THE BELGIAN REIMBURSEMENT PROCEDURE (BRP): ARE ADDED THERAPEUTIC VALUE (ATV) AND ICER AFFECTING THE DRUG REIMBURSEMENT DECISION (DRD)?
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OBJECTIVES: Since 2002, the BRP for medicinal products claiming ATV requires the evaluation of the therapeutic and pharmaco-economic value as compared to alternatives. The study aim was to analyze the effect of ATV and ICER on the DRD.

METHODS: The RIZIV administrative database was used for extracting all files claiming ATV submitted between January 2002 and February 2008. ICERs expressed per QALY or per LYG were pooled. ATV was a binary outcome variable (ATV either present or absent). The DRD was either positive or negative. Statistical analysis (logistic regression /backwards elimination) was performed using SAS EG. The significance level was set at 0.05. Only complete cases were analyzed.

RESULTS: A total of 138 submissions fulfilled the criteria. Data were available for all variables in only 76 (55.1%) cases. ATV and ICER were both significantly (p < 0.01) related with the final DRD. The odds of a positive DRD increase to 9.5-fold if ATV was granted and decrease to 0.45-fold if the ICER increases €10,000. No significant interactions were observed (p > 0.10).

CONCLUSIONS: Based on this sample, our analysis indicates that both ATV and ICER have a prognostic (but opposite) effect on the final DRD in Belgium. Further investigation should consider the potential effects of other variables such as budget impact, disease category, price and others on the DRD.

MARKET AUTHORIZATION (MA) AND REIMBURSEMENT: ANALYSIS OF THE POST-MA TIMELINES AND THE ACCESS TO NEW MEDICINES IN BELGIUM
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OBJECTIVES: The study aim was to investigate the time delays between market authorization, reimbursement submission and reimbursement authorization and to analyze whether the type of submission affects these delays for new products.

METHODS: Data were extracted from the Riziv administrative database. A total of 613 reimbursement files were handled between January 1, 2002 and December 31, 2007. The three submission types were: added (n = 104) or similar (n = 480) therapeutic value or orphan status (n = 29). The following variables were computed: TTS = time between market authorization and reimbursement submission; TSA = time between reimbursement submission and authorization; TMR = time between market authorization and reimbursement authorization. Resubmissions of unapproved claims were excluded to maintain the independency between files. All statistical analyses were executed in SAS EG.

RESULTS: The median (25th–75th percentile)delays (in days) were respectively 137 (46–308), 258 (235–294) and 421 (307–633) for TTS, TSA and TMR. There was no significant difference in TTS between submission types indicating that the need for pharmaco-economic data for added value claims is not jeopardizing TTS. TSA for added value and TMR for orphan submissions were significantly longer indicating the more complex evaluation process which precedes the reimbursement decision.

THE COMPETITIVE ACQUISITION PROGRAM (CAP): WHERE IS IT AFTER TWO YEARS?
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OBJECTIVES: Since 2006 physicians have been able to select the competitive drug acquisition program (CAP) as an alternative method of acquiring drugs and biologics for in-office administration under Medicare. This study examines the evolution of the program from 2006 to present, recounts the legislative and regulatory program impacts and describes issues that remain as potential obstacles to widespread provider acceptance.

METHODS: Historic CAP regulatory and legislative guidance was collected, arranged in order of issuance, abstracted and analyzed. A timeline illustrating evolutionary program modifications was constructed. Remaining issues that may deter provider participation were described and information resources were compiled.

RESULTS: The CAP is a payment model that removes the drug purchasing function from the physician’s office while the drug administration responsibility remains. Despite intent to minimize provider financial risk and ease operational burden, the CAP has been slow to attract participants. There have been legislative and regulatory attempts to modify and improve the program’s attractiveness and ease of use however the majority of physicians providing in-office drugs continue to do so through conventional buy and bill methods. Throughout this time the Medicare drug payment to physician offices has remained at average sales price plus six percent (ASP +6%) and the associated drug administration rates have been fairly stable.

CONCLUSIONS: The number of providers utilizing the buy and bill method was expected to decrease following implementation of the CAP alternative. The CAP program has now been in effect for over two years, has undergone a number of operational modifications, and yet continues to experience low enrollment. At this time it is not possible to determine conclusively the impact of: 1) inadequate provider incentive to drive the conversion, or 2) the deterrent effect of remaining program issues. Further investigation is warranted.

DETERMINANTS OF PHARMACEUTICAL CONSUMPTION IN A GENERAL POPULATION
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OBJECTIVES: To identify characteristics of the individual that may predict pharmaceutical use. We study the impact of socio-demographic (gender, age, marital status, education, rural/urban residence) and need factors (chronic diseases, health-related quality of life, measured by the Greek version of SF-12, previous-year physician consultations and hospitalizations). METHODS: Data was obtained from a nationally representative sample (N = 1005) of the general-non-institutionalized-population in