Department for
Business, Energy
& Industrial Strategy

BUSINESS IMPACT TARGET: SUMMARY TEMPLATE

Non-qualifying Regulatory Provisions (NQRP) summary reporting template

Regulator: Human Tissue Authority

Business Impact Target Reporting Period Covered: 9 June 2017 to 20 June 2018

Excluded Category*	**Summary of measure(s), including any impact data where available****
Measures certified as being below de minimis (measures with an EANDCB below +/- £5 million)	<u>Changes to the licence application process</u> In July 2017, the HTA modified its licence application process to standardise the types of supporting documents provided by applicants at the start of the application process. The changes were made in order to streamline the assessment process, and to provide greater clarity about the information that applicants need to provide to demonstrate that they meet licensing standards. There was no change to the standards that new licence applicants would need to meet. Eleven businesses have been subject to this updated process since July 2017 and the impact has been assessed as falling within the de minimis threshold. <u>Changes to the HTA's Representations Process</u> When the HTA moves to make some decisions (for example to refuse, revoke or vary a licence), the establishment involved is able to make representations against the proposed course of action. The HTA changed its representations process in September 2017 in order to make it less burdensome for all parties. The updated process is intended to resolve issues more promptly whilst still taking into account all relevant factors. This process has not been used since it was updated as no establishments have made representations since this time. The impact on business has been assessed as falling within the de minimis threshold. *Regulatory provisions that would also fall within the excluded category relating to regulatory provisions that implement new or changed obligations from European Union Regulations, Decisions and Directives, and other international commitments and obligations* The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2018 came into force on 1 April 2018. These transposed two EU Directives on coding and import into UK law. The changes the HTA made, as a result of implementing this legislation, affected all establishments in the Human Application sector. These included: • Updates to standard conditions of all Human Application licences • Revised Directions and changes to the Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment • Changes to the licensable activity of distribution • Modifications to licensing standards

Excluded Category*	Summary of measure(s), including any impact data where available**
	• Changes to import licensing, as part of this licensed establishments were required to submit evidence of compliance with the import Directive Of the 134 licensed establishments in the Human Application sector, 46 establishments affected by these changes were businesses. None of the changes of European/International origin place additional burdens beyond those required under legislation of EU origin. Further, all impact on business brought about by the changes has been assessed as falling within the de minimis threshold. *Regulatory provisions that would also fall within the excluded category relating to regulator casework*-. As of June 2018, the HTA licensed 567 establishments across six sectors. Of these, 313 establishments were public sector organisations and 254 were classified as businesses. Although licence numbers fluctuate, these figures are considered to be representative of the reporting period. For this reporting period, the HTA's casework did not introduce any new measures, or changes to activity, that would change the burden of regulation placed on business. This impact of all casework on business is believed to fall within the de minimis threshold. Where figures cover the 2017/18 business year, they are considered as representative of a 12 month period. In 2017/18 business year, the HTA performed 240 site visits to licensed premises, including 5 non-routine inspections. Of the establishments that were visited, 82 were classed as businesses. In this time, 802 shortfalls were identified. There were 184 serious adverse events and reactions reported in the human application sector, 37 serious adverse events and reactions reported in the organ donation and transplantation sector and 232 serious incidents reported in the post mortem sector. In October 2017, the HTA received 432 Compliance Update submissions from licensed establishments in five out of our six regulated sectors. Of these establishments, 208 were classed as businesses. Compliance updates are a biennial requirement and their direct impact on businesses falls within the de minimis threshold. In January 2018, establishments in the Human Application sector were required to submit an annual activity return, this included submissions from 46 businesses. Most of the information collected fulfils EU legislative requirements. Additional information was requested in 2018 on third party

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	agreements and import and export of tissues and cells within the EU. The impact of this collection on businesses did not exceed the de minimis threshold. The HTA has a 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 2017/18, the HTA made a decision on 1214 organ donations from living donors – a panel of HTA Authority Members made a decision on 317 of these. Three of the transplant centres that perform living donor transplants are private hospitals. *Regulatory provisions that would also fall within the excluded category relating to education, communications activities and promotional campaigns* An external newsletter is sent to Designated Individuals (DIs) of licensed premises every two months. This contains general information about the HTA's activities and signposts new/updated guidance and policies. Newsletters are also sent to Independent Assessors on a quarterly basis. None of these had a direct impact on businesses that exceeded the de minimis threshold. Ad-hoc information is also circulated where necessary, such the dissemination of advisory bodies' advice on Chikungunya virus in September 2017. These provide up-to-date, useful information relating to licensed activities, rather than to impose any additional regulatory requirements. None of this information would have an impact on business that exceeded the de minimis threshold.
All other excluded categories	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusions

* For full, legal definitions of these exclusion categories, please see https://www.parliament.uk/business/publications/written-questions-answers-statements/written-statement/Commons/2018-06-20/HCWS776/

** Complete the summary box as 'Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion.' where this is appropriate.