

Full PV Outsourcing of a Global Generics Pharma Company



Challenge

Outsource PV system administration as well as operative PV activities



Solution

Provision of the PV responsible persons in the EU (QPPV) and local PV responsible persons in several territories



Outcome

Reduced complexity due to the interaction with only a single PV service provider

- The company was new founded and took over a significant number of products from another MAHs woman's health portfolio
- No PV system or other PV related structures were in place
- Local structures needed to be established in 45 countries
- PharmaLex offers:
 - Set up of a completely new pharmacovigilance (PV) system including QPPV, LPPVs, PSMF, PV SOP updates, and data migration to new safety database
 - Maintenance of the PV System after marketing authorizations were transferred to the new MAH
- Preparation and maintenance of the PSMF as well as respective PV SOPs and WIs
- Provision and maintenance of PV database 'SafetyBase'
- Data migration to new PV database
 - Complete ICSR processing
 - 5,000 ICSRs per year
 - 35 active substances
- Global and local literature screening for 35 active substances; incl. BfArM ADR portal monitoring, MLM service (EMA)
- Ongoing signal monitoring and detection
- Aggregate report writing (RMPs, PSURs, AtCOs)
- Allows the Company to Act as MAH without having PV structures in place
- Complete PV system based on PLX experience and maintained by PharmaLex
- Full scalability as the company intends to buy further products
- Successful implementation of new global and local PV structures, nomination of QPPV and LPPVs in 45 countries