



Department for
Business, Energy
& Industrial Strategy

BUSINESS IMPACT TARGET: SUMMARY TEMPLATE

Non-qualifying Regulatory Provisions
(NQRP) summary reporting template

Regulator: The Human Tissue Authority

Business Impact Target Reporting Period Covered: 21st June 2019 – 12th December 2019

| Excluded Category* | Summary of measure(s), including any impact data where available** |
|--|--|
| Measures certified as being below <i>de minimis</i> (measures with an EANDCB below +/- £5 million) | <p><u>Casework</u></p> <p>As of June 2019, the HTA licensed 564 establishments across six sectors. Of these, 322 establishments were public sector organisations and 242 were classified as businesses.</p> <p>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.</p> <p>Between 21 June and 12 December 2019, the HTA managed:</p> <ul style="list-style-type: none">• 80 site visits of licensed premises, resulting in 411 shortfalls.• 308 incidents reported across six sectors.• 12 new licence applications.• 357 licence variation requests.• Information submissions for 25 preparation process dossiers. <p>In October 2019, the HTA received 430 Compliance Update submissions from licensed establishments in five out of our six regulated sectors. Compliance updates are a biennial requirement and their direct impact on businesses falls within the <i>de minimis</i> threshold.</p> <p>The HTA has a statutory duty to make a decision on whether or not to approve every proposed case of living organ donation. This is to ensure that every donation takes place with valid consent, and to ensure that the donor is acting free from duress, coercion and reward. In this reporting figure, the HTA made a decision on 606 organ donation cases from living donors – a panel of HTA Authority Members made a decision on 175 of these.</p> <p>On 1 October 2019, the HTA changed the format of its inspection reports to make them shorter and to clarify the way in which inspection findings are reported.</p> <p><u>Education, communications activities and promotional campaigns</u></p> <p>The HTA produces a newsletter for professional stakeholders every two months. This contains general information about the HTA’s activities, and signposts to</p> |

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| | <p>latest news, updated guidance and policies.</p> <p>A quarterly newsletter is sent to Independent Assessors.</p> <p>During the reporting period, the HTA published guidance for each of its sectors on how to meet existing regulatory requirements.</p> <p>In September 2019 the HTA published a regulatory alert on West Nile Virus. This was to raise awareness for our regulated establishments.</p> <p>It also published guidance for establishments on how to prepare for EU Exit.</p> |
| EU Regulations, Decisions and Directives and other international obligations, including the implementation of the EU Withdrawal Bill and EU Withdrawal Agreement | Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion |
| Measures certified as concerning EU Withdrawal Bill operability measures | Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion |
| Pro-competition | Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion |
| Systemic Financial Risk | Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion |
| Civil Emergencies | Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion |
| Fines and Penalties | Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion |
| Misuse of Drugs | Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion |
| Measures certified as relating to the safety of tenants, residents and occupants in response to the Grenfell tragedy | Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion |
| Casework | Following consideration of the exclusion category there are no measures for the reporting period that qualify for the |

| Excluded Category* | Summary of measure(s), including any impact data where available** |
|---|---|
| | exclusion |
| Education, communications and promotion | Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion |
| Activity related to policy development | Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion |
| Changes to management of regulator | Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion |

* For detailed guidance on the exclusion categories, please see <https://www.gov.uk/government/publications/better-regulation-framework>

** 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.