Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Post-implementation Review of the Human Medicines Regulations 2012

Public Consultation – Background Information (Annex A)

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency responsible for regulating medicines and medical devices. We continually review the safety of medicines and vaccines in the UK, and inform healthcare professionals and the public of the latest updates through several means, including public reclassification reports. Suspected side-effects to any drug or vaccine can be reported to MHRA by both healthcare professionals and members of the public via the Yellow Card Scheme

(http://www.mhra.gov.uk/yellowcard)

Ref: MLX391

Introduction:

1. The Medicines and Healthcare products Regulatory Agency is reviewing the impact of the Human Medicines Regulations 2012 ('the 2012 Regulations'). This is part of a wider exercise within government to test the impact of legislation five years after implementation.

2. We would appreciate your help in understanding the impact of the 2012 Regulations by answering the questions detailed at pages 7-10 below.

3. The obligation to carry out a post implementation review is set out in regulation 346 of the 2012 Regulations. In our view, the aspects of the 2012 Regulations that introduced the most significant changes are:

    - The Pharmacovigilance Directive (Directive 2010/84/EU (amending Directive 2001/83/EC) (page 6 below)
    - Cross Border Prescriptions (page 6 below)
    - The repeal of Section 10(7) of the Medicines Act 1968 on Pharmacy wholesale dealing (page 6 below)

4. In addition to the above aspects, we would welcome stakeholders' comments on the other provisions of the 2012 Regulations listed in regulation 346, or more generally on the 2012 Regulations (see background below for additional information on the 2012 Regulations, including regulation 346).

Responding to the consultation

5. In order to conduct the review of the impact of the 2012 Regulations in an open and transparent manner and ensure that the findings are evidence-based, MHRA is seeking views from a wide range of stakeholders. MHRA is interested in the views of individuals and organisations that engage directly with the 2012 Regulations or have a wider interest in the way they operate.

6. This consultation is running from Thursday 15 June 2017 to 23:59 Thursday 6 July 2017. **Responses can be provided by completing the online survey which is available at:** https://surveymonkey.co.uk/r/FYV6PQN

7. Alternatively, please tell us your views by completing the MS Word version of the questionnaire (Annex B in the documents section of the homepage for this consultation) and return it to Judith Thompson, Policy Division, 5th Floor, MHRA, 151 Buckingham Palace Road, London SW1W 9SZ (E. Judith.m,Thompson@mhra.gov.uk).

8. You do not have to answer all of the questions – please feel free to answer as many or as few as you like. Your evidence should consist of objective, factual information about the impact or effect of the 2012 Regulations. Where possible, please give specific examples.

9. Only information directly relevant to the areas of investigation will be considered.

10. All submissions must be received by 23:59 hours on Thursday 6 July 2017.

11. Any comments or questions should be addressed by email to Judith.m.thompson@mhra.gov.uk or by post to Judith Thompson, Policy Division, 5th Floor, MHRA, 151 Buckingham Palace Road, London SW1W 9SZ.

12. The responses submitted will be read by MHRA staff and a summary of the evidence collected will be used to determine whether the existing regulations are working effectively. The findings will form our assessment to the Department of Business, Energy and Industry Strategy (BEIS) on the implementation of the 2012 Regulations to date.

Confidentiality and Freedom of Information

13. Please be aware that any information provided in response to this consultation may be published or disclosed in accordance with our obligations as a public authority under the Freedom of Information Act 2000.

14. Under Section 43 of the Freedom of Information Act, information can be withheld if the disclosure is deemed likely to prejudice the commercial interest of a person or an organisation. Please make it clear if you think that the information you provide would fall into this category and ought to be withheld from public disclosure.

15. We accept anonymised responses, submitted via a third party such as a trade organisation.

16. In line with the Data Protection Act 1998 we will not disclose any personal information in response to a request, and we will withhold information which could be used to identify any individual or an organisation.

17. The Agency will process your personal data in accordance with the Data Protection Act, and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

Background:

18. The questions below seek to:

- establish whether the 2012 Regulations are delivering the intended outcomes;
- identify any unintended consequences arising from the 2012 Regulations;
- re-evaluate estimates of costs and benefits; and,
- make sure the original impact assessment accurately reflects impacts to business and society.

19. The 2012 Regulations consolidated medicines legislation in one place and in a rationalised form. They repealed or revoked most of the Medicines Act 1968 and a large number of statutory instruments. The 2012 Regulations (as amended) regulate medicines on the UK market including authorisation, importation and recognition of prescriptions issued in another EU state.

20. A copy of the most recent version of the 2012 Regulations can be accessed at: http://www.legislation.gov.uk/uksi/2012/1916/pdfs/uksi_20121916_en.pdf. Since 2012 there have been a number of amendments to the 2012 Regulations which are listed below.[1]

21. Further details on the scope of the review as specified in regulation 346 can be found in Annex C of the documents section of the homepage for this consultation. During the consolidation exercise, the MHRA also reviewed the legislation to identify policy changes that would help ensure that the regulatory

[1] SI 2013/1855 http://www.legislation.gov.uk/uksi/2013/1855/pdfs/uksi_20131855_en.pdf,

SI 2013/2593 http://www.legislation.gov.uk/uksi/2013/2593/pdfs/uksi_20132593_en.pdf,

SI 2014/490 http://www.legislation.gov.uk/uksi/2014/490/resources,

SI 2014/1878 http://www.legislation.gov.uk/uksi/2014/1878/pdfs/uksi_20141878_en.pdf

SI 2015/1503 http://www.legislation.gov.uk/uksi/2015/1503/pdfs/uksi_20151503_en.pdf

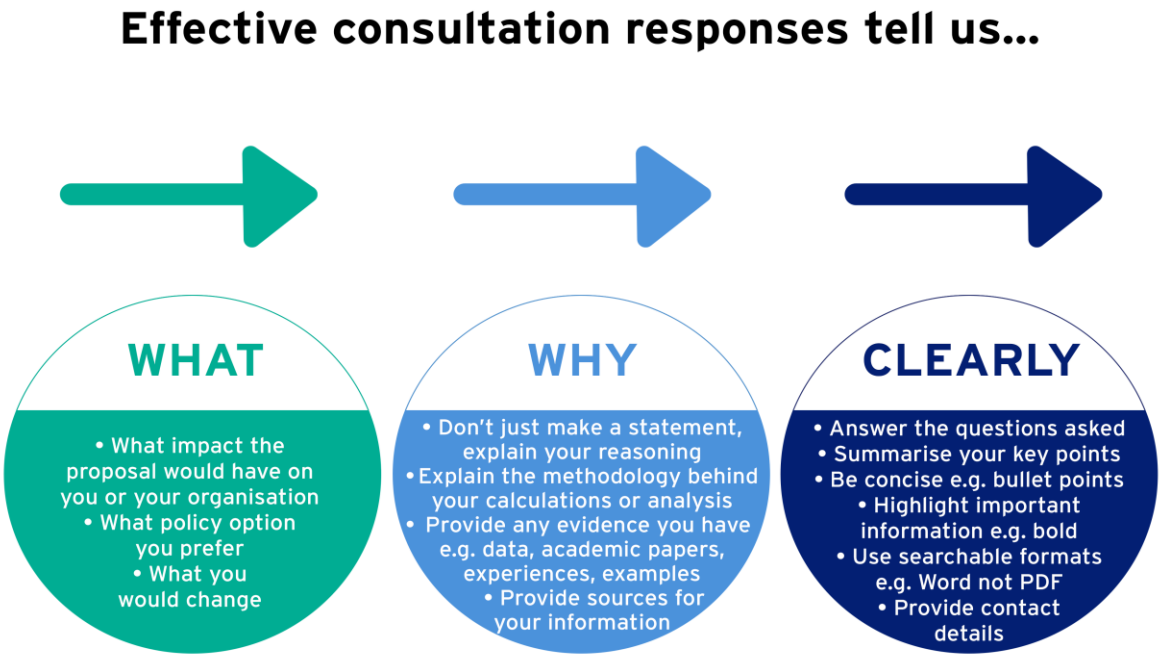
SI 2016/186 http://www.legislation.gov.uk/uksi/2016/186/pdfs/uksi_20160186_en.pdf,

SI 2016/190 http://www.legislation.gov.uk/uksi/2016/190/regulation/12/made

SI 2016/696 http://www.legislation.gov.uk/uksi/2016/696/pdfs/uksi_20160696_en.pdf

framework for medicines remained fit for purpose. Those changes are detailed at paragraphs 23-36 below.

22. We would like to hear your views. In order to assist us with this please follow the advice below:



Section 1 - Pharmacovigilance Directive

23. The 2012 Regulations implemented national requirements of EU pharmacovigilance (PV) legislation, Directive 2010/84/EU, key objectives of which included:

    i) Rationalising EU decision-making on drug safety to deliver measures that are equally implemented across the community

    ii) Strengthened PV systems, allowing continuous improvement while reducing administrative burden

    iii) Greater communication to increase understanding and trust of patients and health professionals.

Section 2 - Cross Border Prescriptions

24. The 2012 Regulations enabled dispensing health professionals to verify the authenticity of a prescription to confirm that it had been issued by a prescriber who was legally entitled to do so and for the prescription to be recognised across all EEA member states.

Section 3 - the repeal of Section 10(7) of the Medicines Act 1968 on Pharmacy wholesale dealing

25. Section 10 (7) of the Medicines Act 1968 provided an exemption in UK law for the requirement for a pharmacist to hold a Wholesale Dealer's Licence if they traded in medicines in certain circumstances.

26. The repeal of Section 10(7) was necessary to comply with EU legislation, in particular articles 77(1) and 77(2) of Directive 2001/83/EC which required anyone undertaking wholesale dealing activities to hold an authorisation. In bringing the UK into compliance with EU legislation, the objective of the 2012 Regulations was to:

    i) Take account of the UK's National Health Service (which is relatively unique among Member States as a health service open to all without the need for private insurance).

    ii) Preserve continued supplies of medicines above all other concerns.

    iii) Minimise extra regulatory cost and administrative burden, particularly for the NHS.

Section - 4 the Human Medicines Regulations 2012 ("the 2012 Regulations")

27. The 2012 Regulations consolidated medicines legislation in one place and in a rationalised form (see also paragraphs 19 and 20 above).

The MHRA is seeking responses to the following questions. Please answer all sections that are of relevance to you or your business. Please respond by completing the on-line questionnaire at:
https://www.surveymonkey.co.uk/r/FYV6PQN

or by completing and submitting the MS Word response form (available to download in the documents section of the homepage for this consultation)

Section 1
Implementation of the Pharmacovigilance (PV) Directive [Regulations 59, 60, 61, 63,64,65,66,68,69,73,75,76,79,82,85,86,97,105,107,108, 113, 115, 132, 133, 142, 266, 327]

Question 1
In your view what best describes the way in which the PV Directive has been implemented in the UK?

Question 2
Has the implementation of the PV Directive in the UK resulted in any consequences for industry which in your view are unintended or which were unforeseen?

Question 3
How has UK implementation of the PV Directive affected the clarity and understanding of pharmacovigilance requirements?

Question 4
What effect has UK implementation of the PV Directive had on patient safety?

Question 5
Is there any potential to refine the UK implementation of the PV Directive to reduce the burden on industry?

Question 6
How does the way in which the PV Directive has been implemented in the UK compare to implementation by other EU member states?

Question 7
Have there been additional benefits or costs arising from UK implementation of the PV Directive?

Section 2
Cross Border prescriptions [Regulations 213, 217A, 218, 219, 219A]

Question 8
Are you aware of any cases where the UK has not recognised prescriptions from other European Economic Area (EEA) countries[2] and vice versa?

Question 9
What effect has cross border recognition of prescriptions had on patients?

Question 10
What effect has cross border recognition of prescriptions had on pharmacists?

Question 11
What effect has cross border recognition of prescriptions had on healthcare professionals (other than pharmacists)?

Question 12
What level of understanding do pharmacists have of cross border prescriptions?

Question 13
What level of understanding do healthcare professionals (other than pharmacists) have of cross border prescriptions?

Question 14
Are you aware of any difficulties that cross border prescriptions have caused for patients?

Question 15
Are you aware of any difficulties that cross border prescriptions have caused for pharmacists?

Question 16
Are you aware of any difficulties that cross border prescriptions have caused for healthcare professionals (other than pharmacists)?

Question 17
Is there any opportunity to reduce burdens on business as a result of cross border prescriptions?

[2] with the exception of certain categories of controlled drugs and that a list of particulars has been included in UK prescriptions intended for dispensing in the EEA

Question 18
In your view, what best describes how the requirements to recognise cross border prescriptions have been implemented in the UK?

Question 19
How has the recognition of cross border prescriptions been implemented in the UK compared to other EU member states?

Question 20
Have there been additional benefits or costs arising from cross border recognition of prescriptions?

Section 3
Repeal of Section 10(7) [Regulation 349 in so far as it repeals section 10(7) of the Medicines Act 1968]

Question 21
Since the repeal of Section 10(7) to what extent have supplies of medicines met the needs of patients?

Question 22
How has the repeal of section 10(7) affected regulatory cost and administrative burden, particularly for the NHS?

Question 23
How has the repeal of Section 10(7) affected the continued access to supply of medicines?

Question 24
How has the repeal of Section 10(7) affected pharmacists?

Question 25
How has the repeal of Section 10(7) affected healthcare professionals (other than pharmacists)?

Question 26
Have there been any unintended consequences that you are aware of arising from the repeal of Section 10(7)?

Question 27
Are there any opportunities to reduce burden on pharmacists as a result of the repeal of Section 10(7)?

Question 28
In your view, what best describes the way in which articles 77(1) and 77(2) have been implemented in the UK, which require anyone undertaking wholesale dealing activities to hold an authorisation? [Regulation 18 of the 2012 Regulations]

Question 29
How have articles 77(1) and 77(2), which require anyone undertaking wholesale dealing activities to hold an authorisation, been implemented across EU member states compared to the UK?

Section 4
Human Medicines Regulations 2012 ("the 2012 Regulations")

Question 30
How effective have the 2012 Regulations been in consolidating medicines legislation in a rationalised form?

Question 31
Have there been in your view any unintended or unforeseen consequences arising from the coming into force of the 2012 Regulations?

Question 32
Are there any opportunities to reduce burden on industry as a result of the 2012 Regulations?

Question 33
Have there been any unintended impacts on groups sharing protected characteristics as defined in the Equality Act 2010 http://www.legislation.gov.uk/ukpga/2010/15/contents arising from the implementation of these Regulations, in particular in terms of eliminating unlawful discrimination, advancing equality of opportunity and fostering good relations?