## PERSISTENCE UNDER TREATMENT WITH RAMIPRIL

Ude M<sup>2</sup>, Schüssel K<sup>1</sup>, Leuner K<sup>2</sup>, Müller WE<sup>2</sup>, Schulz M<sup>1,2</sup>

<sup>1</sup>Deutsches Arzneiprüfungsinstitut (DAPI), Eschborn and <sup>2</sup>Pharmakologisches Institut für Naturwissenschaftler, Goethe-Universität, Frankfurt am Main, Germany

BACKGROUND: Patients suffering from chronic disease such as hypertension require long-term and continuous pharmacotherapy. As a hypothesis, switching from a brand name antihypertensive to a generic one may negatively affect patients' persistence.

OBJECTIVE: To assess persistence in patients treated with brand name ramipril compared to patients switched to a generic ramipril product after the patent expiry in January 2004. METHODS: Reimbursement data for ambulatory prescriptions within the statutory health care system were evaluated based on a representative sample of more than 80% of German pharmacies (www.dapi.de).

Patients were included if they had a ramipril prescription (index prescription) between November 2003 (first ramipril generics on the market) and June 2004. Patients had to be pretreated with ramipril for at least 12 months, and had to have filled at least one ramipril prescription within 12 to 18 months after the index date. Patients being treated with ramipril in fixed combination with felodipin were excluded, as were patients re-switching to brand name ramipril after an index prescription of a generic product.

Patients were classified as brand name or generic patients if they were treated exclusively with brand name or generic ramipril, respectively, in the 12 months following the index date. Depending on the different types of products prescribed within 12 months from the index date, patients were allocated to either monotherapy, therapy with fixed combinations with diuretics, or both.

Persistence was analysed by calculating the medication possession ratio (MPR), defined as days covered with medication divided by the number of days during the observation period, which ranged from the index date until the first prescription during 12 to 18 months after the index date. As the prescribed daily dose is unavailable in the reimbursement data, the MPR was calculated in two different ways: either assuming one DDD (defined daily dose) as prescribed daily dose or based on the number of days supplied with medication assuming that patients were prescribed one tablet / dosage form per day as dose.

RESULTS: 247,846 patients were included in the analysis, of which 163,238 and 84,626 were classified as brand name or generic therapy, respectively. Median MPR values for brand name or generic therapy were 1.039 and 1.339, respectively (MPR based on the DDD), or 0.937 and 0.952 (MPR based on 1 tablet per day). There were no relevant differences in median MPR values between brand name and generic patients treated with either monotherapy, fixed combinations with diuretics, or both.

CONCLUSION: Although data were not corrected for covariates like age and gender (not available in the database) or further co-medication, these results suggest that persistence is not negatively affected by physician induced switching from brand name to generic ramipril – whether patients were treated with monotherapy, fixed combinations with diuretics or both. Calculating MPR based on the DDD may overestimate persistence in this patient population. Nevertheless, these results should not be over-interpreted. Physician induced switching after patent expiry can not be compared with frequent switching because of generic substitution requirements in Germany (*aut idem*).