for Acid Related Disorders (DARD) after the reimbursement of rofecoxib and celecoxib. The substances considered were: NSAID: aceclofenac, acemetacin, diclofenac, ibuprofen, indometacin, meloxicam, nabumeton, naproxen, nimesulide, piroxicam, tenoxicam; Proton Pump Inhibitors: omeprazol, pantoprazol, lansoprazol, rabeprazol, esomeprazol; H2 Receptor Antagonists: cimetidine, famotidine, nizatidine, ranitidine; misoprolol and sucralfate were also studied. **METHODS:** Using data of reimbursed medicines dispensed in the NHS (in DDD units) from January 1995 to June 2001, modelling was performed using SARIMA models. Intervention variables were used to evaluate the influence of the reimbursement of Cox2 inhibitors on overall NSAID and DARD consumption. **RESULTS:** NSAID overall consumption increased for the considered time period from 50.49 DDD/1.000 inhabitants/day in year 2000 to 62.35 DDD/1.000 inhabitants /day 1° semester 2001. DARD consumption also increased from 24.87 DDD/1.000 inhabitants/day to 28 DDD/1.000 inhabitants /day during the above mentioned period of time. **CONCLUSIONS:** The global dispensing of selected NSAID in 1° semester 2001 faced a total increase above the projected value. The Cox2 inhibitors appear to have an add-on effect, rather than a substitutive effect on already existing therapies. Moreover we did not observe decrease on DARD consumption patterns.

PAR4

ETANERCEPT VERSUS INFLIXIMAB PLUS METHOTREXATE IN RHEUMATOID ARTHRITIS: A COST-EFFECTIVENESS ANALYSIS FROM THE ITALIAN NHS PERSPECTIVE

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OBJECTIVES: Rheumatoid Arthritis (RA) is a chronic disease, whose social burden is mostly related to costs that increase with the progression of illness severity and related disability. Thus it is possible that early treatment induces significant cost savings. Recently favourable cost-effectiveness ratios were demonstrated for Etanercept (ETA) versus Infliximab plus Methotrexate (INFLI + METHO) for early RA treatment, in severe US patients previously untreated with METHO. An adaptation of the US model to Italy was undertaken, in order to evaluate cost-effectiveness of ETA, in the Italian National Health care System (NHS) perspective (direct medical costs). **METHODS:** Cost-effectiveness analysis compared ETA 25 mg twice weekly with INFLI 3 mg/kg or 10 mg/kg (mean patient weight 74 Kg was assumed, from clinical trials) q4 or q8 weeks plus oral METHO (16 mg/week). Time horizon was established at two years, according to published long-term follow-up clinical data. Also, drug dosages, efficacy and probabilities of events were based on published clinical trial data. Market prices were applied for medication costs plus official tariffs for IV administration and monitoring for INFLI and METHO. For sepsis as a major adverse event, the NHS hospital tariff was used. The total per patient cost was then calculated and the cost-effectiveness ratio was expressed as cost/patient to prevent radiographycally detected RA progression. **RESULTS:** Total cost/patient for ETA was lower compared to INFLI + METHO at different dosages (respectively, €25,931 vs from €44,745 to €119,215, depending on INFLI schedule), with the only exception of INFLI 3 mg/kg q8 weeks (€24,189). Cost-effectiveness ratio (cost/patient successfully treated) was €41,160 for ETA vs values in the range of €56,122 to €218,743 for INFLI + METHO. **CONCLUSIONS:** ETA was found dominant (less costly and more effective) versus 3 different dosages of INFLI + METHO, and showed a positive cost-effectiveness ratio versus INFLI 3 mg/kg q8 weeks, in the perspective of the Italian NHS.

PAR5

THE TOTAL COSTS OF TREATMENT WITH VALDECOXIB COMPARED TO GENERIC DICLOFENAC ARE SIMILAR IN PATIENTS WITH RHEUMATOID ARTHRITIS IN GERMANY

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OBJECTIVES: To conduct a cost-consequence analysis evaluating the treatment cost difference between valdecoxib and diclofenac in rheumatoid arthritis (RA) treatment from the perspective of German Sickness funds. **METHODS:** Health care resource utilization data were prospectively collected in a double-blind randomized trial of oral valdecoxib 20 mg QD (n = 246) versus diclofenac 75 mg BID (n = 237) of adult patients with RA in 26 countries. The study demonstrated that valdecoxib has a superior GI safety profile and comparable efficacy to diclofenac. The Health care resource data were costed using published German sources. Information evaluated medications, hospitalizations, unscheduled consultations with Health care professionals and use of diagnostic and medical procedures. Pharmacy costs of valdecoxib and generic diclofenac were included. In-depth analyses were conducted to explore the cost-difference attributable to gastrointestinal (GI) serious adverse events (GI-SAEs). The results are presented in cost per patient during the study period and cost per patient per day of treatment in order to adjust for the lower withdrawal rates with valdecoxib. **RESULTS:** The fewer hospitalization days in valdecoxib patients translated into significantly lower hospitalization cost per patient for valdecoxib with a cost difference of €138.17 (95% confidence interval [CI]: €282.84, €10.58). The total Health care costs per patient over a 6-month period for valdecoxib (€659.45) compared to diclofenac (€549.31) showed a cost difference of €110.14 (95% CI: €70.33, €290.62). Accounting for the different withdrawal rates (patients stayed longer on

valdecoxib), valdecoxib had a lower cost (€0.26) per treatment day (95% CI: €-3.23, €2.72). The cost difference associated with GI-SAEs per treatment day was lower for valdecoxib: €1.57 (95% CI; €3.90, €0.75). **CONCLUSIONS:** Valdecoxib relative to diclofenac has significantly lower hospitalization costs per patient, and the total costs for the two treatments are not significantly different, indicating that the superior safety benefits with valdecoxib might be achieved without an increase in total treatment costs.

PAR6

ACUTE GOUTY ARTHRITIS: THE COST-EFFECTIVENESS OF A NEW SELECTIVE COX-2 INHIBITOR (ETORICOXIB) IN THE UK

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OBJECTIVES: To evaluate the cost-effectiveness of etoricoxib, a new selective Cox-2 inhibitor, in the treatment of acute gouty arthritis compared with indomethacin in the United Kingdom. **METHODS:** Using a recent clinical trial comparing etoricoxib with indomethacin in the treatment of acute gouty arthritis, a Markov model was built based on four 8-day treatment cycles spread over four years. In the trial, etoricoxib and indomethacin demonstrated equivalent efficacy but adverse event (AE) and treatment discontinuation rates favored etoricoxib. In calculating the total cost for each type of AE, its frequency in the trial was taken into account. The medical treatment of AEs and the average predicted probability of seeking treatment were obtained from expert opinion and used for the base case analysis. In the model, all patients suffering an AE or discontinuing treatment selected a different treatment for their next gout attack. The model further assumed a general practitioner would treat all patients and that an AE could necessitate one additional GP visit. **RESULTS:** After one cycle of treatment the incremental cost per patient successfully treated with etoricoxib (no AE or discontinuation), including drug therapy costs, was £15.43, decreasing to £6.27 over 4 cycles of treatment. **CONCLUSION:** In this study, etoricoxib was a cost-effective alternative to indomethacin for treatment of acute gouty arthritis based on the modelling calculations using published clinical trial data and conservative assumptions regarding the treatment of AEs.

PAR7

PHARMACOECONOMICS OF COX-2-SELECTIVE INHIBITORS VERSUS NON-SELECTIVE NSAIDS AND CONCOMITANT COUMARIN USE: ECONOMIC EVALUATION LINKED TO A CASE-CONTROL STUDY

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OBJECTIVE: To determine the incremental cost-effectiveness of COX-2-selective versus non-selective non-steroidal anti-inflammatory drugs (NSAIDs) in relation to bleeding in a cohort of coumarin users. **METHODS:** A pharmacoeconomic evaluation was linked to a case-control design within an observational study in concomitant NSAID and coumarin users (with versus without bleeding). Medical costs associated with bleeding as well as costs associated with NSAID-use were determined, according to the Dutch guideline prices and Health care tariffs. Rofecoxib, meloxicam, and nabumetone were considered to be COX-2-selective. Total costs were calculated and compared for two hypothetical scenarios in which patients would use either COX-2-selective NSAIDs or non-selective NSAIDs. Sensitivity analyses were performed varying both the Odds Ratio (OR) and costs of NSAIDs and bleedings. **RESULTS:** A total of 1491 bleeding complications were detected among 4400 coumarin users. Of the bleeders, 14.8% (n = 221) used a non-selective (96.1%) or COX-2-selective (3.9%) NSAID. The OR for bleeding was 3.07 (95% CI 1.18–8.03) for non-selective versus COX-2-selective NSAIDs. The mean cost of a bleeding was €478. Factoring in the excess costs of COX-2-selective over non-selective NSAID-use resulted in net savings of €53,786. In the sensitivity analysis, cost savings remained, except for situations with the OR in the lower range of the confidence interval (1.18–1.26). **CONCLUSIONS:** In coumarin users, the reduction of bleeding complications by the more expensive COX-2-selective inhibitors (compared with non-selective NSAIDs) is also associated with medical cost savings.

PAR8

AVERAGE DAILY DOSE AND COSTS OF REIMBURSED COX-2 INHIBITORS FOR PATIENTS WITH RHEUMATOID ARTHRITIS IN NORWAY

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OBJECTIVES: To assess the average prescribed daily dose and cost of the two reimbursed coxibs, rofecoxib and celecoxib, in Norway. Given the drugs' different price structures, prescribed number of tablets and strength impact the daily treatment cost differentially. As a prerequisite for continued general reimbursement for rofecoxib and celecoxib from July 1, 2003, the Norwegian Ministry of Health required post-marketing data regarding prescription patterns in clinical practice to further evaluate the drugs' relative cost effectiveness. The Ministry's re-evaluation will be based on this and other studies. **METHODS:** All accessible physicians within the field of rheumatology (specialists) in Norway were invited to prospectively register their prescriptions of reimbursed coxibs for patients with Rheumatoid Arthritis (RA) and/or Osteoarthritis (OA), over a period of 2 months (October to December 2002). Data from registration forms and patient records were collected through per-