Department of Health & Social Care

Cost-effectiveness methodology for vaccination programmes

Consultation on the Cost-Effectiveness Methodology for Vaccination Programmes and Procurement (CEMIPP) Report

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Target audience: • Organisations and Committees that appraise cost-effectiveness (particularly within the health and care sector) • Specialists with an interest in health economics (eg. health economists based in academia, public health practitioners including epidemiologists, charities, patient groups and clinicians) • Vaccine industry professionals
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Contents

1. Purpose and scope of consultation

1.1. This is a 12 week consultation to seek views from interested parties on the recommendations in the Cost-Effectiveness Methodology for Immunisation Programmes and Procurement (CEMIPP) report which is published alongside this document. It is an England only consultation.

1.2. The independent CEMIPP group was set up by the then Department of Health to consider whether the method for appraising cost-effectiveness of vaccination programmes should change. Its recommendations, depending on how they are interpreted and which are implemented, could impact on which vaccination programmes are funded in future. They also have potential relevance beyond vaccination programmes to the funding of interventions in the wider health system.

1.3. The issues and the recommendations are necessarily complex and technical. We are therefore particularly looking for views from organisations and committees that appraise cost-effectiveness within the health and care sector as well as specialists with an interest in health economics such as health-economists based in academia, public health practitioners, epidemiologists, charities and patient groups, clinicians and vaccine industry professionals.

1.4. The recommendations from the CEMIPP report are set out at **Annex A**. The CEMIPP group noted in its report that its work was closely related to that of the Department's Appraisal Alignment Working Group (AAWG). The AAWG was set up to consider the divergent approaches to cost-effectiveness analysis across the health and care system. Ministers asked the AAWG to provide a view on the CEMIPP report before it was published. The AAWG's overarching conclusions are at **Annex Bi** and its interpretation of CEMIPP's recommendations is at **Annex Bii**.

1.5. Details on how to respond to this consultation are set out at **Annex C.** The deadline for response is **21 May 2018 [this deadline has been extended to 28 June 2018]**.

1.6. If you have any comments on the consultation process, details on how to respond are at **Annex D**.

1.7. The views of stakeholders are requested before any decisions are made on if and how to implement the CEMIPP report.

2. Why the CEMIPP report was produced

2.1. The Joint Committee on Vaccination and Immunisation (JCVI) is the independent expert committee that advises ministers on the introduction of new, and changes to existing, immunisation programmes in the UK. It bases its recommendations on a wide range of evidence including published literature, submissions from vaccine manufacturers and commissioned studies such as independent analyses of vaccine effectiveness and cost-effectiveness.

2.2. If the JCVI is to recommend a new or changed vaccination programme, it must meet certain conditions including that the programme demonstrates cost-effectiveness. For something to be cost-effective it must not only deliver a health benefit itself, but deliver more health than is being generated by the NHS resources that would need to be freed up from elsewhere in the health budget (these are called health opportunity costs). This consideration ensures that the general consequences for population health and wider NHS patients are considered alongside the benefits for those who may directly benefit from any vaccination programme.

2.3. Decisions on how to spend the health budget require difficult judgements. Basing these judgements on cost-effectiveness ensures the Government can make the best use of resources, aiming to deliver the maximum health benefit to the population, in a fair, consistent and justifiable way.

2.4. The cost-effectiveness analyses that JCVI consider for immunisation are similar to those used by the National Institute for Health and Care Excellence (NICE) when assessing health technologies, (in particular, medicines) for use in the NHS.[1] This ensures some comparability between how vaccines and other medicines are appraised.

2.5. In 2014, after considering whether or not vaccination should be introduced to protect children against meningococcal disease group B, the JCVI asked that the methodology they use to appraise vaccination programmes be reviewed to see if the rules for determining the cost-effectiveness of new or existing programmes should differ from those used for appraising other health-related activities that use public resources.

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[1] **JCVI (2013) Code of practice (including terms of reference)**

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224864/JCVI_Code_of_Practice_revision_2013_-_final.pdf

NICE (2013) Guide to the methods of technology appraisal

https://www.nice.org.uk/process/pmg9/resources/guide-to-the-methods-of-technology-appraisal-2013-pdf-2007975843781

2.6. The Cost-Effectiveness Methodology for Immunisation Programmes and Procurement (CEMIPP) group was set up as a result. It was chaired by John Cairns, a professor of health economics at the London School of Hygiene and Tropical Medicine, and consisted of other academic health economists as well as representatives from bodies such as the JCVI and NICE and analysts from the Department of Health and Social Care and Public Health England. Some stakeholders, including the pharmaceutical industry and some charities, also had an opportunity to feed in views.

2.7. The CEMIPP group considered whether there are ways in which the economic evaluation of immunisation programmes differ sufficiently from that of other health-related activities using public resources such that the methods for appraising cost-effectiveness in vaccination should differ to those used for the wider health system. This independent group submitted its report to the Department in July 2016.

3. The CEMIPP report

3.1. The CEMIPP report is published alongside this consultation document. It makes 27 recommendations grouped under seven broad headings:

- **perspective on costs and outcomes** i.e. what is the appropriate scope or range of factors which should be included when considering the cost-effectiveness of vaccination programmes. For instance, if and how wider societal impacts such as the wellbeing of parents and carers, should be taken into account alongside the direct health benefit of the vaccination itself.
- **incremental analysis of all relevant comparators** i.e. whether cost-effectiveness analysis of a vaccination programme augmented with an additional component (such as protection against an additional strain of a disease) should be assessed as a whole or whether analysis should focus on the cost-effectiveness of the additional component.
- **discounting** i.e. how to determine the value placed on health benefits of vaccination that may not materialise until a number of years in the future.
- **time horizon of evaluation** i.e. as there is uncertainty around forecasting the impacts of vaccination a long way into the future, what time period should a vaccination programme be evaluated against when considering its cost-effectiveness.
- **relationship between cost and outcome** i.e. how should cost-effectiveness analysis incorporate certain vaccine-specific factors which can influence the relationship between costs and outcomes (e.g. herd immunity - when enough people are immunised it is very hard for a pathogen to find anyone who isn't vaccinated. Thus, protecting a population by vaccination may also protect non-immunised people).
- **measuring and valuing health effects** i.e. how should cost-effectiveness analysis measure relevant health factors which may be inadequately captured (e.g. peace of mind effects) and how should analysis value different health effects in different circumstances, for example avoiding ill-health or restoring health.
- **appraisal of evidence** i.e. at what level should a vaccination programme be regarded as value for money and how should uncertainty regarding impacts of a vaccine be incorporated in the decision-making process.

3.2. The 27 recommendations are listed at **Annex A.** The CEMIPP group noted that its recommendations should be viewed as a package.

4. The Appraisal Alignment Working Group (AAWG)

4.1. The Department's Appraisal Alignment Working Group (AAWG) was also set up in 2014. The AAWG is chaired by the Department's Chief Economist, with representation from some of the Department's Arms' Length Bodies as well as some academics. It was set up to consider the divergent approaches to cost-effectiveness analysis across the health and care system. It aims to identify best practice and, where possible, achieve greater alignment of methodologies and techniques across the health and care sector.

4.2. The CEMIPP group noted that its work and that of the AAWG were closely related. As a result of the clear interdependencies between the work of CEMIPP and AAWG, ministers decided to share the CEMIPP report with AAWG before it was published to seek their advice, including on the potential implications of the recommendations within the CEMIPP report beyond immunisation.

4.3. The AAWG provided its advice to ministers at the end of January 2018. Their conclusions are included at **Annex Bi** and **Annex Bii**.

4.4. In summary, the AAWG broadly supported the analytical underpinnings of the CEMIPP report but acknowledged some limitations. The AAWG did not advise on whether or not to implement the CEMIPP report as a whole. It did however note:

- That three significant areas were highlighted by CEMIPP where CEMIPP indicated its recommendations could be implemented now for immunisation:
    - discounting (recommendations: 3.1, 3.2, 3.3, 3.4)
    - time horizon of the evaluation (recommendations: 4.1, 4.2, 4.3)
    - appraisal of evidence – cost-effectiveness threshold (recommendations: 7.2, 7.3, 7.6)

  The AAWG noted that these recommendations had important interdependencies and should be considered within the context of the wider health system; however, if they were to be implemented for immunisation only, it should be as a package rather than individually.

- That some recommendations could be seen to largely reflect current best practice for performing cost-effectiveness analysis for immunisation programmes. The AAWG considered that these could be viewed as a coherent package and could be recommended to JCVI now (recommendations: 2.1, 2.2, 2.3, 5.1, 5.2, 6.1, 7.1, 7.4).

- A number of recommendations were significant and AAWG agreed with CEMIPP that implementation should take place if, and only if, this was recommended as the best practice approach for evaluations across the health system i.e. they should not be implemented for

immunisation alone. Best practice for the wider system is still under consideration by AAWG (recommendations: 1.1, 1.2, 1.3, 6.3, 6.4, 6.5, 6.6).

- That some areas would benefit from further research before implementation could or should be considered. AAWG would consider these as part of the ongoing research it commissions and oversees (recommendations: 6.2, 6.3, 6.4, 6.6, 7.5).

4.5. The AAWG also noted that the impact of the recommendations (in the first bullet of para 4.4), if taken together and as interpreted by Departmental analysts, would likely be to make vaccination programmes less cost-effective at current prices. They would also mean that vaccines would have to be assessed as more cost-effective than health technologies appraised by the National Institute for Health and Care Excellence (NICE) in order to be recommended for funding by the Department of Health and Social Care and the NHS. The AAWG also noted that, taken together, these recommendations should deliver a positive impact on overall population health through the better allocation of health resources towards interventions which were likely to deliver greater health benefit overall. There are specific consultation questions about this group of recommendations.

5. Conclusion

5.1. The Department bases its immunisation programmes on a robust cost-effectiveness methodology and any changes should be based on solid evidence. It appears that the CEMIPP report is based on the best evidence to date. However, the AAWG do acknowledge that there are some uncertainties.

5.2. Many of the recommendations reiterate good practice but others would result in a significant change from current practice. Before making any decisions it is right to let stakeholders consider both the CEMIPP report and the AAWG's conclusions and offer their views. Details about how to access the consultation questions and respond are at **Annex C.** The consultation seeks to obtain reasoned arguments, for or against, recommendations or groups of recommendations in the CEMIPP report.

5.3. Please complete the question template at Citizen Space using the following link:

https://consultations.dh.gov.uk/immunisation-and-high-consequence-infectious-diseases/cemipp-report/

and submit your response by **21 May 2018 [this deadline has been extended to 28 June 2018].**

Annex A: CEMIPP report recommendations

1	**Perspective on costs and outcomes**
1.1	JCVI should adopt, or trial in shadow mode, full economic utility as the scope of impacts to be assessed within evaluations if and only if this is the recommended "best practice approach" for archetypal evaluations selected by the AAWG.
1.2	Case-by-case selection (by the manufacturers, by JCVI or by modelling teams) of impacts to be considered should be avoided to promote consistency across evaluations and fairness to those whose benefits would be displaced (concerning whom bespoke analysis is intrinsically more difficult).
1.3	JCVI or DH should commission an infographic or other summary relating to the displaced benefits that can be used to inform discussions held by JCVI given the intrinsic difficulty of assessing the impact of specific factors upon the displaced.
2	**Incremental analysis of all relevant comparators**
2.1	Evaluations of immunisation programmes should be conducted on an incremental basis.
2.2	The options to be compared should be clearly described and justified. Careful attention should be given to ensuring that the programme configurations compared comprise the range of options (including the status quo) among which the best is likely to be found, for instance including options where a new dose is added and an existing dose is removed.
2.3	JCVI should be asked to advise on the clinical and scientific aspects of the options. Public health experts should be asked to advise on practicalities of implementation and vaccine availability.
3	**Discounting**
3.1	Health impacts (benefits and the displacement effects of expenditure) should be discounted at 1.5%.
3.2	Any non-health benefits and costs outside the health system, included in evaluations, should be discounted at 3.5%.
3.3	These rates should not change within the period of analysis (discussed in the next section).
3.4	Long term impacts not amenable to this discounting paradigm should be explicitly noted and assessed as part of the overall cost-effectiveness considerations.
4	**Time horizon of the evaluation**
4.1	Immunisation programmes should be evaluated using an indefinite timescale and, as a sensitivity test, an analysis should be undertaken to highlight the extent to which the estimated cost-effectiveness is influenced by this choice of discount rate and time horizon.

4.2	Decision makers should be advised on how to interpret the difference between the two sets of results and the role of the QALY gains and losses in the far future in the difference between the results.
4.3	While review of procurement methodology is beyond the remit of this working group, the Department should give consideration to how uncertainty regarding cost-effectiveness, and specifically sensitivity analyses should be included in the procurement methodology.
5	**Relationship between cost and outcome**
5.1	Cost-effectiveness analyses ought to consider systematically whether there are important non-linearities in costs, effectiveness and cost-effectiveness with uptake/output due to factors such as, diminishing returns to finding unvaccinated people, and herd immunity, which need to be quantified.
5.2	Cost-effectiveness analyses of vaccination programmes ought to consider the impact of (avoiding) an epidemic on treatment of non-marginal cases such as postponement of treatment.
6	**Measuring and valuing health effects**
6.1	Cost-effectiveness analyses ought systematically to consider unintended consequences of vaccination programmes, including serotype replacement.
6.2	Research needs to be undertaken regarding ‘peace of mind’ benefits. Until there is such clear evidence a very strong specific case would need to be made as to why a particular programme ought to be treated differently by including such non-QALY benefits.
6.3	The working group recommend that JCVI should follow emerging best practice in terms of how it presents and records any value judgements it makes when applying differential weights, acknowledging that past decisions do not (of themselves) constitute an evidence base for future decisions.
6.4	Where differential weighting of QALYs is generally recommended because of the perceived failure of instruments to capture quality of life in specific groups (for instance children) JCVI should follow emerging best practice, applying any adjustments to impacts of the vaccine under evaluation and of displaced activity.
6.5	JCVI should communicate to AAWG its position on what factors warrant differential weighting within evaluations of health interventions.
6.6	JCVI should follow with interest the deliberations of other bodies including AAWG on how to consider relativistic effects when evaluating the gain or loss of QALYs, with a specific attention on how prevention of QALY loss fits into any theoretical framework that emerges.
7	**Appraisal of evidence**
7.1	DH advised by the JCVI should continue to judge cost-effectiveness over a minimum time horizon of 10 years accounting for the expected value of an epidemic occurring each year. A review of any changes in evidence relevant to cost-effectiveness ought to be undertaken periodically during this period (e.g., every five years) and if appropriate a

	formal updating of the estimates of cost-effectiveness should be commissioned.
7.2	The opportunity costs of investment in immunisation programmes, in terms of displaced health, should be estimated using a figure of £15,000 per QALY. This value to be re-assessed as additional relevant research becomes available.
7.3	The cost-effectiveness threshold should be considered to remain at its newly recommended value (£15,000 per QALY) through the economic evaluation supporting a decision on an immunisation programme. If the threshold changes in the future, the status of current immunisation programmes and those rejected on cost-effectiveness grounds should be reconsidered.
7.4	When considering disinvesting in a vaccine programme on cost-effectiveness grounds the 'point estimate' test ought to be applied, with informal consideration of the 'harm to the NHS' test (option (ii) above). However, decisions to disinvest should not be made based on purely quantitative economic analyses focusing on costs and QALYs; political, administrative and fairness considerations ought to be taken into account, along with careful consideration of the options to be evaluated.
7.5	Research is required that would increase our understanding of incorporating equity concerns, for example, equity weighting of health benefits foregone as a result of activities displaced by immunisation programmes.
7.6	In order to assess whether the risk of an immunisation programme being not cost-effective is acceptable, the JCVI should require that 90% of scenarios in a Monte Carlo simulation fall below a £25,000 per QALY threshold.

Annex Bi: AAWG's analytical conclusions on the CEMIPP report

The CEMIPP report and its recommendations

1. The review of Cost-Effectiveness Methodology for Immunisation Programmes and Procurements (CEMIPP review), presented to the Department of Health and Social Care[2] (DHSC) in 2016, makes recommendations for fundamental changes to the rules for appraising the cost-effectiveness for vaccines. The Public Health and Innovation minister at the time, Nicola Blackwood, referred the report to the Appraisal Alignment Working Group (AAWG) for its analytical assessment of the report, especially given its potential implications for health appraisals beyond immunisation.

2. The CEMIPP report gives 27 detailed recommendations, and intended them to be "viewed as a package". Three of the recommendations are particularly significant in terms of their difference from current practice of the independent Departmental expert committee which advises the UK health departments on immunisation (the Joint Committee on Vaccination and Immunisation - JCVI):

   2.i. A lowering of the cost-effectiveness threshold from £20,000 per QALY to £15,000 per QALY. This is in line with recent evidence[3] estimating healthcare opportunity costs[4] as well as the methodology used by DHSC in its impact assessments. Everything else being equal, a lower cost-effectiveness threshold for immunisation would imply a stricter hurdle for new vaccines to be found cost-effective compared to existing methodology.

   2.ii. A lowering of the discount rate for health impacts from 3.5% per year to 1.5% per year. A lower discount rate implies that greater weight is given to costs and benefits further into the future.

   2.iii. An indefinite time horizon of analysis (i.e. the time period over which impacts of a vaccine are considered), with the inclusion of a sensitivity test to account for a lower discount rate.

   The CEMIPP review emphasised that these changes should be considered together, especially due to a number of interdependencies between some of the recommendations, particularly the time horizon and discount rate. The "sensitivity test" in respect of the time horizon is particularly significant given the implications a lower discount rate can have on

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[2] The Department of Health and Social Care's name changed from the Department of Health (DH) in January 2018. For clarity of reading, the Department is referred to as the Department of Health and Social Care (DHSC) throughout this report except where referred to in previous quotes.

[3] Claxton et al., '*Methods for the Estimation of the NICE Cost Effectiveness Threshold*', CHE Research Paper 81 (2013) www.york.ac.uk/che/research/teehta/thresholds/

[4] The foregone benefits of expenditure that, within a fixed overall health budget, would otherwise have been conducted.

valuing health impacts in the far future (where CEMIPP viewed there to be some relatively key factors for vaccines in particular).

The impact CEMIPP's recommendations would have on vaccines

3. Commercially sensitive Department of Health and Social Care analysis of the impact of these recommendations suggests that, taken together (and subject to potential ambiguity relating to the application of the sensitivity test in (2iii) above), implementation of the recommendations would likely lead to a lowering of the cost-effective price for vaccines. This would make it less likely for vaccines to be deemed cost-effective and approved at current prices.
4. How this then affects costs and/ or decisions on which vaccines are procured is less certain, as the price paid by the government is a factor of both the cost-effective price and the commercial environment for each vaccine.

The AAWG's commentary on the recommendations

5. The AAWG also considers that CEMIPP's recommendations need to be considered as a package, rather than taken selectively. The AAWG is of the view that, taken together, the recommendations likely reduce the cost-effective price and therefore make it less likely for vaccines to be approved at current prices.
6. The AAWG has carefully considered CEMIPP's recommendations as well as new and ongoing analysis into estimating health opportunity costs. Many of the recommendations are closely aligned to what the AAWG considers to be best practice which it recommends for health appraisals to ensure resources are allocated as effectively as possible (on the basis of the best available evidence). CEMIPP's recommendations are generally well grounded in analysis and backed by a strengthening evidence base.
7. Beyond the impact on specific vaccination programmes, CEMIPP's recommendations seek to deliver a positive impact on overall population health through a better allocation of healthcare expenditure. A lower cost-effectiveness threshold applied to health interventions appraised by JCVI would provide a possibility for funds to be reallocated to other, potentially more cost-effective interventions in the wider healthcare system.

Wider implications of CEMIPP's recommendations

8. The AAWG recognises that a number of the significant recommendations – including the cost-effectiveness threshold – have potential direct relevance beyond immunisation. There is logical and analytical consistency in noting that if changes to thresholds and time horizons are considered for vaccines, they should also be considered more broadly – for example, considering stricter rules in relation to the appraisal of new drugs by the National Institute for Health and Care Excellence (NICE). Implementing the recommendations of the CEMIPP review in such a broad sense would bring all appraisal methodology closer in line with DHSC practice and likely confer health and economic benefits through improved allocation of resources across the health system.

9. In the event that ministers view it not to be the appropriate juncture for considering implementation of CEMIPP's recommendations beyond immunisation, it is then pertinent to consider whether it is then desirable to make changes to immunisation only:

   9.i. on the one hand a change in vaccine methodology alone would bring that methodology more in line with our best understanding of opportunity cost in the NHS and the methodology used by the Department of Health and Social Care in the assessment of impacts of its policies, and therefore likely improve the allocation of healthcare expenditure for both health and economic benefit;

   9.ii. on the other hand, changing methodology in just this part of the health system could tilt the playing field between vaccines assessed by JCVI and medicines assessed by NICE. Such changes would imply a stricter hurdle for vaccines to be found cost-effective compared to other drugs (or public health interventions) assessed by NICE and potentially signal a move away from prevention.

10. Changes to the threshold, discount rate and time horizon would be a major undertaking, requiring full options development (particularly around time horizon sensitivities) and proper consultation. The AAWG is happy to advise ministers further if they wish to consider particular approaches and policies for implementation. To date, the AAWG has taken informal analytical input only from a small set of stakeholders, who have a mix of views on these issues.

11. Irrespective of decisions relating to the threshold, discount rate and time horizon, which the AAWG considers important to view as a package, there are a number of smaller recommendations within the CEMIPP review that merit implementation, many of which reflect current best practice of analysis for the cost-effectiveness of vaccines. These could be recommended to JCVI for their consideration and implementation.

Annex Bii: AAWG’s interpretation of CEMIPP recommendations

To help structure the consultation questions, CEMIPP's recommendations have been broadly categorised into four groups based on AAWG's interpretation of the CEMIPP report:

1. Those with important interdependencies that should be considered within the context of the wider health system but, if they were to be implemented now for immunisation only, should be considered as a package rather than individually.

    This relates to recommendations:

    3.1, 3.2, 3.3, 3.4, 4.1, 4.2, 4.3, 7.2, 7.3, and 7.6

2. Those which the AAWG considered current best practice for performing cost-effectiveness analysis for immunisation programmes and could be viewed as a coherent package and recommended to JCVI now.

    This relates to recommendations:

    2.1, 2.2, 2.3, 5.1, 5.2, 6.1, 7.1, and 7.4

3. Recommendations that should not be implemented for immunisation alone (which CEMIPP also advised) but if, and only if, they were considered best practice for evaluations across the health system. Best practice for the wider system is still under consideration by AAWG.

    This relates to recommendations:

    1.1, 1.2, 1.3, 6.3, 6.4, 6.5, and 6.6

4. Areas which would benefit from further research before implementation could or should be considered. AAWG would consider these as part of the ongoing research it commissions and oversees.

    This relates to recommendations:

    6.2, 6.3, 6.4, 6.6, and 7.5

Annex C: How to respond to the consultation

This consultation seeks views from interested parties (particularly specialists with an interest in health economics) on the recommendations in the Cost-Effectiveness Methodology for Immunisation Programmes and Procurement (CEMIPP) report which is published alongside this document. The view of the Appraisal Alignment Working Group (AAWG) is included alongside some of these consultation questions.

Responses should be submitted **by 21 May 2018 [this deadline has been extended to 28 June 2018]** via the template at Citizen Space which is accessed using the following link:

https://consultations.dh.gov.uk/immunisation-and-high-consequence-infectious-diseases/cemipp-report/

Supplementary information

If you have additional evidence you wish to submit, this can be sent to ic-mb@dh.gsi.gov.uk quoting the reference number you will be provided with after submitting your consultation response in Citizen Space.

Postal response

If you wish to receive a paper copy of the consultation form, please contact the Immunisation and High Consequence Infectious Diseases Team at ic-mb@dh.gsi.gov.uk or by mail at:

Immunisation and High Consequence Infectious Diseases Team
Global and Public Health Group
Department of Health and Social Care
6th Floor, 39 Victoria Street
London SW1H 0EU

Please note that, although hard copy responses will be accepted, electronic responses via Citizen Space are preferred. We ask that hard copies are therefore only submitted by those unable to use Citizen Space.

Annex D: Comments on the consultation process

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact the Consultations Coordinator

Department of Health and Social Care
2e26, Quarry House
Leeds
LS2 7UE

e-mail: consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

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The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.