and MTG patients. Additionally, hospitalizations in intensive care units (50% SG vs. 22% MTG patients), emergency visits (21% SG vs. 6% MTG) and the presence of adenoma complications (73% SG vs. 44% MTG) constitute a source of cost increment in these patients. Patients who accomplish with the most strict study clinical control criteria (GH <1 >95% and IGF-1 >100%) showed the lowest direct cost of the disease ($16,659 vs. $12,990). CONCLUSIONS: The economic cost of agramain is dependently on the clinical control of the disease. Direct cost of illness is the half that the cost in non-controlled patients.

CONCLUSIONS: To gain insight into the re-evaluation process of HTA agencies after an initial rejection and identify the adaptations that led to the approval of re-submitted dossiers. METHODS: Phase I: manual search of 57 health care agencies’ websites for published diabetes-related assessments (January 2007-May 2010). Phase II: the two most re-assessed drugs for which detailed information was available were selected for further evaluation (insulin gliptine and exenatide). For these drugs, all reports published prior to 2007 were also included. RESULTS: Phase I identified 117 relevant single technology appraisals; 18 were re-evaluations. Six agencies performed re-evaluations of the same drug after an initial rejection: CADTH, CVZ, HAS, PBAC, AHTAPol and SMC. To date, SMC evaluated 32 submissions for 13 anti-diabetic drugs, PBAC published 20 (eight drugs), CADTH 13 (four drugs), CVZ 14 (four drugs) and AHTAPol 10 (two drugs). In Phase II insulin gliptine (four re-submissions to PBAC and 1 to CADTH) and exenatide (two re-submissions to PBAC, 1 to CVZ and 1 to AHTAPol) were evaluated. It became clear that payers do focus on overall cost. The approach that was chosen for those two drugs was to control overall cost either by restricting access or by setting on a lower price. CVZ accepted exenatide for reimbursement only after restricting access to a subgroup of obese type 2 diabetes mellitus patients (with an ICER of €5,231). Instead of patient segmentation PBAC insisted on lowering the price for both medications (rationalise for insulin gliptine being concerned, that prescribing cannot be contained within the defined population). AHTAPol limited exenatide reimbursement to 50% to control prescribing prices.

CONCLUSIONS: For the diabetes cases analyzed HTA agencies attempted to control health care expenditure by either lowering drug costs or by narrowing the definition of the target population, the latter inevitably allowing fewer patients access to the drug.

RESULTS: Of a total of 163 reports (published between 2007 and 2010), eight reports in Polish language on diabetes were identified and assessed. Two reports can be viewed as secondary assessment of regulatory safety discussions. The other six reports assessed the implementation of new diabetes compounds with assessments of efficacy, safety as secondary assessment of regulatory safety discussions. The other six reports assessed the safety concerns associated with the risk of cancer and concluded based on EMA and FDA research that no substantial variation of criteria applied and evidence considered relevant within the assessment process of IQWiG compared to other agencies. This might lead to regional variations in the availability of drugs. It is important to be aware of the different requirements of agencies, when designing trials and planning market access.

PHYSICAL PERSPECTIVE

The Polish perspective

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OBJECTIVES: The AOTM in Poland was established to give Moh in Poland advice on reimbursement. The aim of this research is to create an overview of HTA reports on diabetes compounds in Poland and the results of the decision making. METHODS: A search was conducted on the webpage of AOTM (http://www.aotm.gov.pl) for HTA reports on the following products: Rosiglitazone, Pioglitazone, Stagliptin, Vildagliptin, Saxagliptin, Exenatide, Lispro, Liraglutide, Gliclazide, Detemir, Aspart, Gliulisene and Lispro.

RESULTS: Of a total of 163 reports (published between 2007 and 2010), eight reports in Polish language on diabetes were identified and assessed. Two reports can be viewed as secondary assessment of regulatory safety discussions. The other six reports assessed the implementation of new diabetes compounds with assessment of efficacy and cost-effectiveness of the drugs. Two reports assessed safety concerns associated with the risk of cancer and concluded based on EMA and FDA research that no

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METHODS: We argue that this indirect effect is due to physicians’ learning from the DMP-based treatments data from their medical practices. Using consultation data from IMS Health, we test for indirect effects of DMPs on patient outcomes. We pool data from two time periods: 2007 and 2010. We then use data from the year 2007 for our empirical analysis. We use data from 2007 because the year 2010 does not contain enough data to test for an indirect effect. We use data from the year 2007 because the year 2007 does not contain enough data to test for an indirect effect. We use data from the year 2007 because the year 2007 does not contain enough data to test for an indirect effect. We use data from the year 2007 because the year 2007 does not contain enough data to test for an indirect effect.

RESULTS: The mean survival time (duration between first diagnosis and first complication) of the medical treatment of diabetes in a DMP is 14,82 years, differing significantly from the 15,76 years without a DMP. These tests are followed for controlling patient variables: sex, age, HbA1C, BMI and the insurance status. Learnings from DMPs, indirectly affecting DM care, significantly postpone complications for younger diabetics and practices with fewer diabetics. CONCLUSIONS: Contributing to assessments of DMPs, the study discusses policy implications, as it is shown that care quality is improved by physicians learning from DMPs.

The IQWiG perspective

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OBJECTIVES: A substantial number of new pharmaceutical treatment strategies have been introduced for the treatment of diabetes mellitus type II. The availability of these drugs for patients in different countries depends on the evaluation standards and methods applied in various phases of drug assessment. Objective of this research was to review the requirements and criteria applied for the assessment of antidiabetic drugs along the regulatory process by EMA (Europe) and FDA (USA) for the assessment of efficacy and safety as well as for reimbursement decisions by NICE (England) and IQWiG (Germany) and to compare their consistency, with a special focus on IQWiG’s procedures. METHODS: A review of relevant current method documents and reports on evaluations of antidiabetic drugs published by IQWiG was conducted. These were compared with guidance documents issued by FDA, EMA and NICE with respect to endpoints considered in diabetes and their definition, criteria for the type of evidence, and potential comparators. RESULTS: Consistently, across all agencies severe and non-severe hypoglycemia were considered highly relevant. There was, however, a substantial heterogeneity in the definition of hypoglycemia. The surro- gate parameter HbA1C, as primary endpoint was accepted by all agencies investigated apart from IQWiG. In its assessments, evidence from randomized as well as from observational studies was accepted by NICE. For safety evaluations preliminary data were taken into consideration by EMA and FDA in addition to randomized controlled trials. IQWiG on the other hand focused exclusively on randomized controlled trials for the assessment of effectiveness as well as safety. CONCLUSIONS: There is a substantial variation of criteria applied and evidence considered relevant within the assessment process of IQWiG compared to other agencies. This might lead to regional variations in the availability of drugs. It is important to be aware of the different requirements of agencies, when designing trials and planning market access.

OBJECTIVES: To examine the rate and predictors of diabetes monitoring in the US. METHODS: This cross-sectional retrospective study was conducted on a representa- tive, non-institutionalized sample of the US population, using the self-reported information from the 2007 Household Component (HC) of the MEPS. According to the American Diabetes Association (ADA) 2007 practice guidelines, proper monitoring is defined as at least two A1c tests, one eye and one foot examination annually. Health status was measured by SF-12Version2a, a logistic regression model was used to examine the predictors of proper monitoring. Differences in health status and medical expenditures between patients with and without proper monitoring were examined using t-tests. Estimates were weighted to the total population (WTP). RESULTS: Among 1,747 (WTP: 19,320,394) patients with diabetes, 80.64% had at least two A1c tests; 63.29% had an eye examination; and 67.51% had a foot examina- tion. Older patients (OR:1.021, 95% confidence interval [CI]: 1.012–1.030), non-Hispanic Caucasians compared with African American patients (OR: 1.236, 95% CI: 0.933–1.636), patients with a higher education level (OR:1.211, 95% CI: 1.056–1.390), insurance coverage (OR:2.216, 95% CI: 1.408–3.486), use of oral anti-diabetic drugs (OR:2.935, 95% CI: 2.131–4.042) and insulin (OR:3.453, 95% CI: 2.477–4.814) were more likely to undergo the proper monitoring. Well monitored patients had a higher Mental Component Summary score (30.09 ± 0.37 vs. 48.31 ± 0.43, P < 0.05), but a lower Physical Component Summary score (39.95 ± 0.34 vs. 42.28 ± 0.47, P < 0.05)