DIA 2014 50th Annual Meeting

Celebrate the Past – Invent the Future

June 15 – 19, San Diego (CA) Convention Center

Session 246 – *EMA-FDA Collaboration in Pharmacovigilance: Common Objectives & Common Challenges*

EMA-FDA Collaboration in Pharmacovigilance: Common Objectives & Common Challenges explored common EMA and FDA objectives and challenges in pharmacovigilance, how these are addressed, and how EMA-FDA collaboration supports them.

Dr. Peter Arlett (Head of Pharmacovigilance Department, EMA) opened the session with an introduction to the collaboration between EMA and FDA. While this international collaboration mainly focused on ICH and ad-hoc bilateral discussions in the 1990s, it has been profoundly strengthened after these two agencies signed confidentiality arrangements in 2003.

Dr. Arlett elaborated on their common pharmacovigilance objectives, which include, among others, promotion and protection of public health through safe and effective use of medicines, supporting R&D innovation to fulfil unmet medical needs, and undertaking robust decisions underpinned by good analysis of all relevant evidence. He provided further examples of common challenges that can arise such as benefit-risk balance, manufacturing failures and counterfeits, divergences between jurisdictions (EU vs. US law), and very high expectations of

stakeholders. He explained that underpinning pharmacovigilance by robust law makes it more difficult to harmonize internationally. He concluded that EMA and FDA are collaborating multiple times every day and that this collaboration can only deepen, and proposed several ways forward that comprise ongoing opportunities for convergence of guidance, templates and processes, sharing of data, and coordination of safety reviews.

Dr. Gerald J. Dal Pan (Director, Office of Surveillance and Epidemiology, CDER, FDA) emphasised that FDA and EMA need to collaborate on post-marketing drug safety because they each cover large populations, have similar scientific approaches and often look at the same data. He specified that the aim is to augment – NOT replace – other international collaborations. Their overall goal is to share data, ideas and approaches on particular drug safety matters and to understand the reasoning behind each other's decisions.

Dr. Dal Pan stressed that arriving at the same conclusions is NOT their goal, because many reasons can explain differences in conclusions between the two agencies. He provided several practical examples of sharing postmarketing drug safety information between FDA and EMA that are currently in place, including monthly pharmacovigilance teleconferences and *ad hoc* drug safety discussions on risk management and upcoming regulatory actions.

Valerie E. Simmons, MD, FFPM (EU QPPV, Executive, Global Patient Safety, Eli Lilly and Company Ltd, UK) presented an industry view on this subject. She provided several examples of successful international collaborations such as the International Conference on Harmonization (ICH), the Council for International Organizations of Medical Sciences (CIOMS) and other scientific collaborations,

while acknowledging that these may not equate to any harmonised regulatory decisions. She argued that perhaps the ultimate harmonization is not an ideal output of collaboration but rather a simplification of processes; if so, goals for further EMA-FDA collaboration would be the minimization of discrepancy, duplication and non-value added activities, and more emphasis on benefit-risk management. She stressed redefined focus on what was clinically important and would make a positive contribution to patient safety.

During the closing panel discussion, Valerie illuminated several points on international collaboration from the industry perspective, such as: Whether individual ICSRs from patient support and/or market research programs provide additional useful information for drug safety, and how to rationalize their collection; the feasibility of streamlined routine PV inspections; simplifying the concept of assessing expectedness of ADRs; and if there is opportunity for a common understanding of “important risk.”

Agata Aleksandra Lazowska is a PhD Student in Pharmacy (Department of Drug Regulatory Affairs, with a focus on Pharmacovigilance) at the University of Bonn (Germany).