PHARMACEUTICAL INSPECTION CONVENTION PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME		EUROPEAN ECONOMIC AREA HEADS OF MEDICINES AGENCIES

LETTER OF AGREEMENT

BETWEEN THE

EEA HEADS OF MEDICINES AGENCIES

AND THE

PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

The Heads of Medicines Agencies of the European Economic Area (EEA HMA) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S), hereinafter jointly referred to as "the Parties";

Recognising that the they share a common goal to protect public health and safety;

Desiring to share information on the assessment of Pharmaceutical Inspectorates with a view to

(i) better use of resources and avoid the duplication of activities; and
(ii) maintain mutual confidence and promote quality assurance of inspections;

Recognising the need to train GxP inspectors and auditors involved in

(i) inspecting manufacturers of medicinal products, whether in the form of active pharmaceutical ingredients or finished dosage form, against GxP standards;
(ii) assessing the compliance of Pharmaceutical Inspectorates against quality system requirements;

Have reached the following agreement, referred to as 'the Agreement', which shall neither constitute a legal obligation nor a financial liability on either side:

1. Exchange of information on audits

1.1 The Parties agree to co-operate in exchanging information in the context of the EEA Joint Audit Programme (JAP) of GMP inspectorates and the PIC/S Joint Reassessment Programme (JRP) of Participating Authorities as well as of Authorities having applied for PIC/S membership insofar the information is related to compliance with EEA or PIC/S requirements.

1.2 The Parties recognise that in the EEA context the EEA JAP and the PIC/S JRP are deemed equivalent. The compliance with EEA-specific legislative requirements is assessed by EEA auditors operating in either framework (JAP and JRP).

1.3 The Parties agree to exchange auditing schedules with a view to avoid any duplication with international QA activities in the framework of BEMA, MRAs, and WHO Vaccines Programme.

1.4 To foster (i) mutual acceptance of audit outcomes between the two programmes in general; and (ii) mutual recognition of audits in the EEA context in particular, the Parties endeavour to maintain equivalent auditing tools and programmes and exchange reports upon request by either party subject to the agreement of the authority audited.

1.5 The Parties encourage the joint participation of JAP and JRP auditors during audits carried out in the EEA (e.g. 1 PIC/S auditor in a JAP audit or 1 JAP auditor in a PIC/S audit).

1.6 The Parties shall abide by the rules of confidentiality as defined within the EEA and PIC/S frameworks. If any of the parties become aware that an effort is made to obtain reports by judicial or legislative mandate they will promptly inform the other party as well as the authority audited.

2. Training of inspectors and auditors

The Parties agree to jointly train auditors involved in the assessment of Medicines Agencies. In the field of GxP and more particularly GMP and GDP, the Parties agree to co-operate in the development of training, which shall be common for EEA and PIC/S inspectors. To maximise resources PIC/S training shall be open to EEA inspectors and vice versa.

3. Commencement, review, amendment and termination

3.1 This Agreement will come into effect on the day on which it is signed by the Parties.

3.2 This Agreement will be reviewed after 3 (three) years and then periodically.

3.3 The Agreement may be amended at any time with the written consent of the Parties. Any such amendment will come into effect on the date determined by the Parties.

3.4. Either Party may terminate this Agreement by written notice to the other Party. The Agreement will then terminate 30 calendar days after the receipt of the notice to terminate.

Date and signatures:

Date: 15-08-2016	Date: 02-06-2016
D.P. Hargreaves.	
Name Paul Hargreaves	Name Klaus Cichutek
Title Chair of PIC/S	Title Chair of the HMA Management Group
	Name Hugo Hurts Title Chair of the HMA
FOR THE PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME (PIC/S)	FOR THE EEA HEADS OF MEDICINES AGENCIES (EEA HMA)