Introduction: Knowledge of time course, management and outcome of adverse drug reactions (ADRs) is important for a better understanding of the safety profile of a drug. The Netherlands Pharmacovigilance Centre Lareb has developed a web-based intensive monitoring system which tries to capture this data.

Aim: To study the safety profile of metformin in daily practice.

Methods: We performed a prospective, observational cohort study. First-time metformin users were recruited through pharmacies between 1 February 2008 and 1 April 2012. Patients were invited to complete six web-based questionnaires 2 weeks, 6 weeks, 3 months, 6 months, 9 months and 12 months after the start of metformin. Information was gathered about patient characteristics, ADRs and drug use. Drugs were coded using the Dutch drug dictionary (Z-index). Indications and ADRs were coded using the Medicinal Dictionary for Regulatory Activities (MedDRA) terminology.

Results: A total number of 2490 patients (59% male, 41% female) signed up for the study. Mean age of the study population was 59.2 years (SD 10.9, range 12–89 years). The response rates for the first up to the sixth questionnaire were 67, 66, 61, 54, 49 and 47%, respectively. At baseline 1958 patients (76%) were using one or more concomitant drugs. A total of 860 patients (35%) reported the occurrence of at least one possible ADR related to the use of metformin. ADRs reported in ≥1% of the patients were diarrhoea (14.9%), nausea (6.4%), abdominal discomfort (4.7%), flatulence (3.7%), headache (3.3%), abdominal pain (2.3%), dizziness (2.2%), fatigue (2.0%), constipation (1.5%), pruritus (1.2%), abdominal pain upper (1.1%) and dyspepsia (1.0%). The median latency time for these ADRs was 1–6 days, with exception of pruritus with a median latency time of 16 days. The percentages of patients who reported the presence of an ADR were 27, 30, 28, 24, 20 and 19% for the six successive questionnaires. This indicates that a large proportion of the patients was suffering from ADRs in the period of 2–6 weeks after the start of metformin. The majority of the patients (76%) undertook no action regarding metformin after the occurrence of an ADR. This suggests that the overall impact and severity of ADRs was relatively low, so that no action was required.

Conclusion: This study gives insights in the safety profile of metformin in clinical practice. Future research should focus on the impact of ADRs on patient’s quality of life, to gather even more information about drug related ADRs.

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A Harmonised Scheme to Support Developing Risk Management Guidelines Beyond ICH Countries

H. Le Louët,1 J.C. Delumeau,2 Y. Moride,3 W.W. Chen,4 S.A. Abdellah, H.A. Nguyen,5 S. Shaihid, Abdul Rahman,6 W. Suvankesawong,6 S. Thol7

1) University Paris Est Créteil, Pharmacovigilance and Risk Management, Créteil, France, (2) Bayer South East Asia, Pharmacovigilance, Singapore, Singapore, (3) University of Montreal, Faculty of Pharmacy, Montreal, Canada, (4) Taiwan Drug Relief Foundation, National ADR Reporting Center, Taipei, Taiwan Republic of China, (5) National Agency of Drug and Food Control, Surveillance and Risk Analysis of Therapeutic Products, Jakarta, Indonesia, (6) Drug Information and ADR Centre, Pharmacovigilance, Hanoi, Vietnam, (7) Ministry of Health, National Pharmaceutical Control Bureau, Putrajaya, Malaysia, (8) Food and Drug Administration, Health Product Vigilance Centre, Bangkok,