Non-qualifying Regulatory Provisions Summary Reporting Template

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

NQRP Category	Summary of measure(s), including any impact data where available
A – EU and International	The EU Import and Coding Directives, due to come into force on or before the 29th of April 2017, will affect businesses regulated by the HTA. However, it is expected that none of the changes of European/International origin place additional burdens on HTA business beyond those required under legislation of EU or international origin (i.e. no gold-plating has occurred). 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.
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.

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D - Civil Emergencies	The HTA has not introduced or changed any regulatory provisions relating to civil emergencies in this reporting period. Guidance issued to Mortuaries relating to storage contingency arrangements only applies to public sector organisations, as no businesses store bodies.
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	In 2015/16, the HTA performed 234 site visits to licenced premises, including 3 non-routine inspections. 239 minor shortfalls and 26 major shortfalls were identified, with 101 Corrective and Preventative Action (CAPA) plans put in place. There were 60 serious adverse events and reactions in the human application sector, 36 serious adverse events and reactions in organ donation and transplantation and 102 serious incidents in mortuaries. The HTA also has statutory duty to make a decision on every living organ donation. This is to ensure that every donation takes place with valid consent and free of duress, coercion and reward. In 2015/16, the HTA made a decision on 1,172 organ donations from living donors – a panel of HTA Authority Members made a decision on 238 of these. A small proportion of the transplant centres that perform living donor transplants are private. The HTA also has a duty to make a decision on bone marrow and peripheral blood stem cell (PBSC) donations when the donor is a child not competent to consent or an adult that lacks capacity to consent.

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	Information on casework is collated and published in the HTA Annual Review. The 2016/17 Annual Review is due for publication in June/July 2017. No activities listed in this section represent a change in the burden of regulation placed on business, except where these result from a separate qualifying regulatory provision that has been assessed.
L2 – Education, communications and promotion	An external newsletter is circulated to Designated Individuals (DIs) of licensed premises every two months. This contains general information about the HTAs activities and signposts new/updated guidance and policies. Newsletters are also sent to Independent Assessors on a quarterly basis. None of the material produced creates a new regulatory standard that businesses will be expected to follow apart from those assessed as QRPs. A number of training sessions and workshops were held in 2015-17, including training for Independent Assessors, Accredited Assessors and Coroner's Officers. Attendance at educational and promotional events is not compulsory. Position statements are issued to provide greater clarity where needed: a new statement regarding extending existing licences to cover the removal of tissue from the deceased for research was published in this reporting period. Ad-hoc information is also circulated where necessary, such the dissemination of advisory bodies' advice on the Zika virus in February 2016 and a regulatory alert on Syphilis testing products in November 2016. These are intended to provide up-to-date, useful information relating to licenced activities rather than to impose any additional regulatory requirements.
L3 – Activity related to policy development	We issued a consultation relating to proposed updates to the HTA Codes and Standards in 2016. There was also a consultation regarding the Fees Model Review in 2016, though this did not result in a Regulatory Provision as fees are not in scope for the BIT.
L4 – Changes to management of regulator	The HTA has not undergone and significant organisational changes in this period. The Licencing and Inspection Review outcomes, due for implementation in 2017, may impact upon the regulatory burden on businesses. This will form part of the 2017/18 QRP and NQRP process where necessary.

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Other Comments	There are a number of publications that do not apply to businesses so are not regulatory provisions for the purposes of the BIT. These include: - The Code of Practice for the Human Transplantation (Wales) Act, as there are no businesses undertaking organ donation in Wales. - Policies and guidance in the Post Mortem sector relating to the storage of bodies, as businesses operating in this area only provide storage for tissue samples.