Methods. All available relevant documents on addenda commissioned up to the end of 2017 were screened and their essential content extracted. Differences between the HTA agency and FJC recommendations were tested, and concordance was analyzed using agreement statistics (Cohen's kappa and Fleiss' kappa).

Results. Most of the 90 addenda commissioned up to the end of 2017 concerned oncological products. In all contingent comparisons, positive changes in added benefit or evidence level on a subpopulation basis (n = 124) were more common than negative changes. Agreement of assessments, addenda, and appraisals reached a moderate strength for added benefit (Fleiss' kappa 0.47, range 0.41 - 0.54). Overall agreement between addenda and appraisals on a binary nominal basis was poor for added benefit (Cohen's kappa 0.18, range 0.01 - 0.36) and fair for evidence quality (Cohen's kappa 0.35, 0.19–0.52). Cohen's kappa ranged from "less than by chance" (respiratory diseases) to "perfect" (neurological diseases), but was only statistically significant for neurological and other diseases. Three addenda are presented in detail as examples.

Conclusions. Addenda have a high impact on decision-makers' appraisals, offering additional analyses of supplementary evidence submitted by the manufacturers. Nevertheless, the agreement between addenda and appraisals varies, highlighting different methodological approaches and decision-making factors between the HTA agency and the FJC.

PP86 Reimbursement of Combination Oncology Products: Can Two (Companies) Tango?

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Introduction. A range of innovative, targeted anti-cancer therapies have been developed over the past 20 years. More recently, companies have been developing combinations of these drugs. While this promises substantial efficacy benefits, dual-brand oncology therapy combinations may potentially create substantial economic burden. Obtaining a positive health technology assessment (HTA) recommendation and public reimbursement can be a major challenge, and may be more difficult when each constituent monotherapy is marketed by a different company. We evaluated whether dual-brand oncology therapies developed by a single manufacturer had faster or better outcomes than those developed by two separate manufacturers.

Methods. Recent combination oncology drug products were screened in November 2018 to identify whether one or two manufacturers were involved. The websites of various HTA organizations were screened and the relevant data extracted.

Results. A total of 78 recommendations for dual-brand oncology treatments were identified across the HTA agencies screened: 26 of these were for combinations by the same manufacturer and 52 were for combinations with two manufacturers. Dual-brand therapies developed by a single manufacturer were more likely to receive full or optimized/conditional recommendations (58% "recommended" and 12% "optimized/conditional") than those marketed by two separate manufacturers (42% "recommended" and 8% "optimized/conditional"). Dual-brand therapies with two manufacturers were more likely to receive negative HTA recommendations than those marketed by a single manufacturer (50% versus 31%). However, the median time from marketing authorization to recommendation in European countries was the same (6 months), regardless of whether each constituent monotherapy was marketed by one or two manufacturers.

Conclusions. HTA agencies were more likely to issue negative recommendations for dual-brand oncology treatments marketed by two separate companies, compared with those marketed by a single company. A single company may have more flexibility in price setting, which may facilitate more positive HTA recommendations.

PP87 Inpatient Drug Reimbursement: Approaches For A Democratic Process

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Introduction. In the context of limited healthcare resources and high healthcare expenditures, the introduction of new, cost-intensive medicines forces decision-makers to prioritize drug funding, especially in the areas of orphan diseases and oncology. In democratic societies, health policy decisions need to be evidence-based, transparent, fair, and efficient. Therefore, in some countries standardized (transparent) processes exist. In Austria, decisions on the reimbursement of new medicines have not been made for a long time. The aim of the present study was to develop different scenarios for a standardized, centralized reimbursement process for expensive hospital drugs in Austria that favors democratic decisions.

Methods. A multi-stage approach was undertaken. Firstly, the reimbursement processes (only for original preparations) in Austria and other selected countries were investigated. Secondly, the strengths and weaknesses of these processes were analyzed based on predefined criteria, following the concepts of "accountability for reasonableness" (A4R) and "deliberative decision making". Thirdly, scenarios for an Austria-wide uniform reimbursement process for hospital drugs were developed.

Results. Three scenarios were identified: (i) a reimbursement process for hospital drugs that follows the existing reimbursement process in the outpatient sector in Austria; (ii) a cooperative of decentralized Pharmaceutical and Therapeutics Committees for procurement, use, and reimbursement decisions for hospital drugs; and (iii) an adaptation of the existing reimbursement process of non-drug, highly specialized technologies to pharmaceutical interventions.

https://doi.org/10.1017/S0266462319002277 Published online by Cambridge University Press