Session N.00449

16. Pharmacovigilance for bedaquiline, delamanid and other TB drugs and regimens

Thursday, 03 December 2015, 09:00 - 16:00

Room Sir Francis Drake-Westin

Type of session	Workshop
Track	Drug-resistant TB care and treatment, including trials
Organised by	USAID/SIAPS, WHO, End-TB Project (PIH, MSF, IRD), KNCV TB Foundation, MSF
Duration	Full-day
Max attendees	150
Meeting type	Open meeting
Description	The WHO recommends new TB medicine use under conditions that include active pharmacovigilance and proper management of adverse drug reactions (ADRs). Adverse drug events from poor product quality, medication errors and ADRs contribute significantly to morbidity and mortality. Many countries have introduced new TB medicines or introduced new TB regimens. Monitoring patient safety is essential since new TB medicines have not been tested in a wide population. Building a pharmacovigilance system should go hand in hand with ongoing scale-up of new TB medicine use.
Target audience	**1.** National TB programme managers, technical partners, national regulatory authorities, donors **2.** Physicians, nurses, healthcare workers, academics
Objectives	**1.** Learn about preventing and minimising risks to improve patient safety **2.** Share recent practical experiences with cohort event monitoring for new TB drugs **3.** Understand components needed for planning, implementing, budgeting and maintaining a PVS **4.** Share the currently available resources to assist countries in planning, implementing, and maintaining PVS
Expected outcome	1) Participants have learnt the importance of building and maintaining country pharmacovigilance systems (PVS) according to WHO policies, while balancing patient access to new TB medicines for drug-resistant TB treatment; 2) Participants recognise the diverse perspectives of regulators, clinicians, programme managers, patients and donors concerning access and patient safety; 3) Practical experiences of PVS are shared and lessons are learnt from these examples; 4) Participants know where to access resources to assist in the planning and implementation of PVS in their countries.
Keywords	patient safety; pharmacovigilance; adverse events
Coordinator(s)	Chinwe Owunna (USA), Askar Yedilbayev (USA)
Chair(s)	Ernesto Jaramillo (Switzerland), Michael Rich (USA)
Presentations	1. Active surveillance of TB drug safety concerns: WHO policy and strategy Dennis Falzon (Switzerland) 2. Building pharmacovigilance systems - not a luxury but a necessity; TA to countries and lessons learnt Niranjan Konduri (USA), Chinwe Owunna (USA) 3. Reflections on challenges, success and future directions on active pharmacovigilance for new TB drugs Susan Van Den Hof (Netherlands), Edine Tiemersma (Netherlands) 4. Perspective from National Regulatory Authority 5. Increasing access to bedaquiline: USAID donation programme Ya Diul Mukadi (USA) 6. Choice of pharmacovigilance systems: when is cohort event monitoring necessary? Michael Rich (USA) 7. Early adopter #1: synthesis of lessons learnt from Belarus Alena Skrahina (Belarus) 8. Early adopter #2: synthesis of lessons learnt from Vietnam Nguyen Viet Nhung (Viet Nam) 9. Practical experience of pharmacovigilance in the introduction of bedaquiline in Armenia Catherine Hewison (France) 10. Budget components for pharmacovigilance activities: experience from Indonesia Triya Novita Dinihari (Indonesia)