BASEL, SWITZERLAND — 17th April, 2013 — Pharmaceutical professionals, regulatory agencies and academics will share knowledge and experience at DIA Europe's conference on the Impact of the New Pharmacovigilance Legislation on Regulatory Affairs .

The event, to be held in London from 4th to 5th June, will highlight how changes in legislation will affect the way product assessment is carried out in both pre- and post-authorisation phases, introduce new obligations to Marketing Authorisation Holders, and bring in continuous benefit-risk assessment. The conference will also look at the impact of the new Pharmacovigilance Risk Assessment Committee (PRAC) on the life-cycle management of products, and the PRAC's interactions with other committees.

Session highlights at the conference include:

- Overview of PRAC and new pharmacovigilance requirements
- The operation of the PRAC and the new Periodic Safety Update Report/Periodic Benefit-Risk Evaluation Report (PSUR/PBRER) and Risk Management Plan (RMP) requirements, including how assessments will be handled by PRAC
- Overview of the key elements for Post-authorisation Safety Studies (PASS) and Post-authorisation Efficacy Studies (PAES)
- New pharmacovigilance legislation and how it is impacting drug development
- Involvement of two sets of rapporteurs in the procedures and impact on regulatory affairs

- Referrals, opinions and conditions
- New pharmacovigilance legislation and the opportunities for regulatory affairs
- Panel discussion on impact on drug development and approval

To find out more, or to register, visit www.diahome.org/PhvImpact2013 .

ABOUT DIA

DIA is a neutral, global, professional, member-driven association of nearly 18,000 professionals involved in the discovery, development, and life cycle management of

pharmaceuticals, biotechnology, medical devices and related health care products. Through our international educational offerings and myriad networking opportunities, DIA provides a global forum for knowledge exchange that fosters the innovation of products, technologies and services to improve health and well being worldwide. Headquarters are in Horsham, Pa., USA, with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India and Beijing, China. www.diahome.org