

A Consultation on implementing ‘safety features’ under the Falsified Medicines Directive

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MHRA Safety Features Team
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Contact details:
MHRA Safety Features Team FMD.safetyfeatures@mhra.gov.uk

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1 Introduction

The subject of the consultation

1.1 The EU Falsified Medicines Directive (2011/62/EU) (FMD) was adopted in 2011 and introduced new harmonised measures to ensure that medicines in the European Union (EU) are safe and that trade in medicines is properly controlled. Elements of the Directive – including a common logo to identify legal online pharmacies, and tougher rules on the control and inspection of producers of active pharmaceutical ingredients have already been implemented. Member States have until 9 February 2019 to implement the final part of the Directive, the ‘safety features’ Regulation. The Commission adopted Delegated Regulation (EU) 2016/61, which supplements FMD by laying down detailed rules on the safety features (EU 2016/161), published in February 2016. This provides the detail of an end-to-end verification system where medicinal products bearing the safety features can be identified and authenticated. EU regulations apply automatically in all EU Member States and the Delegated Regulation will therefore be directly applicable as part of UK law with the exception of the flexibilities in the Delegated Regulation, over which we are required to formally consult and then take additional legal steps if we are to make use of them.

1.2 This consultation invites views on the proposed steps that the Government intends to take to make sure the United Kingdom (UK) meets its obligations to transpose the provisions of the Falsified Medicines Directive (FMD) requiring ‘safety features’ to appear on the packaging of certain medicinal products. The detailed rules for the ‘safety features’ are set out in Commission Delegated Regulation (EU) 2016/161, but are essentially:

- a unique identifier (a 2D data matrix code and human readable information) that can be scanned at fixed points along the supply chain; and
- an anti-tampering device allowing verification of whether the packaging of a medicinal product has been tampered.

1.3 The safety features element of the Falsified Medicines Directive is not a track and trace system but is an end-to-end verification system. Data associated with individual packs will be uploaded into the repository at the time of manufacture and the data will be decommissioned when supplied to patients. Medicines will be able to be authenticated on a risk-based approach through the supply chain with verification and decommissioning (changing the active status of the product in the national and European repositories to prevent any further verification) taking place before the product is supplied to the patient.

1.4 Implementation of the Falsified Medicines Directive is unique, in that the European Commission has placed the obligation for setting up and managing the IT infrastructure on industry stakeholders rather than Member States themselves. This means that the Delegated Regulation puts the responsibility on manufacturers and marketing authorisation holders to build, manage and pay for a national repository for the UK – an IT hub in which details of all packs of medicines bearing the safety features will be stored. To fulfil these requirements, a not-for-profit company, SecurMed UK, has been set up by stakeholders in the UK medicines supply chain. Wholesalers and those supplying medicines to the public are also entitled to participate in the legal entity on a voluntary basis. The Medicines and Healthcare products Regulatory Agency (MHRA) and Department of Health and Social Care (DHSC) have a supervisory role as national competent authorities.

1.5 The Delegated Regulation sets out the structure of the repositories system and how it shall function. Within the system there will be a central European hub in addition to national information repositories. There are requirements on marketing authorisation holders to ensure that the required information is uploaded as well as requirements setting out how the national and European repositories must handle the exchange of this information. The system must have the functionality to not only manage the information once it is uploaded, but also allow the verification and decommissioning of medicinal products across European borders.

1.6 Each competent authority shall be granted access to the repository systems, and the information contained within it for the following purposes:

- supervision of the functioning of the repositories and investigating potential incidents of falsification;
- reimbursement; and
- pharmacovigilance or pharmacoepidemiology.

1.7 There are additional obligations set out for marketing authorisation holders to ensure that products which have been recalled, stolen or supplied as free samples are verified and decommissioned in the repositories system.

1.8 A small number of flexibilities are offered to Member States within the Delegated Regulation to accommodate the way in which medicines are supplied on a national basis. The most significant of these is set out in Article 23 of the Delegated Regulation. This provides Member States with legal flexibility regarding their respective supply chains about where the decommissioning process should take place for persons or institutions captured under Article 23 ('Article 23 providers').

1.9 This consultation is the formal process, providing interested parties the opportunity to engage with the Government on how it can best implement the

requirements, taking into account better Regulation objectives of ensuring risk-based and proportionate implementation. The consultation document aims to:

- explain the scope of the policy in relation to the ‘safety features’;
- explain the flexibilities within the Delegated Regulation, where the UK can determine policy decisions to accommodate the complexities within the UK medicines supply chain;
- present the Government’s proposed approach to implementation;
- consult on the available options for implementation; and
- provide stakeholders with a list of questions to assist our understanding of the best way to implement this policy.

1.10 Accompanying this consultation is a Statutory Instrument (SI) that is proposed to implement the requirements for safety features to appear on the packaging of certain medicinal products and an Impact Assessment (IA) which is focused on the areas of the regulation where the UK has flexibility to refine our implementation approach, as reflected by the different costs within that document. Alongside this consultation, guidance for wholesalers and parallel import licence holders and parallel distributors (PLPI) and a “list of medicines in and out of scope” has been published. Signposted will be a Community Pharmacy Guidance (CPA).

1.11 Article 2 of the Delegated Regulation sets out the scope of products that are required to bear the safety features as follows:

- prescription medicines unless they are listed in Annex I of the Delegated Regulation;
- non-prescription medicines listed in Annex II of the Delegated Regulation; and
- medicinal products to which Member States have extended the scope of the application of the unique identifier or of the anti-tampering device.

Who should read this?

1.12 This consultation should be read by those in the UK who will be affected by the changes proposed. This will be any individual, organisation, institution or group that is a stakeholder in or impacted by the UK medicines supply chain, as well as those who manufacture medicines, operate as a wholesaler dealer or supply medicines to the public. This will include, though not limited to:

- the pharmaceutical industry;
- wholesalers;
- patient groups;
- other regulatory authorities;
- the NHS; and
- persons authorised to supply medicines to the public.

Development of the Delegated Regulation – UK approach

1.13 During the development of the Delegated Regulation, the EU Commission sought views from Member States via an ‘expert group’. The UK was represented by MHRA and DHSC at the expert group and sought to align the requirements as far as possible with existing practice in the UK. Representatives were clear about the complex nature of the UK supply chain, seeking during the process to minimise negative impacts whilst ensuring that the UK can realise the benefits to patient safety.

1.14 Article 3 of the Delegated Regulation lists a number of definitions including a ‘healthcare institution’ as meaning ‘a hospital, in-or outpatient clinic or health centre’. The UK has classed General Practitioners (GPs) and Dispensing Doctors as health centres and therefore healthcare institutions. However, to remain equitable to what pharmacies have to do, we would expect Dispensing Doctors to decommission as pharmacies.

UK proposed approach to implementation

1.15 The UK submitted the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union on 29 March 2017. However, we recognise the importance of a close cooperative relationship between the UK and the EU in the field of medicines regulation, and science- and research collaboration. The Government is committed to ensuring a positive outcome for the sector that enhances competitiveness and builds on the success that we are rightly proud of, as we exit the EU. The Government’s overall aim is to ensure that patients in the UK and across the EU continue to access the best and most innovative medicines; and

are assured that their safety is protected through ongoing cooperation and the strongest regulatory framework. The Government's aim is to focus on providing safe and effective regulation and facilitate collaboration on major science, research, and technology initiatives.

1.16 Until exit negotiations are concluded, the UK remains a full member of the EU and all the rights and obligations of EU membership remain in force. The European Union (Withdrawal) Bill will ensure that, so far as possible, the same rules and laws will apply in the UK after exit as the day before. The Bill will convert existing direct EU law such as EU regulations into UK law as it applies in the UK at the date of exit. It will also preserve the laws we have made in the UK to implement our EU obligations, such as laws already made to implement the Falsified Medicines Directive, and the Delegated Regulation being consulted on now, which will apply in UK law from 9 February 2019.

Timetable for implementation

1.17 Once the Delegated Regulation applies in the UK, the safety features will be required to be placed on the packaging of medicines which fall within the remit of the Delegated Regulation, before they can be placed on the market. Companies will have to apply to update any authorisations impacted by these provisions no later than 9 February 2019. From this date, other parts of the supply chain will also need to fulfil their obligations in terms of verification and decommissioning of medicinal products required to bear the safety features from this point onwards.

1.18 The Government aims to finalise implementation plans on areas covered within this consultation later in 2018. We understand the UK's approach to implementation needs to be finalised as soon as possible.

Discussion

UK Regulatory changes

1.19 The requirements in the Falsified Medicines Directive for safety features to appear on the packaging of certain medicinal products will be transposed into UK law through amendments to the Human Medicines Regulations 2012. The EU Delegated Regulation will be directly applicable in the UK and so its provisions will not need transposing into UK legislation. However, the Government is required to legislate nationally to accommodate the flexibilities around specific characteristics of the supply chain. The draft Statutory Instrument (SI) included with this consultation sets out the proposed amendments to the Human Medicines Regulations.

1.20 Sanctions are also required in order to make the provisions enforceable in the UK, and are important in acting as a deterrent to behaviour that would put public health at risk. One approach, as set out in the draft SI, would be the sole use of criminal sanctions for failure to comply with the requirements of the Delegated Regulation – with a person liable on summary conviction to an unlimited fine or liable on conviction on indictment to a fine, or to imprisonment for a term not exceeding two years, or to both. However, Government is minded to move to an approach that would use a mixture of both criminal and civil sanctions. Such civil sanction might include written warnings, stop notices and civil fines, before the application of criminal sanctions which would only be used for the most serious (intentionally fraudulent) breaches. We welcome views on this subject in response to this consultation.

Question 1 What form of sanctions regime do you think would be the most effective to enforce the regulations across the UK medicines supply chain?

To ensure that your evidence can be taken into account, please take note of the guidance in Annex B and if it relates to the impact assessment please reference the relevant question number from the list of specific questions.

Impact Assessment

1.21 A consultation stage impact assessment of the proposed changes has been published alongside this consultation. This is our initial analysis and is published with evidence gaps. This analysis focuses only on the UK decisions on any flexibilities available under the Delegated Regulation.

1.22 Therefore, please focus your responses to the various questions throughout this consultation only on those areas where the UK has legal flexibility to make policy decisions. Proposals beyond the legal scope of the flexibilities will not be analysed as part of this consultation.

1.23 The impact assessment is focused mainly on the flexibility under Article 23 of the Delegated Regulation. In the context of the UK supply chain, which has a large number of different distribution channels from which patients obtain medicines, we need to ensure that this scheme can be implemented in a way that is as clear and simple as possible.

Question 2

Can you provide any additional evidence or comment on the existing impact analysis to develop the cost benefit analysis around these specific flexibilities in the impact assessment?

To ensure that your evidence can be taken into account, please take note of the guidance in Annex B and if it relates to the impact assessment please reference the relevant question number from the list of specific questions.

2. Scope of the Regulation

2.1 As noted in the introduction, Article 2 of the Delegated Regulation sets out the scope of products that are required to bear the safety features.

2.2 The Falsified Medicines Directive allows for the scope of the application of the unique identifier to be extended to other products for the purposes of reimbursement or pharmacovigilance, and for the scope of the application of the anti-tampering device to be extended to other products for the purpose of patient safety. The Government does not consider that there is a need to extend the scope of the safety features to other medicinal products at this time and believes that doing so would create additional burden on business disproportionate to its benefits because of the diverse way in which medicines are supplied in the UK. The UK currently allows the addition of an anti-tampering device onto any medicine and proposes to continue to allow this, without extending the requirement to do so.

Question 3

Do you agree with the Government's proposed approach not to extend the requirements for the unique identifier or anti-tampering device to any additional products at this time?

To ensure that your evidence can be taken into account, please take note of the guidance in Annex B and if it relates to the impact assessment please reference the relevant question number from the list of specific questions.

3. Application of the unique identifier

3.1 This chapter deals with Chapter II of the Delegated Regulation, which focuses on the technical specifications of the unique identifier. It requires manufacturers to place a unique identifier on the packaging of all medicinal products within scope of the Delegated Regulation and establishes the rules on what should be included within the unique identifier. It includes specifications as to how those pieces of information need to be encoded within a 2D data matrix code as well as the quality of printing of the barcode. Alongside the barcode manufacturers also have obligations to print certain elements of the unique identifier in a human-readable format.

Policy options and flexibilities

3.2 Under Articles 4 and 7, the Delegated Regulation allows Member States to require that a national reimbursement number, or other national number identifying the product is added to the unique identifier and printed in human-readable information on the packaging. Whilst the UK currently does not have a national reimbursement number for prescription medicines, as part of implementation preparation the Government has considered the merits of using other national numbers. One possibility considered was the addition of the NHS dictionary of medicines and devices (dm+d) codes, which is the NHS standard for communicating information set up to support NHS procurement. However, this would create a burden for manufacturers; firstly due to extra constraints on packaging because of the need to add additional information and secondly by complicating the supply of multi-national packs. The Government is therefore minded *not* to require a reimbursement number or other national number identifying the product. Our intention is to map products to UK NHS identifiers through the information that is already required to be uploaded by marketing authorisation holders into the pan-European Repository (European Hub).

Question 4

Do you agree with the Government's proposed approach *not* to require a reimbursement number, or other national number identifying the medicinal product, to be placed on products bearing the safety features?

To ensure that your evidence can be taken into account, please take note of the guidance in Annex B and if it relates to the impact assessment please reference the relevant question number from the list of specific questions.

3.3 Under a guidance document, the UK currently allows companies to provide additional information useful for patients on the label or in the patient information that accompanies the medicine. Article 8 of the Delegated Regulation allows the 2D data matrix code carrying the unique identifier to be used to deliver this additional helpful information if the national competent authority, which in the UK is the MHRA, allows this. The UK proposes to allow marketing authorisation holders to use the 2D data matrix code to have other information embedded within it, if desired by the manufacturer, and provided the information accessed has been fully assessed as part of the medicines licensing process.

Question 5

Do you agree that manufacturers should be allowed to include information other than the unique identifier in the 2D data matrix code?

To ensure that your evidence can be taken into account, please take note of the guidance in Annex B and if it relates to the impact assessment please reference the relevant question number from the list of specific questions.

4. Verification and decommissioning of the Safety Features – Manufacturers and Wholesalers

4.1 This chapter covers Articles in Chapters IV and V of the Delegated Regulation. These chapters set out obligations around verification and decommissioning for manufacturers and wholesalers.

Objectives

4.2 The Delegated Regulation is clear that manufacturers must verify that the 2D data matrix code is readable and contains the correct information. Manufacturers must also keep records of every operation they perform with or on the unique identifier on a pack of medicinal product for at least one year after the expiry date or five years after the pack has been released for sale, whichever is the longer period. There are also requirements around verification before removing or replacing the safety features as well as obligations to ensure that instances of suspected falsification or tampering are reported to the competent authorities.

4.3 Articles 20 and 21 set out the obligations on wholesalers concerning when they need to verify medicines packs. If the wholesaler is not receiving the medicinal product directly from a manufacturer or is receiving the medicine from another wholesaler who has not been nominated by the marketing authorisation holder (MAH) to supply the product, the receiving wholesaler will need to verify the product to confirm that it is authentic.

4.4 Under Article 22, wholesalers also have responsibilities to decommission products in certain circumstances and alongside connectivity linked to verification they must have processes in place to be able to decommission products. This includes products being exported outside the EU, returned products that cannot be resold, products intended for destruction and samples requested by competent authorities.

Policy options and flexibilities under Article 23

4.5 Article 23 of the Delegated Regulation provides for some flexibility in the supply chain about where verification and decommissioning must take place. It allows Member States to choose whether it is best to require wholesalers to verify and

decommission a medicinal product before supplying to certain Article 23 providers, thereby exempting those which fall under that category from the obligation to do so.

4.6 The Delegated Regulation lists the Article 23 providers who can be exempted as:

- persons authorised or entitled to supply medicinal products to the public who do not operate within a healthcare institution or within a pharmacy;
- veterinarians and retailers of veterinary medicinal products;
- dental practitioners;
- optometrists and opticians;
- paramedics and emergency medical practitioners;
- armed forces, police and other governmental institutions maintaining stocks of medicinal products for the purposes of civil protection and disaster control;
- universities and other higher education establishments using medicinal products for the purposes of research and education, with the exceptions of healthcare institutions;
- prisons;
- schools;
- hospices; and
- nursing homes.

4.7 When considering the different policy options allowed by this flexibility, the Government has been clear that it wants to find a solution which is simple and clear to communicate, to reduce the risk of confusion and products not being verified and decommissioned. It also sought to identify a solution which results in the lowest burden to UK stakeholders as a whole. The Government has considered whether to require wholesalers to verify and decommission on behalf of none, some or all of the Article 23 providers listed above. There are three broad policy options:

- 1) Requiring wholesalers to verify and decommission on behalf of all Article 23 providers listed above;
- 2) Requiring wholesalers to verify and decommission for certain Article 23 providers, while leaving others to carry this out themselves; or
- 3) Not requiring wholesalers to verify and decommission on behalf of any of these Article 23 providers, meaning the product would need to be verified and decommissioned by the person supplying it to the public in all cases.

4.8 The UK has a complex medicine supply chain. Whichever decision is taken with regard to each group of Article 23 providers, any of the options would require business process changes and additional costs to parts of the supply chain.

4.9 If the responsibility for verifying and decommissioning is placed on wholesalers they would have to put processes in place to separate items which need verifying and decommissioning from those being verified and supplied but not decommissioned; i.e. those supplied to healthcare institutions or pharmacies from those supplied to Article 23 providers. Wholesalers would need to make individual decisions on how they would achieve this and how these changes can best be implemented. We have been engaging with them informally about this.

4.10 Similarly, the practicality of these Article 23 providers verifying and decommissioning items themselves has also been explored individually, including the costs and risks this presents to the safety features scheme as a whole. Alongside this, the Government has conducted a number of meetings with stakeholders from groups potentially affected by this flexibility, alongside a cost analysis which is set out in the accompanying impact assessment.

4.11 Given the number and range of Article 23 providers authorised to supply medicines to the public, the corresponding costs to these providers verifying and decommissioning products themselves have been evaluated and are considered to be disproportionately high. Overall, the most effective solution for the UK would be to incorporate the requirement to verify and decommission into the responsibilities of wholesalers, as they will already have responsibilities to verify and decommission products in other circumstances and so will therefore already have to ensure that they have this capability to verify and decommission products for other reasons as set out above. The Government will offer further guidance and support to ensure wholesalers can continue to supply products to those Article 23 providers.

4.12 The Government has established that Article 23 providers in the main, handle medicines supplied as stock items for a number of patients and also receive medicines supplied for named patients. Stock medicines are supplied from organisations holding a wholesale dealer authorisation and do not usually pass through a healthcare institution.

4.13 Medicines which an Article 23 provider receives for a named patient in their care will have been dispensed from a pharmacy against a prescription and the pack will have been verified and decommissioned by the pharmacy as part of the supply activity.

4.14 The Government is proposing to require the wholesale dealer to verify and decommission medicinal products bearing the safety features before supplying any of the individuals or organisations listed in Article 23.

Question 6

Do you agree with the Government's proposal to put in place provisions requiring wholesalers to verify and decommission medicinal products bearing the safety features before supplying them to any Article 23 provider authorised to supply medicines to the public?

To ensure that your evidence can be taken into account, please take note of the guidance in Annex B and if it relates to the impact assessment please reference the relevant question number from the list of specific questions.

5. Verification and decommissioning of the unique identifier – persons authorised to supply medicinal products to the public

5.1 Chapter VI sets out the obligations for those supplying medicines that carry the safety features to patients. Decommissioning by persons authorised or entitled to supply medicinal products to the public (unless exempted under the Article 23 flexibility discussed above) should happen as close to the time of supply to the patient as possible. However, persons operating within healthcare institutions can carry out the verification and decommissioning at any time the product is in their possession, provided that no sale takes place between the delivery of the product to the healthcare institution and the supply of it to the public.

5.2 Chapter VI also sets out the requirements where technical problems prevent the verification and decommissioning of products as well as obligations on persons authorised to supply products to the public to ensure that instances of suspected falsification are reported to the competent authorities.

Policy options and flexibilities under Article 26

5.3 Article 26 (3) provides flexibility to exempt persons operating within a healthcare institution from the obligations of verification and decommissioning if the following conditions are met:

- a) the person authorised or entitled to supply medicinal products to the public obtains the medicinal product through a wholesaler belonging to the same legal entity as the healthcare institution;
- b) the verification and decommissioning of the unique identifier is performed by the wholesaler that supplies the product to the healthcare institution;
- c) no sale of the medicinal product takes place between the wholesaler supplying the product and that healthcare institution; and
- d) the medicinal product is supplied to the public within that healthcare institution.

5.4 Under condition of Article 26 (3) (a) the wholesaler must belong to the same legal entity as the healthcare institution. This means that the exemption could only apply to a healthcare institution that also holds a wholesale dealers licence. In order to use

this exemption the healthcare institution would instead have to verify and decommission the product under its wholesale licence. However, as a healthcare institution can already carry out the verification and decommissioning at any time the product is in their possession, the Government does not consider that there is any need to implement this exemption in the UK.

Question 7

Do you agree that there is no practical benefit to exempting persons operating within a healthcare institution in the UK from the obligations of verification and decommissioning under the conditions set out above?

To ensure that your evidence can be taken into account, please take note of the guidance in Annex B and if it relates to the impact assessment please reference the relevant question number from the list of specific questions.

Annex A – Consultation questions and how to respond

Summary of questions

- **Question 1:** What form of sanctions regime do you think would be the most effective to enforce the regulations across the UK medicines supply chain?
- **Question 2:** Can you provide any additional evidence or comment on the existing impact analysis to develop the cost benefit analysis in the impact assessment?
- **Question 3:** Do you agree with the Government's proposed approach not to extend the requirements for the unique identifier or anti-tampering device to any additional products at this time?
- **Question 4:** Do you agree with the Government's proposed approach not to require a reimbursement number, or other national number identifying the medicinal product, to be placed on products bearing the safety features?
- **Question 5:** Do you agree that manufacturers should be allowed to include information other than the unique identifier in the 2D data matrix code?
- **Question 6:** Do you agree with the Government's proposal to put in place provisions requiring wholesalers to verify and decommission medicinal products bearing the safety features before supplying them to any Article 23 provider authorised to supply medicines to the public?
- **Question 7:** Do you agree that there is no practical benefit to exempting persons operating within a healthcare institution in the UK from the obligations of verification and decommissioning under the conditions set out in chapter 5?

How to respond

A.1 The Government invites responses on the specific questions raised. The questions can be found through the document and are also listed in full in Annex A and the response template.

A.2 This consultation will close on 23 September 2018.

A.3 Response can be sent by email to: FMD.safetyfeatures@mhra.gov.uk

A.4 When responding please use the response template provided.

Confidentiality of Information

A.5 Information published in response to this consultation, including personal information may be published or disclosed in accordance with the access to information regimes. These are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 2018 (DPA) and the Environmental Information Regulations 2004.

A.6 If you want the information that you provide to be treated as confidential it would be helpful if you could explain to us why you regard the information you have provided as confidential. Any information not published, including personal information, may still be subject to disclosure in accordance with the Freedom of Information Act. If we receive a request for disclosure of such unpublished information, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. We will not take a standard confidentiality statement included in an email message as a specific request for non-disclosure.

A.7 The MHRA will process your personal data in accordance with the DPA and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties. However, the information you send us may need to be published in a summary of responses to this consultation.

Consultation Principles

A.8 This consultation is being run in accordance with the government's Consultation Principles. We will be consulting for 10 weeks. This is to give stakeholders adequate time in which to respond while also ensuring that Government is able to meet industry's concern to have the UK approach to implementation finalised as soon as possible.

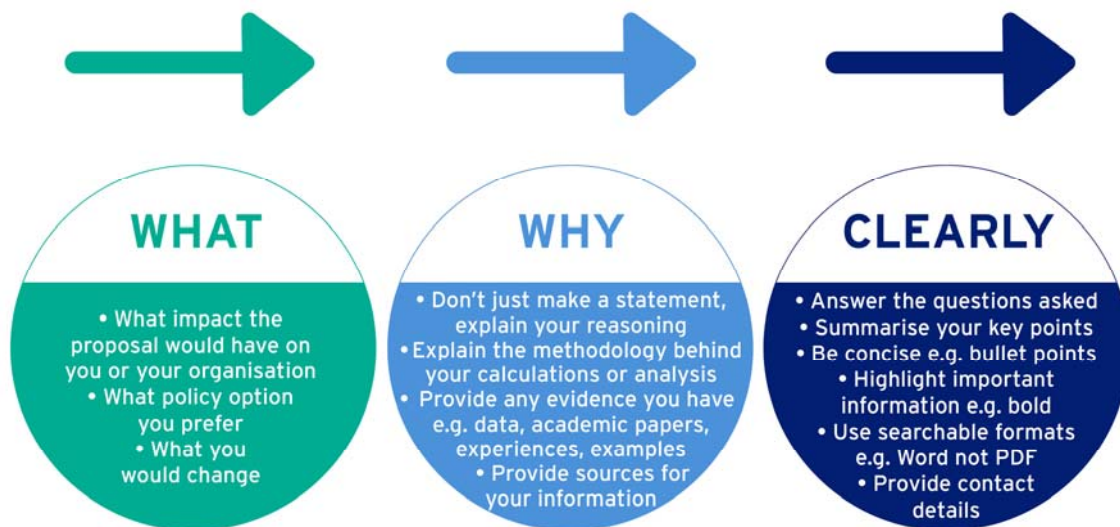
A.9 The Consultation Principles are available on the Cabinet Office website:

<https://www.gov.uk/government/publications/consultation-principles-guidance>

Annex B – Guidance on responding to questions

B.1 The guidance below is intended to help you to provide an impactful response.

Effective consultation responses tell us...



B.2 **Focus on the questions asked:** please respond to the questions asked within the consultation; issues beyond the scope of consultation will not be analysed as part of the Government's consultation response.

- If your response relates to the impact assessment – please also highlight the question number within that document your response relates to.
- If your response relates to the legal statutory instrument – please also highlight the paragraph within that document your response relates to.

B.3 **Contain a clear position statement:** please indicate whether you support or oppose the proposal, or indicate which of the available options is preferred.

B.4 **Demonstrate the impact of the proposal:** whether that is on the respondent as an individual, profession, company or organisation.

B.5 **Provide the reasoning behind the opinion given offering specific examples:** please provide evidence to support your view, whether from your own data or

analysis done by others. Good evidence includes the provision of sources, methodology, calculations and raw data when appropriate. Without this, the team cannot validate and use the data provided.

B.6 Provide ideas for how the proposal could be improved or how negative impacts could be mitigated: If respondents oppose the policy, please provide alternative suggestions that would help Government achieve its objective.

B.7 Clearly identify who the response is from, and in what capacity you are responding: For example if you are a patient, a member of the public, a health professional, industry sector or are responding on behalf of an interest group or company. It is helpful if respondents provide a named person's contact details for follow-up questions.

B.8 Be concise and clear, with the important information at the top: It is useful to have a two to three line summary. Bullet points and formatting such as highlighting help to flag key pieces of information. Data in a tabular form rather than text is easier to interpret. Whilst not essential, it is also useful to receive responses in electronic, searchable formats (Excel) rather than scanned pdfs or written letters.