MPP POLICY ON CONTRACT COMPLIANCE AUDIT RIGHTS

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Medicines Patent Pool
Policy on contract compliance audit rights

The intent of this Policy is to provide clear guidance on the principles and procedures that apply at the time of triggering contractual audit rights over MPP's licensees, in accordance with the terms and conditions of the applicable Licence Agreement.

The MPP considers that an effective audit policy will help to ensure that licensees' operations are conducted within the boundaries of the contractual framework agreed with the MPP and with any applicable legal or regulatory obligations.

It is also the intention of the MPP to illustrate its genuine commitment to the comprehensive performance of its obligations vis-à-vis licensors and licensees, and to accomplish all necessary and reasonable actions required to prevent any potential breach of its licence agreements.

Although this Policy broadly defines the approach for triggering MPP's contractual audit rights, it is the corresponding licence agreement executed by MPP and each licensee that will govern and determine the relevant framework of rights and obligations.

The audit exercise will be conducted by reputable independent experts/auditors under the instructions of the MPP, in line with the contractual obligations of each licence agreement.

This Policy may be amended from time to time at MPP's sole discretion. Any amendment will be approved by the Governance Board and made publicly available on the website of the MPP at www.medicinespatentpool.org.

1. ***MPP will trigger its audit rights in line with the terms and conditions of the respective licence agreement, under the following circumstances:***

   A. MPP will implement a program of routine audits and will select 1-2 licensees per year to be audited, with the aim of eventually auditing all its licensees. The identity of the licensees to be audited will be determined on a yearly basis. For the purposes of determining which licensee to audit, the following non-exhaustive list of factors will be considered:

      i. Total aggregated value of the licensed products being commercialized by such licensee;

      ii. Total number of on-going development projects by licensee;

      iii. Licensee's history of performance with regards to development timelines;

      iv. History of performance with regards to filing with a Stringent Regulatory Authority (SRA) or World Health Organization Prequalification programme, as applicable, in line with the requirements of the applicable licence agreement;

      v. History of performance with regards to national regulatory registrations;

vi. History of performance with respect to completeness and timeliness of reporting obligations; and

vii. Time lapse since last audit by MPP and/or licensor.

B. MPP will conduct "for cause" audits if:

i. There are major or repeated irregularities or inconsistencies in quarterly reports such as: not reporting on the development and/or sales of products, unexplained inconsistencies within or across reports, unexplained fluctuations in sales of products throughout reports;

ii. There is a credible notice of breach brought by any third party;

iii. There is a reasonable suspicion of diversion of products, in breach of the terms and conditions of the applicable licence; or

iv. MPP receives a request by the licensor, showing reasonable cause to MPP's satisfaction.

2. Scope of the audit

The following non-exhaustive list outlines some key potential areas to be covered by an audit. This list is provided for the purposes of guidance and clarification, but the scope of each audit exercise will ultimately depend on the terms and conditions of the pertinent licence agreement.

A. Sourcing of API from licensed source (if applicable);

B. Compliance with the relevant development/registration/commercialisation timelines of licensed product(s) by licensee

C. Accurate and timely reporting of sales, volumes, royalties (if applicable), etc.;

D. Compliance of terms of distribution agreements with applicable licence;

E. Compliance with terms governing the diversion of product/API outside Territory or to private sector (if applicable) in breach of the licence;

F. Compliance with the relevant quality provisions.

3. Findings of the audit, and further actions to be taken by the MPP in light of those findings

The findings of the audit will be reviewed by the MPP, and appropriate action will be taken in accordance with the terms and conditions of the applicable licence.

A. If audit reveals no indication of irregularities or non-compliance, no further action will be taken by the MPP;

B. If audit reveals irregularities that amount to a non-material breach of any of the terms and conditions of the licence, MPP will provide notice and request compliance by licensee in the future;

C. If audit reveals any breach that is material, MPP will provide notice of breach and opportunity to cure, in accordance with the terms and conditions of the applicable licence;

D. If audit reveals a breach that requires immediate termination under the applicable licence, the MPP shall terminate the agreement immediately, in accordance with the procedures set forth in the relevant licence agreement.

The results of an audit will not be made public, as they may contain confidential information belonging to licensees.