Human Tissue Authority (HTA)

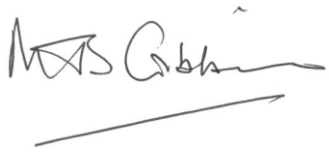
Department of Health

Non-qualifying regulatory provision assurance statement: confirmed

The Regulatory Policy Committee (RPC) is content that, on the basis of the summary information provided, none of the measures or activities covered in the summary document should be considered as qualifying regulatory provisions for the purposes of the business impact target. The RPC has not been asked to provide a detailed view on any specific activity in this statement or comment on any activities not covered in either this summary document or a separate assessment of a qualifying regulatory provision.

Comments on the non-qualifying regulatory provision summary

This NQRP summary (RPC-4055(1)-DH-HTA) covers provisions that are additional to those included in the NQRP summary submitted in February 2017 (RPC-3616(1)-DH-HTA). These provisions were not included in the previous NQRP summary, as it was unclear to the regulator at the time whether guidance and policy which provided clarity on EU requirements were QRPs or NQRPs. The regulator has subsequently confirmed that these are NQRPs, and has therefore issued a revised NQRP summary encompassing these provisions.



Michael Gibbons CBE, Chairman

Regulatory Policy Committee

Non-qualifying Regulatory Provisions Summary Reporting Template

Regulator: Human Tissue Authority
Business Impact Target Reporting Period Covered: May 2015 – 08 June 2017

Business Impact Target Reporting Period Covered: Excluded Category*	Summary of measure(s), including any impact data where available**
A – EU and International	The HTA issued three updates to guidance and policy documents that provide clarity on complying with EU requirements in the Human Application sector. This encompasses: a) Guidance clarifying testing requirements for Human T-lymphotropic Virus, type I (HTLV-1) for donors of tissues and cells intended for human application, as set out in Annex II of Commission Directive 2006/17/EC. b) Extension of existing HTA and MHRA policy on the Regulation of Blood as a Starting Material for Advanced Therapy medicinal Product (ATMP) Manufacture, that allows collection of blood as a starting material for an ATMP to be performed under either a Tissues and Cells or Blood Establishment Licence. c) Guidance for establishments on meeting HTA licensing requirements for the procurement of tumour samples to be used as a starting material in the manufacture of an Advanced Therapy Medicinal Product (ATMP), specifically on demonstrating how this meets with the requirements of EU Directive 2004/23/EC with respect to donation, procurement and testing. This consolidated guidance on existing requirements. We do not expect that this guidance will result in any additional burdens of

	HTA regulated businesses beyond those already required under legislation of the EU or international origin. See NQRP Summary Statement RPC-3616(1)-DH-HTA for other provisions introduced in this reporting period.
B – Economic Regulation	The HTA has not introduced or changed any regulatory provisions relating to economic regulation in this reporting period.
C – Price Control	The HTA has not introduced or changed any regulatory provisions relating to price control in this reporting period.
D - Civil Emergencies	The HTA has not introduced or changed any regulatory provisions relating to civil emergencies in this reporting period.
E – Fines and Penalties	The HTA has not introduced or changed any regulatory provisions relating to fines and penalties in this reporting period.
F – Pro-Competition	The HTA has not introduced or changed any regulatory provisions that are pro-competition in this reporting period.
G – Large Infrastructure projects	The HTA has not introduced or changed any regulatory provisions relating to large infrastructure projects in this reporting period.
H – Misuse of Drugs/National Minimum Wage	The HTA has not introduced or changed any regulatory provisions relating to price control in this reporting period.
I – Systemic Financial Risk	The HTA has not introduced or changed any regulatory provisions relating to systematic financial risk in this reporting period.
K – Industry Codes	The HTA has not worked on any industry-driven codes in this period.
L1 – Casework	The HTA has not undertaken any casework in relation to these updates. See NQRP Summary Statement RPC-3616(1)-DH-HTA for other casework in this reporting period.
L2 – Education, communications and promotion	An external newsletter is circulated to Designated Individuals (DIs) of licensed premises every two months, which signposts updated guidance and policies. Newsletters are also sent to Independent Assessors on a quarterly basis. See NQRP Summary Statement RPC-3616(1)-DH-HTA for education,

	communications and promotion activities relating to other provisions introduced in this reporting period.
L3 – Activity related to policy development	The HTA has not undertaken any policy development activity in relation to this guidance. See NQRP Summary Statement RPC-3616(1)-DH-HTA for detail of activity relating to other provisions introduced in this reporting period.
L4 – Changes to management of regulator	The HTA has not undergone and significant organisational changes in this reporting period.