Annex 2

Responsibilities of licensed partners in pharmacovigilance

Licensed partners:

Partner 1 (P) – licenses out

Partner 2 (P2) – licenses in

1st case: **Only the partner that licenses in (P2) is present in the Republic of Croatia**

- P1 and P2 exchange mutually spontaneous adverse reaction reports, adverse reactions from literature and all other adverse reactions). P1 is globally responsible for adverse reaction monitoring and medicinal product's safety.
- P2 as a marketing authorisation holder for this licensed medicinal product in the Republic of Croatia is obliged to report urgently all SUSARs for their common product (SUSARs also from other countries).
- P2 in Croatia reports all other adverse reactions that appear on the territory of the Republic of Croatia for this medicinal product regardless to the source of information (spontaneous reports from healthcare professionals, literature, epidemiological studies, registries). These adverse reactions are actually adverse reactions of the in-licensing partner (P2).
- PSUR:
    - P1 must include in his PSUR all data received from P2 and must indicate the number of packs sold by P2 and include the entire calculation (from P1 and P2) for the population exposure to this product.
    - P2 must at the time of PSUR submission, submit also PSUR P1 (global) and his PSUR which is about his medicinal product with a reference to the PSUR prepared by P1 submitted along with the PSUR from P2. The PSUR from P2might be summerised.

2nd case: **Only the partner that licenses in (P2) is present in the Republic of Croatia**

- P1 and P2 exchange mutually spontaneous adverse reaction reports, adverse reactions from literature and all other adverse reactions). P1 is globally responsible for adverse reaction monitoring and medicinal product's safety.
- P1 and P2 agree upon who will be responsible for regulatory affairs in the Republic of Croatia and inform the Agency about it. Most commonly it is P1, hence he is normally responsible for adverse reactions and medicine's safety at the global level. In this case P1 is responsible for urgent reporting of suspected unexpected serious adverse reaction (SUSAR) for their common products (SUSARS also from other countries).
- P1 in Croatia reports all other adverse reactions appeared on the territory of the Republic of Croatia for this medicine (obtained from P1 and P2) regardless of the information source (spontaneous reports from healthcare professionals, literature, epidemiological studies, registries). These adverse reactions aare adverse reactions from both partners.
- PSUR:

- P1 should include in his PSUR all the data obtained from P2 and must indicate the number of packs sold by P2 and include the entire calculation (from P1 and P2) for the population exposure to this product.
- P1 and P2 submit only the common PSUR prepared by P1, if agreed that P1 is responsible for adverse reactions monitoring in Croatia.