baseline and 3 months in 344/383 patients who took ≥1 dose of study drug. Patients were obese (mean [± SD] BMI = 32.3 [± 7.7] kg/m^2) and >80% had T2DM. Mean HbA_{1c} was 9.1% (± 1.5) at baseline and 8.3% (± 1.2) after 3 months; 11.6% reached HbA_{1c} ≤7%. The mealtime insulin dose at 3 months was 38.6 IU (± 28.0). A cluster of 4 factors that favourably affected glycaemic control was identified: T2DM, lower baseline HbA_{1c} >1 hypoglycaemic event, and being Caucasian. Patients with T1DM and those taking at least one cardiovascular medication were less likely to reach target. Comparing the overall p-values for the crude and adjusted odds ratios suggested that HbA_{1c} at baseline, type of diabetes and higher number of hypoglycaemic events were interrelated, while racial group was independent of the other factors. **CONCLUSIONS:** Patients who achieved HbA_{1c} ≤7.0% 3 months after the addition of insulin glulisine were likely to have T2DM, a lower baseline HbA_{1c}, more hypoglycaemic episodes and be Caucasian.

PDB14

ASSESSMENT OF THE CLINICAL AND ECONOMIC BENEFITS OF ADEQUATE INSULIN INITIATION AND INTENSIFICATION IN PEOPLE WITH TYPE 2 DIABETES MELLITUS

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OBJECTIVES: To assess the clinical and economic benefits associated with adequate and early insulin initiation and intensification in people with T2DM. **METHODS:** A systematic review was performed using published papers from January 2000 to August 2010 that assessed intervention, disease, study design and outcomes. Studies were classified as initiation and intensification based on predefined criteria. Individual studies from systematic reviews and meta-analysis identified in our review were searched and included if relevant. **RESULTS:** We screened 2690 articles, of which 76 (40 initiation and 36 intensification) studies were included. Baseline HbA1c values were in all initiation studies >8.5%. Endpoint HbA1c values were reduced with insulin in all studies, with endpoint values ranging from 6.6% to 9.8%. Similar baseline and endpoint HbA1c were seen with the intensification studies (endpoint HbA1c ranging from 6.4% to 9.6%). Addition of insulin to oral anti-diabetic agents (OADs) resulted in better glycaemic control in most studies. Blood glucose levels reduced substantially with OADs+insulin compared to OADs alone. Quality of life outcomes and treatment satisfaction were reported in six studies and not significantly different for insulin versus OADs. Hypoglycaemic events were lower with insulin initiation versus OADs (1.39+1.16 vs. 2.30+1.87; 9/27 vs. 17/28). However, all insulin types were associated with weight gain though the comparison with OADs elicited varying results. Economic outcomes were reported in four studies with insulin initiation. Some studies reported a reduced incidence in diabetes-related complications with insulin, resulting in lower diabetes-related medical and total healthcare costs in these patients. Two studies showed that initiating insulin in those failing OADs resulted in increase in life expectancy and quality-adjusted life expectancy. **CONCLUSIONS:** Proactive management of uncontrolled glycaemia in people with T2DM should be considered with early insulin initiation and intensification. Further studies are required to explore the economic benefits with early insulin initiation and intensification.

PDB15

USE OF HYPOGLICEMIC DRUGS IN SERBIA: PHARMACOTHERAPEUTIC VERSUS PHARMACOECONOMIC ASPECTS

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OBJECTIVES: To analyse the use of hypoglycemic drugs in Serbia from pharmacotherapeutic and pharmacoeconomic point. To see the influence of pharmacotherapeutic guidelines and cost on use of hipoglicemic drugs when compared with the countries with developed pharmacotherapy. **METHODS:** Use of hypoglicemic drugs in Serbia was obtained from National Agency for drugs in Serbia (ALIMS). The costs of hypoglycemic drugs was obtained from Serbian reimbursment company. The use of drugs was expressed in DDD/1000 inh/day, and compared to the price of drugs in the cathegory. **RESULTS:** The total use of hypoglycemic drugs in Serbia (56 DDD/1000inh/day) was similar to the use of drugs in this cathegory in another countries. Use of insulins was lower in Serbia, probably because slightly different pharmacotherapeutic approach to DM Typ II in Serbia. The structure of oral hypoglycemics was similar in Serbia and in comparator countries (Norway, Finland). While metformin was the most often used hypoglicemic drug in countries with developed pharmacotherapy, in Serbia the most often used drugs were sulfonylurea drugs, with glibenclamide and gliclaside being in the first place. Gliclaside, being on the second place in Serbia, is the most expensive hypoglicemic drug (price per DDD 12.15 Serbian dinars). If gliclaside would be changed with another, less expensive drug, the national reimbursment company would spare significant amount of money. Glimepiride, the most often used and the cheaper sulfonylurea derivative in countries with developed phrmacotherapy, was on the third place in Serbia. **CONCLUSIONS:** The total use of hypoglycemics in Serbia is comparable to countries with developed pharmacotherapy, indicating the satisfiing level of the treatment of diabetes mellitus. However, the structure og hypoglycemics used is suboptimal from pharmacotherapeutic and from pharmacoeconomic point of wiev. Significant improvement are needed, which would improve pharmacotherapy and pharmacoeconomic aspect of use of this drugs.

PDB16

FIRST RESULTS OF THE POST-MARKETING SURVEY OF VILDAGLIPTIN IN FRANCE

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OBJECTIVES: To assess the characteristics of type 2 diabetes patients treated with vildagliptin (a new DPP-4 inhibitor) and to evaluate potential misuse, treatment adherence, effectiveness and tolerability of vildagliptin under real-life conditions of care in France. **METHODS:** Following a request by the French Health Technology Agency (Haute Autorité de Santé) an observational cohort study was started in 2010. The study population included a representative sample of patients with type 2 diabetes initiating a treatment with vildagliptin. Patients were enrolled through a national sample of vildagliptin prescribers Data collected included sociodemographic characteristics, clinical history, comorbidities, detailed treatment and laboratory data, physical exam and adherence. **RESULTS:** Overall, 482 GPs and 84 endocrinologists enrolled 1702 patients. Sixty percent were males, mean age was 63 (±11) years, mean disease duration was 7 (±6.5) years and mean HbA1C 7.8% (±1.2). Forty-five percent were obese and 39% overweight, 70% were treated for hypertension and 66% for dyslipidaemia, and 1256 patients (74%) were treated with vildagliptin/metformin fixed combination (Eucreas, FC) and 442 (26%) with vildagliptin (Galvus). Main reasons for initiating vildagliptin were: previous treatment failure (82%), weight gain (17%), reducing the numbers of pills (16%) and intolerance to a previous treatment (12%). In accordance to the precautions of use, 1366 patients (80%) underwent liver function tests, and 1552 patients (91%) blood creatinine measurement prior to treatment initiation. In few cases, vildagliptin was prescribed to patients for whom the product was not recommended: at baseline, 2.1% of treated patients presented elevations in alanine/aspartate aminotransferase > 3 times the upper limit of normal, 0.3% a NYHA class III congestive heart failure (no class IV) and 9.3% did not respect the precautions of use for renal function. **CONCLUSIONS:** Most prescriptions of vildagliptin were in accordance with the summary of product characteristics in this large, randomly selected French population.

PDB17

OFF-LABEL AND NON-LICENSED ENDOCRINOLOGY MEDICINE USE IN TURKEY: A RETROSPECTIVE ANALYSIS OF COMPUTER RECORDS IN THE TURKISH MINISTRY OF HEALTH

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OBJECTIVES: Off-label is defined by the Turkish Ministry of Health (MoHT) as the use of licensed pharmaceutical products in doses outside of or exceeding the scope of the registered indication, and the use of non-licensed but imported medicinal products for the purpose of individual treatment. The use of off-label or non-licensed endocrinology medicines were evaluated in order to provide an understanding of Turkey's perspective within this area of healthcare provisions. **METHODS:** A computer search was performed of IEGM's database. A patient base using off-label endocrinology medicine applications from 19 June 2009 to 19 June 2010 were searched. **RESULTS:** The computer search for the showed that 357 applications were submitted for off-label endocrinology medicine use. It was concluded that the highest application percentage was established by "osteoporosis" in all of the applications (43%, 155/357). The highest application was established by Ankara province (28%, 44/155). University hospitals had the highest off-label osteoporosis medicine use applications within the given timeline (65%, 102/155). Specialized physicians in the fields of endocrinology and metabolism (adult and paediatric) had the highest number of off-label osteoporosis applications (71%, 111/155). It was concluded that the highest application percentage was established by "teriparatide use in osteoporosis" (87%, 136/155) in all of the osteoporosis applications. 92 of 136 applications were approved. There was a significiant difference between the T score (L1-4) of rejected and approved applications for patients (3.07±1,85 and 3.23±1.63, respectively) ($p<0.001$). Yet there was not a significiant difference between ages of patients for whom applications were rejected or approved. **CONCLUSIONS:** It could be said that off-label use can lead to reimbursement restrictions in endocrinology, especially for teriparatide-like oncology medicines. In Turkey, physicians who want to prescribe an off-label or non-licensed pharmaceutical or a medicine which has a different use from reimbursement indications, need to apply through the off-label medicine use process.

PDB18

AUSTRALIA: MANAGEMENT OF THE DIABETIC FOOT WITH PEDIMED® UNDER REAL USE CONDITIONS

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OBJECTIVES: Xerosis is a common disorder among diabetic patients; 82.1% of diabetic patients suffer from xerosis, which may or may not be combined with fissures or cracking. It causes disorders which play a major role in the onset of ulceration. Xerosis exacerbates the development and the recurrence, in particular, of hyperkeratosis. To evaluate, under real use conditions, the effect of Pedimed (Glycerine, petroleum jelly, piroctone olamine, tocopheryl nicotinate, hydroalcoholic ruscus extr) on diabetic foot. **METHODS:** Observation study of diabetic patients with high risk factor for foot ulceration in Australian centres, with data collected via questionnaires from patients receiving PediMed® to measure acceptability and xerosis assessment from physicians and healthcare professionals. **RESULTS:** Mean age of subjects is 57 years (± 13.3), 64% presenting with type 2 diabetes. The XAS score measured by the doctor at inclusion is 6.4 (± 2.4) and 6.3 (± 2.6), respectively for the right and left foot. At 4 weeks, measured by the same doctor, the XAS score is 2.7 (± 2.3) and 3.0 (± 2.3) respectively for the right and left foot. Improvements are statis-