Pharmacovigilance Officer

Title:	Pharmacovigilance Officer
Location:	Geneva, Paris, Brussels, Amsterdam or Barcelona - with a preference for Geneva
Duration:	3 years Full-time position
Reporting to:	International Pharmacist Coordinator

I. MSF INTERNATIONAL

Médecins Sans Frontières (MSF) is a leading international independent medical relief organisation, dedicated to providing expert medical relief to vulnerable populations at times of conflict or disaster. In over 80 countries worldwide, MSF provides both life-saving emergency relief and longer-term assistance to make basic healthcare services available to the most vulnerable or excluded communities.

MSF's aim is to provide impartial assistance, on the basis of need alone, regardless of ethnic origin, gender, creed or political affiliation. To maintain its independence from political interference, MSF relies on donations from individuals around the world for at least 50 percent of its income. This private funding gives MSF the freedom to respond to the greatest needs as fast as possible.

MSF International is the legal entity that binds MSF's 19 sections, 24 associations and other offices together. Based in Geneva, MSF International provides coordination, information and support to the MSF movement, and implements international projects and initiatives as requested.

II. POSITION BACKGROUND

Approximately 600,000 cases of MDR-TB occur in the world annually, representing nearly 5% of the world's annual TB burden. One of the most important challenges is the current Standard Of Care (SOC), which has poor efficacy (50-60% treatment success), poor tolerability and remains very expensive.

Recently, several new anti-tuberculosis agents have been developed, including bedaquiline (TMC207; B), delamanid (OPC-67683, D) and PA-824 (Pa). These new agents have the potential to prove highly effective in a shorter and oral regimen, especially when combined with one another and with existing antituberculosis drugs. Repurposed antibiotics such as linezolid (L) and clofazimine without current indications in tuberculosis are also found of interest as companion medicines to these new agents.

MSF is implementing two complementary clinical trials (the TB-PRACTECAL trial and the EndTB trial) to identify shorter, more effective and less toxic MDR-TB treatment regimen(s) that are feasible to scale up. The two trials investigate the safety and efficacy of different combinations of drugs that include a) newly registered products (e.g. Bedaquilin and delamanid), b) new chemical entities (PA 824) and c) other antibiotics already used in the treatment of XDR-TB. In parallel MSF also aims at facilitating the introduction of newly registered drugs as part of the current SOC through its MDR-TB programs (EndTB output 1).

Bedaquiline and delamanid have been granted conditional approval by the FDA and/or the EMA and the safety information available for these new drugs is therefore limited. On the other hand PA-824 is still at an early development stage, and data on prolonged used (e.g. ≥ 2 months) are not available yet. Finally, these new drugs have seldom been used in combination with other medications, including anti-retrovirals.

As a trial sponsor, MSF is responsible for implementing appropriate safety monitoring throughout the clinical trials and to set up measures to protect trial participants from harm. In addition, it is of primary importance that an appropriate pharmacovigilance (PV) system be implemented to monitor the safety of the newly registered drugs under field program conditions. MSF is also willing to use this last part as a pilot test for developing a larger pharmacovigilance system.

MSF is thus setting up a PV platform to address these needs.

III. PLACE IN THE ORGANISATION

The position will report:

- Hierarchically to the International Pharmacist Coordinator
- Functionally to the relevant managers of each clinical trial (TB-PRACTECAL and the EndTB trials), the implementation project (End-TB output 1) and the pharmacovigilance pilot part (International Pharmacist Coordinator)

Given the different components of the projects and the numerous locations for implementation, the PV officer will be in contact with the trials co investigators, the project managers, the international pharmacist coordinator, the clinical trials pharmacists, the field teams, the TB referents in the MSF OCs, and occasionally with the Data Management and Clinical Trials Monitors

IV. OBJECTIVES OF THE POSITION

The PV Officer will be responsible for setting up and conducting pre- and post-marketing pharmacovigilance (PV) activities for the 2 MDR TB trials and the introduction of the new drugs in some of its MDRTB projects. He/she will bring essential PV knowledge, skills and experience to the project teams. He/she will ensure that the PV activities comply with international regulatory requirements applicable to safety reporting and pharmacovigilance in clinical trials.

V. MAIN RESPONSIBILITIES

1. MDR TB projects planning

Set a pharmacovigilance system for the clinical trials and for the implementation project complying with the international regulatory requirements:

- Assist project teams in creating Standard Operating Procedures (SOPs), Working Instructions (WI), forms and templates for efficient and effective processing of safety data collection at investigational sites (e.g. Individual Case Safety Reports (ICSRs) and aggregated reports)
- Develop flowchart for post-marketing PV activities
- Develop PV training material for medical teams in the field
- Create and maintain project-specific working files

2. MDR TB projects conduct

Implement the pharmacovigilance – safety monitoring:

- Triage incoming adverse event reports for completeness, legibility and validity
- Enter ICSRs into safety database / tracking system
- Request follow-up information and perform query management
- Code data in the safety database
- Support Medical Review Boards in assessing cases for reportability
- Submit, according to applicable legislation, Serious Adverse Events (SAEs) to pharmaceutical companies, regulatory authorities and Ethics Committees
- Support Data Management in the conduct of periodic reconciliation of SAEs between the drug safety and clinical trial databases
- Coordinates the compilation and timely submission of required reports to regulatory authorities, pharmaceutical companies, Data and Safety Monitoring Board (DSMB) and Ethics Committees (e.g. ISCRs and annual safety reports)
- Act as a focal point for Safety Database customization and troubleshooting
- Manage Safety Database users accounts
- Provide basic training to Safety Database users

3. MDR TB projects close-out and reporting

- Support statisticians in compiling the clinical study reports

VI. PROFILE REQUIREMENTS

Essential Criteria

- Registered MD or Pharmacist
- Excellent knowledge of clinical trials and PV regulations and international norms (e.g. ICH-E6 and ICH-E2A-F)
- Familiarity with MedDRA and WHO-DRUG dictionaries
- Experience in using Safety Databases applications

- Experience in adverse events reports triage and processing
- Experience with preparation of investigational and post-marketing regulatory reports
- Strong ability to stick to deadlines and react quickly to needs
- Strong organisation and planning skills
- Excellent interpersonal skills and a proven ability to gain buy-in and commitment from a range of people
- Proven experience of working independently under minimal supervision
- Fluency in written and spoken English
- Ability to work with teams that are not based in one locale.

Desirable Criteria

- Experience setting up a drug safety and PV system
- Good Pharmacovigilance Practice certification
- Knowledge and understanding of the treatment options and challenges for TB and MDR-TB.
- Knowledge of French (and/or Russian)

Starting date:	January 2015
Contract:	36 months position (possible renewable based on evaluation of the position)
Location:	Geneva, Paris, Brussels, Amsterdam or Barcelona - with a preference for Geneva
Deadline for applications:	**12 December 2014**

Please submit all applications **only by email** to:
IO-recruitment.gva@msf.org stating "**Pharmacovigilance**" in the title.
Please submit your CV and cover letter in
ONE file and name the file with your LAST NAME.

-Only short-listed candidates will be contacted-