Health Institution Exemption

Draft MHRA guidance

Thank you for reviewing this draft guidance. In order to capture all of your comments, please use this template for your response. We have asked some specific questions in the text. They have been reproduced here to record your response.

Please email your completed template to HIE@MHRA.GOV.UK

At the end of this document is a template for specific text changes.

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| --- | --- |
| Name |  |
| Organisation |  |
| Date |  |

Definitions and scope

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| QUESTION A |
| Some examples of what we consider to be health institutions are obvious eg NHS Trusts/ NHS Boards, but what about the following? |
| a) Collaborations led by a health institutions to provide healthcare? | Yes/no |
| b) Collaborations led by a health institutions for product development with/without commercial intent? | Yes/no |
| c) Free standing commercial laboratories? | Yes/no |
| Any other examples? |
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Performance studies and clinical investigations

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| QUESTION B |
| a) Is this a right approach to the regulation of devices in clinical investigations and performance studies? | Yes/no |
| b) Is this approach proportionate and desirable? | Yes/no |
| c) What is an appropriate QMS for use in a clinical investigation/performance study? |
| Please specify. |  |
| d) Should clinical investigations/performance studies: |  |
| Be registered with MHRA? | Yes/no |
| Comply with relevant GSPR? | Yes/no |
| Have the same level of justification? | Yes/no |
| e) Do general principles apply to performance studies (IVDR Article 57) and ‘other clinical investigations’ (MDR Article 82) when applying the exemption? |  |
| IVDR Article 57 | yes/no |
| MDR Article 82 | yes/no |
| f) Any other comments? |
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The justification

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| QUESTION C |
| Please could you provide other examples that we can use to help health institutions understand what is needed? |
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| QUESTION D |
| a) Should the health institution regularly monitor the market and test similar devices for equivalence? | Yes/no |
| b) Should the health institution stop making or modifying and using the device once an equivalent CE marked product is made available? | Yes/no |
| c) any other comments |
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Information publicly available

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| QUESTION E |
| a) Should there be a register of health institutions applying this exemption? | Yes/no |
| b) Should parts A and B of the form be made publicly available centrally? | Yes/no |
| c) Should part C of the form also be made publicly available? | Yes/no |
| d) Should MHRA consider the need to carry out market surveillance activities of registered exemptions? | Yes/no |
| e) Any other comments |
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Documentation requirements

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| QUESTION F |
| a) Can these requirements be applied in emergency situations? – eg development of an assay for an emergent epidemic such as SARS or MERS? | Yes/no |
| b) If not what is the alternative route? |
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| QUESTION G |
| a) Should this additional documentation requirement also apply to IVDs in class A, B or C? | Yes/no |
| b) If so, what is the robust, risk-based rationale and where can people go for guidance on IVD classification? |
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Surveillance

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| QUESTION H |
| Should MHRA reserve the right to impose review and reporting requirements for all serious incidents plus trend reporting of other incidents in the future? | Yes/no |

Governance

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| QUESTION I |
| Although not a requirement in the Regulations, should MHRA require health institutions to employ/subcontract/have access to competent regulatory advisers in lieu of a Person Responsible for Regulatory Compliance? (ref Article 15 IVDR and MDR)? | Yes/no |

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| QUESTION J |
| a) Although not a requirement in the Regulations, should MHRA require or recommend health institutions to submit higher risk classification devices to a conformity assessment route using a Notified Body or other suitably qualified independent body? | Yes/no |
| b) If not should this be justified? |
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| QUESTION K |
| How much cross over is there with FDA deliberations on Laboratory Developed Tests?<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/LaboratoryDevelopedTests/UCM536965.pdf>  |
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Glossary

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| QUESTION M |
| Please list any additional terms that you would like to be included in a glossary. |
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| Page  | Line | Comment | Text change | Rationale |
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Use new pages as required