Confidentiality Agreement

between

the Ministry of Health of the Republic of Kosovo

and

the Medicines and Healthcare products Regulatory Agency of the United Kingdom of Great Britain and Northern Ireland

Introduction

1. The Ministry of Health of the Republic of Kosovo (the Ministry) (acting for an on behalf of the Kosovo Medicines Agency (the KMA)) and the Medicines and Healthcare products Regulatory Agency of the United Kingdom of Great Britain and Northern Ireland (UK) (the MHRA), are the regulatory authorities (collectively, the Participants) with responsibility in their respective countries for the authorisation, granting, renewal, variation, suspension, and revocation of licences, certificates, or other regulatory mechanisms relating to those medicinal products and medical devices for human use which are clinically investigated, marketed, supplied, manufactured, or assembled in the UK and Kosovo respectively.

2. The Ministry acknowledges that the MHRA is authorised, subject to relevant data protection requirements, to exchange information and documentation relating to medicinal products and medical devices in accordance with the domestic laws under which it is constituted.

3. The Participants consider that from time to time circumstances will arise where sharing information held by one regulatory authority will assist the other regulatory authority in carrying out its regulatory functions in relation to medical devices or to ensure the safety, quality, and efficacy of medicinal products for human use which are under clinical investigation, authorised for marketing, under review for marketing authorisation in both the UK and Kosovo or unilaterally recognised by the Ministry as laid down in a Normative Act issued by the Ministry.

4. The Ministry will co-operate with the MHRA to facilitate the sharing between the Ministry and the MHRA of otherwise non-public documents and information for the purposes of assisting the Ministry in carrying out its functions. This agreement sets out a co-operation and framework understanding of the information which the Ministry and the MHRA may share with each other and the basis upon which they may share it. Non-public documents or information means any document or information not in the public domain that is held by a Participant and is treated as confidential by that Participant in accordance with the domestic laws applicable to the Participant.

5. In this Confidentiality Agreement, the term "medicinal products for human use" excludes all medicinal products subject to evaluation or authorised by the European Medicines Agency (EMA) under the centralised procedure as well as medicinal products authorised at national level by European Union Member States that are subject to official European Union arbitration and referrals.

Information that may be shared between the MHRA and the Ministry

6. The type of information that may be shared between the regulatory authorities includes, but is not limited to:

   I. Post-authorisation pharmacovigilance data held by one Participant which raises safety concerns about a product manufactured or distributed in the territory of the other authority.

   II. Information on quality defect or product recalls held by one Participant in relation to medicinal products and medical devices which are distributed or have been manufactured in the territory of the other Participant.

   III. Information contained in marketing authorisation applications and applications to vary a marketing authorisation received by one Participant which are of significant public health interest to the other Participant to which they are disclosed.

   IV. Information contained in reports on inspections done by one Participant which are of significant public health interest to the other Participant to which they are disclosed.

7. The Participants, their officials or representatives, may in their absolute discretion limit the scope of the above information, particularly if its dissemination or