UIPS Symposium – Real-World Evidence for Regulation and Health Technology Assessment of Pharmaceuticals: current use and where do we go next?

Background: In recent years, the interest and need for real-world evidence (RWE) has been increasing due to the advent of innovative, yet expensive, pharmaceutical drugs, e.g. in the context of the evidence gaps for rare diseases. Numerous initiatives are undergoing worldwide to assess the potential use of RWE in decision making on drug regulation and health technology assessment (HTA). However, despite such initiatives, it remains unclear if and how decision makers in regulatory agencies and HTA agencies should proceed with the use of RWE in their processes.

Aim: The aim of this symposium is to review the current status of RWE use and to address future directions for the implementation of RWE in decision making of both regulatory and HTA agencies. To this effect, specialist speakers are invited to represent views from academia, regulatory- and HTA agencies.

Speakers:

1) **Mr. Amr Makady**, **PharmD, MSc:**
    a. Summary of findings from research on RWE use in HTA of drugs
    b. Points to be addressed:
        i. What is RWD/E?
        ii. Current policies and practice for RWE in HTA
        iii. Potential future steps and ongoing initiatives
2) **Prof. Dr. Bert Leufkens, PhD:**
    a. Regulatory agency's perspective on RWE use for decision making
    b. Points to be addressed:
        i. If and how RWE is used in regulatory decision making
        ii. EMA initiatives on RWE: learning and future directions
3) **Dr. Francois Meyer, PhD:**
    a. HTA agency's perspective on RWE use for decision making
    b. Points to be addressed:
        i. EUnetHTA WP5 activities on RWE: learnings and future directions
        ii. EUnetHTA-EMA collaboration: can RWE bring the regulatory and HTA worlds together?
4) **Prof. Dr. Diana Delnoij, PhD:**
    a. HTA agency's perspective on RWE use for quality of care
    b. Points to be addressed:
        i. What is understood under "quality of care"?
        ii. Could RWE contribute to measuring quality of care

Time Planning:

12:00 – 13:00	Registration & Lunch	
13:00 – 13:05	Welcome & Introduction	Wim Goettsch
13:05 – 13.25	Presentation 1 (incl. 5 min Q&A)	Amr Makady
13.25 – 13.45	Presentation 2 (incl. 5 min Q&A)	Bert Leufkens
13.45 – 14.05	Presentation 3 (incl. 5 min Q&A)	Francois Meyer
14.05 – 14.25	Coffee Break	
14.25 – 14.45	Presentation 4 (incl. 5 min Q&A)	Diana Delnoij
14.45 – 15.20	Panel & General Discussion	Diana, Bert & Francois
15.20 – 15.25	Wrap-up & Closure	Sarah Kleijnen

Registration via: https://goo.gl/forms/8meSbj1C2ieGLEtz1

(maximum numbers of participants: 70)