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

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1. Summary

In July 2018 the Government launched a public consultation on the steps proposed to make sure the 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 consultation closed in September, and this document is the Agency's official response to the more than 50 replies received from a wide range of stakeholders.

As with all EU regulations, the Delegated Regulation on safety features will apply automatically in all EU Member States and therefore, as of 9 February 2019, these new requirements will be directly applicable as part of UK law.

Our consultation focused on the national flexibilities in the Delegated Regulation, and the level of sanctions applied to a breach of each new requirement, for which we are obliged to take additional legal steps, culminating in the laying of a Statutory Instrument in Parliament.

Conclusion

Overall, the responses broadly supported the Government's proposed positions regarding the level of sanctions imposed and on each national flexibility, where the UK has legal scope to make changes. Therefore, the Government intends to implement as per the positions proposed in our consultation, with the exception of Article 26(3), which exempts those within a healthcare institution from decommissioning under certain conditions. The Government did not originally see any benefit of applying this flexibility, but now understands it could be beneficial for certain healthcare institutions, in line with the criteria fixed in the Delegated Regulation.

Any questions about the consultation process, or regarding FMD and the safety features more broadly can be directed to fmd.safetyfeatures@mhra.gov.uk.

Further information and a wide range of guidance related to FMD and the safety features is available on Gov.uk:

https://www.gov.uk/guidance/implementing-the-falsified-medicines-directive-safety-features

EU Exit

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. 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 Delegated Regulation on safety features will apply automatically in all EU Member States and therefore, as of 9 February 2019, these new requirements will be directly applicable as part of UK law.

The UK and EU negotiating teams have reached agreement on the terms of an implementation period that would start on 30 March 2019 and last until 31 December 2020, during which time the UK would continue to abide by all requirements of the FMD, including the Delegated Regulation on safety features. We firmly believe it is in the interests of both the EU and the UK to strike a deal. That remains the goal on both sides and we are confident that this will be achieved.

Looking beyond the intended implementation period, the UK's position on medicines regulation, including identifying and removing falsified medicines from the legitimate supply chain, remains clear. We want to retain a close working partnership with the EU to ensure patients continue to have timely access to safe medicines.

In the event that the UK leaves the EU in March 2019 with no deal in place, and as stated in the Agency's broader consultation, on which a formal response is expected in due course, we expect the UK would not have access to the EU central data hub, and therefore stakeholders would be unable to upload, verify and decommission the unique identifier on packs of medicines in the UK. Therefore, the legal obligation related to this would be removed for actors in the UK supply chain. Packs containing the FMD safety features would still be accepted in the UK, provided that they are in line with other UK packaging requirements. In the interests of public safety, we will evaluate the options around a future national falsified medicines framework, which would inform the detail of any short or longer-term modifications.

2. Flexibilities

A small number of flexibilities, on which we have consulted, are offered to Member States within the Delegated Regulation to accommodate the way in which medicines are supplied on a national basis.

Article 23

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').

Article 23 allows Member States to require wholesalers to decommission medicines on behalf of persons or organisations providing medicines directly to the public, other than pharmacies and healthcare institutions. Responses supported our preferred option for wholesalers to decommission medicines on behalf of all such providers, as this is the least burdensome solution overall.

Our overall position is that persons authorised or entitled to supply medicinal products to the public *who do not operate within a healthcare institution or within a pharmacy* are not required to decommission the medicines themselves. There is a further specific list of persons and institutions captured under Article 23, whom do not have to decommission medicines, even if they would be considered a healthcare institution or 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.

Some wholesalers disagreed with our position, however, the vast majority of respondents, including most wholesalers, acknowledged that decommissioning on behalf of Article 23 providers would be the least burdensome option overall.

Responses led to a discussion over which providers, not explicitly listed above, might fit the definition of a ‘healthcare institution’ and therefore could not fall under Article 23. We do not have any additional legal flexibility to expand the scope of Article 23, therefore where organisations are considered a healthcare institution or pharmacy they must decommissioning medicines themselves. However, we do understand the need to provide further clarity in this area and we have committed to publish further guidance on this.

Other flexibilities

Responses supported the Government's position on the remaining national flexibilities, with the exception of the Article 26(3) exemption, as summarised below:

Flexibility	***Proposal in consultation***	***Consultation response***	***Final Government position***
Article 2(1)(c): Extending the scope of the unique identifier or tamper-evident packaging	*Allow tamper-evident to continue but do not extend the unique identifier to medicines which are otherwise out of scope for the purposes of reimbursement or pharmacovigilance*	*Support of Government position*	*As in consultation*
Articles 4 & 7: Addition of a national reimbursement number	*No requirement*	*Support of Government position*	*As in consultation*
Article 8: Allowing additional information to be added to the 2D barcode	*Allow*	*Support of Government position*	*As in consultation*
Article 26: Exempting persons within a healthcare institution from decommissioning under certain circumstances	*No use for this exemption therefore no reason to allow*	*Overall support of Government position but some respondents in favour of allowing this exemption*	*Change of Government position to allow under the restrictions set out in the Delegated Regulation*

2(1)(c) – Extending the scope of the unique identifier or tamper evident packaging

The Delegated Regulation 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.

Responses to the consultation supported the Government's position not to extend the scope of the safety features to other medicinal products. While we will allow the addition of an anti-tampering device onto any medicine outside of scope, there would be no requirement to do so. A minority of respondents wanted the requirement for a unique identifier to be extended to more medicines for reasons of practicality. However, 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.

Article 4 & 7 – Addition of a national reimbursement number

Under the Delegated Regulation Member States can 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.

Responses supported 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, but to instead rely on mapping to such information within the EU hub. A minority of respondents preferred the Dictionary of Medicines and Devices (dm+d) code actually placed on the packaging, which is something we would permit but not require.

Article 8 – Allowing additional information to be added to the 2D barcode

The Delegated Regulation allows the 2D data matrix code carrying the unique identifier to be used to deliver additional information if the national competent authority allows this. The Government's position is to allow for this information to be included, if desired by the manufacturer, and provided the information has been fully assessed as part of the medicine's licensing process. Responses largely supported this position.

Article 26 – Exempting persons within a healthcare institution from decommissioning under certain circumstances

The Delegated Regulation provides flexibility to exempt persons operating within a healthcare institution from the obligations of verification and decommissioning as long as all 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.

At the time of consultation we were unaware of any practical benefit to this exemption in the UK. However, we now understand that many NHS hospital Pharmacy Departments do hold warehouse and distribution agreements (WDAs). Allowing the Article 26(3) exemption, may provide some hospitals with additional flexibility, especially for those hospitals which have many different and geographically separate facilities or sites. Therefore, the Government's position is to allow the exemption under Article 26(3) under the restrictions set out in the Delegated Regulation.

3. Sanctions

Appropriate sanctions are 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.

Respondents to the consultation largely agreed to a phased approach with non-criminal enforcement measures, such as a formal written warning or suspension or revocation of their licence to practice (where appropriate), long before any criminal proceedings would be considered. Respondents largely agreed with criminal sanctions for the most serious breaches, as justified, and necessary to preserve the integrity and consistency of the medicines supply chain and protect patient safety. In order to further support this approach, the Government will introduce statutory 'enforcement notices' for breaches of the requirements around supplying medicines to the public. These must be issued before criminal proceedings can be considered against persons supplying medicines to the public, providing further reassurance that criminal prosecution would only be considered as a last resort. MHRA will also continue to work with other regulators to help bring organisations into compliance.

Furthermore, we are aware that there will likely be a large proportion of medicines that will pass through the system in the initial period following implementation which may be in scope of the new requirements but may not yet exhibit the new packaging, and it will not be immediately obvious to those asked to scan these products whether they should be scanned or not; i.e. were they placed on the market before or after 9 February 2019. In such circumstances it is crucial to prevent unnecessary disruption to the supply of medicines, and we would expect organisations to have clear operating procedures in place, and to empower individuals to make judgment calls that they would feel able to justify. The Government is aware that various stakeholders are producing sector-specific guidance on this important issue for a variety of audiences.

4. Impact assessment

A consultation stage impact assessment of the proposed changes was published alongside the consultation. This analysis focused only on the UK decisions on any flexibilities available under the Delegated Regulation. Proposals beyond the legal scope of the flexibilities were not analysed as part of the consultation.

Respondents were asked to 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. We have reviewed additional impact evidence provided and will consider this in the final analysis where appropriate.

5. Conclusion and next steps

Overall, the responses support the Government's proposed positions regarding the level of sanctions imposed and on each national flexibility. The Government intends to implement as per the positions proposed in our consultation, apart from the Article 26(3) exemption, where the Government has agreed to change its position, as outlined above.