Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Post-implementation Review of the Human Medicines Regulations 2012

Final Report – August 2017

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)

Introduction

1. The Medicines and Healthcare products Regulatory Agency (MHRA) has undertaken a Post-implementation review (PIR) 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, based on evidence collected before, during and after implementation.

2. The PIR explores:

    a. the extent to which the 2012 Regulations are delivering the intended outcomes;

    b. whether there have been any unintended consequences arising from the 2012 Regulations; and,

    c. the impacts that have resulted.

3. The PIR makes recommendations about whether to renew, amend, remove or replace the existing 2012 Regulations.

Background

4. 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 They repealed or revoked most of the Medicines Act 1968 and around 200 statutory instruments. The 2012 Regulations were developed with input from interested parties, including over 200 responses to a public consultation (MLX 375 – https://www.ipqpubs.com/wp-content/uploads/2011/10/Review-of-UK-medicines-legislation-MLX-375.pdf) from October 2011 to January 2012 on a draft of the Regulations, and over 20 responses to a related public consultation (MLX 374 - http://webarchive.nationalarchives.gov.uk/20141206153533/http:/www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con137708.pdf) on the implementation of the Pharmacovigilance Directive (see paragraph 9 below).

5. The 2012 Regulations resulted in shorter, simplified law, designed to be easier to understand and apply. The policy intention was to save time and costs for business and civil society organisations in the public sector in understanding and applying the law, and reduce the likelihood of costly legal cases arising from different interpretations of the law.

6. The 2012 Regulations (as amended) govern medicines on the UK market including authorisation to market, manufacture, importation, distribution and

supply of medicines, and recognition of prescriptions issued in another EU state.

7. A copy 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] These amendments included arrangements for the recognition of Cross Border Prescriptions (see Paragraph 10 below), changes to implement the Falsified Medicines Directive (see Annex 4 below), and changes to allow particular groups of healthcare professionals to have additional prescribing responsibilities (see Annex 4 below).

8. During the consolidation exercise, the MHRA also reviewed the legislation to identify policy changes that would help ensure that the regulatory framework for medicines remained fit for purpose. The principal changes are detailed below.

The Pharmacovigilance Directive

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

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

   b. Strengthened PV systems, allowing continuous improvement while reducing administrative burden

[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

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

Cross Border Prescriptions

10. The 2012 Regulations, as amended in 2013, 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 EU member states. This transposed Commission Implementing Directive 2012/52/EU into UK law to address problems of cross-border recognition of prescriptions.

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

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

12. The repeal of Section 10(7) was necessary to comply with EU legislation, specifically Articles 77(1) and 77(2) of Directive 2001/83/EC which require 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:

    a. 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).

    b. Preserve continued supplies of medicines above all other concerns.

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

Scope of the Post-implementation Review (PIR)

13. The obligation to carry out a PIR of the 2012 Regulations is set out in regulation 346 which defines the PIR scope. Regulation 346 is shown in full at **Annex 1**. It imposes an obligation on the Secretary of State for Health to carry out a 5 yearly review of the listed provisions of the 2012 Regulations, having regard to how the EU legislation which those

provisions implement has been implemented in other EU Member States. The report of that review must set out the objectives of the regulatory system, assess the extent to which those objectives are achieved, whether they remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

14. The PIR was undertaken in a targeted way, with the focus of the review being the principal changes introduced by the 2012 Regulations (detailed in paragraphs 9-12 above), whilst being mindful of the importance of considering all the regulations listed under Regulation 346 as within scope of the review.

15. Where the PIR touched upon EU-derived legislation, for example the principal changes detailed at paragraphs 9-12 above, the review considered whether the EU legislation had been transposed into UK law with the minimum possible burden to industry, whilst maintaining the integrity of the EU harmonised proposals. The rationale and merits of such EU-derived legislation was considered out of scope of the PIR.

Research and Analysis

16. The starting point for the PIR was the impact assessments (IAs) produced at the time the 2012 Regulations were being developed, together with the subsequent regulatory triage assessment (RTA) on cross border prescriptions, to identify the original assumptions and policy intentions. Those IAs are listed below and can all be found in a single document accessed at: http://www.legislation.gov.uk/ukia/2012/361/pdfs/ukia_20120361_en.pdf The RTA on cross border prescriptions produced in 2013 as part of subsequent amendments to the 2012 regulations, is also listed, and is annexed to this report at Annex 2.

    a. Consolidation of UK medicines legislation impact assessment

    b. Transposition of Pharmacovigilance Directive 2010/84/EU impact assessment

    c. Repeal of Section 10(7) of the Medicines Act 1968 impact assessment

    d. Cross border prescriptions regulatory triage assessment (RTA) (**Annex 2**)

17. The expectations in all three impact assessments and the RTA, and the operation of the 2012 Regulations since they came into force, show the 2012 Regulations overall to be low impact in terms of net benefit present value, and low risk in terms of the nature and scale of policy change, with widespread support for the consolidation of previous medicines legislation to create a more simplified and robust regulatory framework. Table 1 below summarises the costs/benefits identified in the above impact assessments and RTA.

Table 1:

Impact Assessment (IA)/Regulatory Triage Assessment (RTA)	**Total Costs** (best estimate, present value unless otherwise stated)	**Total Benefits** (best estimate, present value unless otherwise stated)	**Net Benefit Present Value** (best estimate)
Consolidation of UK medicines legislation IA	£2.4m	£11.5m	£9.0m
Pharmacovigilance Directive IA	£65.9m	£48.9m	Minus £17.0m
Repeal of Section 10(7) IA	£28.3m	Unquantifiable **	Minus £28.3m
Cross border prescriptions RTA	£10.27m (midpoint estimate)	n/a	n/a

Notes to Table 1:

** *MHRA could not estimate the benefits because it was difficult to assess the probability of EU acting on UK non-compliance with articles 77(1) and 77(2) of Directive 2001/83/EC.*

18. The PIR addressed three key questions as recommended in PIR guidance:

    a. To what extent are the 2012 regulations working?

b. Is government intervention still required?

c. Is the existing form of the 2012 regulations still the most appropriate approach? Or can they be improved/replaced to reduce the burden on business and/or society?

19. Given the overall low impact, low risk nature of the 2012 Regulations, the research sought qualitative evidence from organisations affected by them, to determine whether they had met their objectives, and whether the way they had been implemented could be improved. The evidence sought was not aimed at quantifying and monetising the costs and benefits of the 2012 Regulations.

20. With regards to the three principal changes introduced by the 2012 Regulations, the above questions were addressed primarily through a structured questionnaire in a public consultation exercise that ran from 15 June to 6 July 2017 and that attracted over 60 responses. (MLX 391 –

    https://www.gov.uk/government/consultations/consultation-on-the-post-implementation-review-of-the-human-medicines-regulations-2012-mlx-391

21. A summary of the responses to MLX 391 is attached at **Annex 3** and a list of those who responded to the consultation is on page 45. The key points arising from those responses, and the MHRA's response, are covered below. These key points and the MHRA response, were shared with the MHRA's Medicines Industry Liaison Group (MLG), comprising a representative cross section of pharmaceutical industry trade associations. MLG members recognised the three principal changes identified in the consultation and the issues raised by the respondents to the consultation, and noted the MHRA's proposed response.

Implementation of the Pharmacovigilance (PV) Directive

22. There was broad consensus amongst respondents that the directive had been transposed into UK law in a proportionate way with no 'gold plating' and minimised burden on business whilst at the same time ensuring a harmonised approach with other EU member states.

23. Six respondents indicated that the PV Directive had resulted in improvements in patient safety. Another respondent considered it was too early to say whether the legislation had led to improvements in patient safety, although there may be benefits from increased PV activity

resulting in better reporting and awareness of drug safety issues in clinical settings.

24. One area highlighted as an ongoing issue, particularly for generic Marketing Authorisation (MA) holders, was the requirement to create and maintain Risk Management Plans and to prepare and distribute Risk Minimisation Measures, as these are not always in the public domain for the originator. Some generic MA holders consider that the costs associated with this requirement is a barrier to market entry.

25. In the light of the responses received, the MHRA is considering the options for remediation, for example further encouraging work sharing between such MA holders.

Cross Border Prescriptions

26. A handful of respondents highlighted how the processing of cross border prescriptions has resulted in an increased workload for community pharmacists.

27. There was recognition, however, that the ability to dispense prescriptions across the European Economic Area (EEA) had improved access to medicines for patients. There was also recognition of economic benefits to patients in other EU member states arising from having their prescriptions dispensed in the UK where dispensing prices are comparatively cheaper in many cases. For example, patients travelling from the Republic of Ireland to Northern Ireland.

28. The majority of respondents considered that there was generally good recognition amongst community pharmacists about the potential to receive and dispense EU prescriptions, but less so amongst other healthcare professionals. Perhaps understandably, respondents indicated that pharmacists who process EU generated prescriptions less frequently are less familiar with the arrangements for doing so.

29. Respondents highlighted some practical issues associated with the processing of EU generated prescriptions, for example inconsistent formatting of prescriptions, incomplete information on the prescription, prescriptions not written in English, prescriptions for medication not

available in the UK, and prescriptions being presented out of normal office hours. Respondents suggested that these issues can result in an additional workload for prescribers as the original prescription cannot be processed.

30. Given the issues arising from the public consultation exercise, MHRA will review the guidance currently available to pharmacists and healthcare professionals to identify whether it merits being revised and/or reissued to raise awareness and understanding of the cross border prescription processing arrangements.

31. In addition, MHRA has identified related issues centred around on-line consultation and remote prescribing, including cases of EEA registered doctors issuing prescriptions for controlled drugs. Those issues are being reviewed by MHRA, working in partnership with other regulators with an interest – CQC, GPhC and GMC.

Repeal of Section 10(7)

32. At the time the 2012 Regulations were consulted upon in late 2011/early 2012 the pharmacy sector expressed concern about the impact on the supply of medicines of the repeal of the pharmacy wholesale dealing exemption under Section 10(7) of the Medicines Act 1968, in particular the ability to preserve medical supplies within the NHS arena. In response to those concerns, MHRA worked extensively with pharmacy representative bodies and subsequently published a guidance note outlining how the concerns would be addressed to ensure the essential supply of medicines to patients within the healthcare system was not adversely affected. A copy of the note can be accessed here: https://www.gov.uk/government/publications/repeal-of-wholesale-dealer-licence-exemption-for-pharmacists.

33. As outlined in the above guidance note, MHRA took the view that the supply of medicines by community and hospital pharmacies to other healthcare professionals in the UK who need to hold small quantities of medicines for treatment of or onward supply to their patients represents an important and appropriate part of the professional practice of both community and hospital pharmacy. In addition, MHRA recognised that community and hospital pharmacies may need to obtain small quantities of a medicine from other pharmacies to meet a patient's individual needs. Both these activities are considered by MHRA to fall within the definition

of provision of healthcare services. In such circumstances, and provided the transaction meets all of the following criteria, MHRA does not deem such transactions as commercial dealing and pharmacies are not required to hold a wholesale dealers licence (WDA(H)):

- it takes place on an occasional basis
- the quantity of medicines supplied is small
- the supply is made on a not for profit basis
- the supply is not for onward wholesale distribution.

Conversely, MHRA considered that pharmacies who wish to engage in commercial trading in medicines are entitled to do so only if they hold a WDA(H) and comply with all the relevant requirements.

34. Over 20 responses to the PIR public consultation echoed the earlier concerns about the potential impact of the repeal of Section 10(7) on the ability to preserve medical supplies, particularly in the NHS. These concerns are detailed at paragraph 44 of **Annex 3**. In summary, respondents consider that while it is reasonable to restrict wholesale dealing when it is being carried out commercially for profit, it has not been helpful to extend this restriction to the supply chain involving hospitals, pharmacies, and hospices.

35. In addition, 10 respondents indicated there were opportunities for burden reduction in terms of the repeal of Section 10(7). These are summarised at paragraph 45 of **Annex 3**, and include as suggestions:

    a. To introduce revised guidance on the requirements for a WDA(H), including to be clearer about how the repeal of Section 10(7) works in practice, and to reflect the fact that more NHS Trusts now outsource their pharmacy departments to a third party; and,

    b. To review how Articles 77(1) and 77(2) have been implemented in other EU member states to see if there are lessons to learn.

36. Medicine supply problems can occur for a number of reasons, such as manufacturing problems, difficulties in obtaining raw materials or regulatory issues. The Department of Health (DH) monitors supply shortages that may occur. Both MHRA and DH work with licensed pharmaceutical manufacturers and distributors to mitigate supply shortages. In addition, DH, MHRA and Home Office have held joint meetings with representatives from hospices and NHS ambulance trusts since the repeal of Section 10(7) to discuss supply arrangements for medicines. There have been no reports of patients not receiving their medicines because of the repeal of Section 10(7).

37. In the light of the issues raised in the course of the public consultation, MHRA will review its current guidance on the repeal of Section 10(7) and consider whether revised guidance is merited.

38. In addition, MHRA is addressing issues recently identified within the UK regulated supply chain involving diversion of controlled drugs and prescription only drugs in the UK and beyond, specifically benzodiazepines and other hypnotics/anxiolytics such as Zopiclone and Zolpidem termed as 'Z' drugs. It has been established that large volumes of these medicines are being diverted from the regulated supply chain for sale and supply on the criminal market by a number of wholesale dealers and pharmacies employing unethical and potentially illegal practices. There have been several arrests, and prosecutions are likely to follow.

Further provisions within scope of the PIR

39. For the other provisions within scope of the PIR under regulation 346, a working group of senior staff from across the MHRA (the working group) used well-established stakeholder engagement networks, including the Medicines Industry Liaison Group, to answer the three key questions at paragraph 18 above. This was supplemented by responses to questions about these other provisions in the structured questionnaire of the public consultation. **Annex 3** includes commentary (paragraphs 51-65 of Annex 3) on those provisions.

40. Respondents to the consultation were generally supportive of the 2012 consolidation, although some respondents highlighted a number of issues with these other provisions. For example, a respondent outlined the merits of extending prescribing responsibilities to particular groups of healthcare professionals operating in emergency care settings. They also highlighted a perceived inconsistency in the application of an exemption under the

2012 Regulations, with one group of healthcare professionals subject to the exemption, but another group not included despite undertaking analogous work. Another respondent suggested that it would be helpful for the 2012 Regulations to be more readily available on-line with the latest iteration showing the most recent changes to improve understanding for all with an interest in the regulations.

41. The working group's analysis of the provisions in the 2012 Regulations within the scope of the PIR, including a record of the objectives pursued by those provisions, is detailed at **Annex 4**, with the working group's overall conclusions shown in the far right-hand column of the table.

42. The working group concluded that apart from the principal changes to the 2012 Regulations detailed above, the other provisions of the 2012 Regulations within scope of the PIR were either:

    a. Related to the Falsified Medicines Directive: as that Directive has still to be implemented fully it is too early to assess whether the objectives of the legislation have been met and are proportionate; or

    b. Introduced within the last 12-18 months: it is therefore too early to assess whether the objectives of the legislation have been met and are proportionate; or

    c. Minor changes or corrections to the original 2012 Regulations which remain appropriate for meeting the objectives of the legislation; or

    d. Specific provisions relating to search and rescue paramedics, physiotherapists, therapeutic radiographers, and optometrists: all considered to remain appropriate for meeting the objectives of the legislation.

43. In addition, the working group had regard to the Department of Health's view that the provisions associated with allowing asthma inhalers to be held by schools were outside of scope of the review (see **Annex 4,** page 85).

Key Points Summary and Conclusion

44. There is widespread recognition from our stakeholder engagement networks and the consultation that on balance the 2012 Regulations represent a sound consolidation of fragmented and complex medicines legislation in one place, and in a simplified form to improve the coherence of the regulatory framework.

45. The PIR has identified, however, some areas where further work is merited, and makes the following recommendations:

    a. **Recommendation 1:** MHRA to consider what more could be done to remove the potential barrier to market entry for generic Marketing Authorisation holders arising from the current requirement to create and maintain Risk Management Plans and prepare and distribute Risk Minimisation Measures. Timing: by March 2018.

    b. **Recommendation 2:** MHRA to review the guidance currently available to pharmacists and healthcare professionals on cross border prescriptions with a view to publishing revised guidance to aid awareness and understanding. Timing: To review existing guidance by December 2017, and if merited arrange publication of revised guidance by March 2018.

    c. **Recommendation 3:** MHRA to consider the concerns expressed about the repeal of Section 10(7), and what further action might be appropriate, such as revised guidance. Timing: by December 2018, timed to align with any new guidance on the safety feature element of the Falsified Medicines Directive coming into force in the UK.

    d. **Recommendation 4:** MHRA to consider, in consultation with NHS England and DH, the issues raised in the public consultation about extending prescribing responsibilities, as part of the well-established process of making amendments to the 2012 Regulations, and to consider how best to publicise future amendments to the 2012 Regulations. Timing: by March 2018 as part of the next set of amendments to the Regulations.

46. Recommendations 1-3 are reflected in the template submitted to the Regulatory Policy Committee (RPC) on 18 August 2017 regarding the principal changes to the 2012 Regulations. A copy of the completed RPC template is attached at **Annex 5**.

Annex 1

Regulation 346 of The Human Medicines Regulations 2012 is outlined below, and defines the scope of the Post-Implementation Review of the 2012 Regulations.

Review

346.—(1) The Secretary of State must from time to time carry out a review of the provisions listed in paragraph (2).

(2) Those provisions are—

(a) Part 11;

(b) regulations—

(i) 59,

(ii) 60(3)(b), (9) and (10),

(iii) 61,

(iv) 63,

(v) 64(4)(b), (d) and (e), (5)(a) and (6)(c),

(vi) 65(2),

(vii) 66(5) and (6),

(viii) 68(2)(a) and (b) and (5),

(ix) 69(2)(a) and (b), (5) and (10),

(x) 75(2)(b) and (c),

(xi) 76,

(xii) 79,

(xiii) 85,

(xiv) 86,

(xv) 97,

(xvi) 105(3)(b),

(xvii) 107(2),

(xviii) 108(5),

(xix) 115(2)(b) and (c),

(xx) 132(2),

(xxi) 133(5) and (6),

(xxii) 266(4) and (5),

(xxiii)327(2)(g),

(xxiv)331, and

(xxv) regulation 349 insofar as it repeals Section 10(7) of the Medicines Act 1968; and

(c) Schedules —

(i) 8 paragraphs 12, 13, 19, and 23,

(ii) 12 paragraph 21, and

(iii) 27 paragraphs 14 and 15.

(3) The Secretary of State must

(a) set out the conclusions of a review carried out in accordance with paragraph (1) in a report; and

(b) publish the report.

(4) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the 2001 Directive and Directive 2010/84/EU of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community Code relating to medicinal products for human use(1) are implemented in other member States in relation to the subject matter of the provisions mentioned in paragraph (2).

(5) The report must in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by the provisions of these Regulations that implement those Directives in relation to the subject matter of the provisions mentioned in paragraph (2)(a), (b)(i) to (xxiv) and (c);

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(6) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.

(7) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

(**1**)

OJ No L 348, 31.12.2010, p.74.

Annex 2

Regulatory Triage Assessment	
Title of regulatory proposal	The Human Medicines (Amendment) (No 3) Regulations 2013
Lead Department/Agency	Medicines and Healthcare products Regulatory Agency (MHRA)
Expected date of implementation	December 2013 SNR 6
Origin	EU
Date	30/10/13
Lead Departmental Contact	Anne Ryan, Policy Division, MHRA
Departmental Triage Assessment	Low-cost regulation (fast track)

Rationale for intervention and intended effects

This proposal seeks to transpose Commission Implementing Directive 2012/52/EU into UK law to address problems of cross-border recognition of prescriptions.

Context
In April 2011, Directive 2011/24/EU on the application of patients' rights in cross-border healthcare came into force. Article 11 of this directive provided for measures to be developed to improve the recognition of prescriptions for medicines issued in another EU Member State.

Reasons for and description of intervention
Findings of the Matrix Insight Study (2012, see Annex) suggest that 41% of UK-issued prescriptions taken abroad are rejected by local pharmacists and not dispensed. Similarly, the Study suggests that more than 70% of EU-issued prescriptions taken to the UK and attempted to be redeemed are rejected by UK pharmacists and not dispensed. The Study contends that verification and authenticity issues of prescriptions are the most common barriers to dispensing. This situation might lead to negative effects on patient health as a result of medication gaps and could trigger costs from obtaining prescriptions from local GPs. No evidence of actual harm has been found.

Directive 2012/52/EU aims to improve recognition of prescriptions issued by EU Member States by **setting out a non-exhaustive list of elements to be included in prescriptions** intended for dispensing in another Member State to address issues of verification and authenticity. Prescribers will only be required to add these mandatory elements if specifically asked for a cross border prescription by a patient.

Intended effects of intervention
The **intended effects of this measure is to enable a dispensing health professional to verify the authenticity of a prescription** to confirm that it has been issued by a prescriber who is legally entitled to do so.

Viable policy options (including alternatives to regulation)

Option 1: Transpose Commission Implementing Directive 2012/52/EU into UK law

This is the only policy option under consideration and there are no alternatives to regulation. We are under an obligation to transpose the Directive's requirements into UK law and will be doing so through copy-out to ensure no gold-plating.

Initial assessment of business impact

Please note that this RTA responds to a number of RPC comments and is therefore longer than the previous version.

Affected businesses

The RPC noted in their opinion of 5 August 2013 that MHRA should provide further detail of the health professionals affected by the Directive. The Agency responded to this by contacting the professional regulatory bodies and conducting internet searches to obtain information on the affected groups. The proposal could impact any registered health care professional who is eligible to prescribe medicines – a total of 311,784 individuals. The table below provides a breakdown of the affected professions together with the source of the data.

Affected Profession	# of Professionals	Source
Licensed Doctors	**240,382**	
General Practitioners	60,651	General Medical Council (GMC) website: http://www.gmc-uk.org/doctors/register/search_stats.asp
Specialists (Consultants)	72,646	
Junior Doctors	ca 65,000	A contact in the British Medical Association (BMA) provided these estimates as the GMC does not record numbers of Junior and SAS doctors.
Staff and Associate Specialist (SAS) Doctors	ca 14,500	
Dentists	**39,894**	General Dental Council (GDC) Annual report and accounts 2012
Nurse Prescribers	**28,299**	
Independent Nurse Prescribers	1,422	Nurse and Midwifery Council (NMC) contact via email
Supplementary Nurse Prescribers	26,877	
Pharmacist Prescribers	**3,020**	General Pharmaceutical Council (GPhC) contact via email; NB: 913 pharmacists are registered as independent and supplementary prescribers;
Independent Pharmacist Prescribers	2,523	
Supplementary Pharmacist Prescribers	1,410	
Optometrist Independent Prescribers	**189**	
Total number of affected professionals	**311,784**	

NB: Independent nurse and pharmacist prescribers can prescribe any medicine apart from a few controlled drugs for the treatment of addiction. Supplementary prescribers can only prescribe medicines which are specified in a written clinical management plan agreed for an individual patient with a doctor or dentist.

Scale of impacts – one-off familiarisation costs

There are **two types of prescriptions: NHS-prescriptions and 'private/independent'** (i.e. non-NHS) prescriptions. For both types, cross-border versions can be requested by the patient. Prescribers will be required to include the 16 elements described in the Directive only if a cross-border prescription is requested. For both NHS and private prescriptions there might be **possible one-off familiarisation costs** for prescribers. **Private sector costs** may be incurred when a prescriber issues an **independent cross-border prescription** and has to familiarise him or herself with the requirements for the first time.

The RPC noted in its opinion that more clarity and information needs to be provided in relation to familiarisation costs for providers of 'independent' private prescriptions. In

response to the RPC comments the Agency contacted all relevant professional regulatory bodies (see Annex for list of bodies and details) to:

1) establish the number of 'independent' private prescribers or prescriptions *and*
2) establish how they envision members to familiarise themselves with the new requirements and how much time and money they would spend doing so.

In relation to the first line of enquiry, the Agency was advised by the Department of Health (DH), the Royal College of General Practitioners (RCGP), the NHS Business Services Authority (NHSBSA) and the British Medical Association (BMA) that data on the number of private prescriptions is not recorded by themselves or by anyone they know of.

No organisation was able to provide a quantitative estimate of the number of private prescriptions. The BMA and DH advised the Agency that any prescriber can write a private prescription without having to record it. This explains why obtaining a quantitative estimate of the number of private prescriptions would not be possible.

The BMA noted that there are 800 GPs who do only private work and that there are 22,000 consultants who do some independent work. No other organisation was able to make similar quantitative estimates about their members. The organisations advised the Agency independently from each other and at different times. Details of our efforts to gather evidence and engage with the different organisations can be found in the annex.

In relation to the second line of enquiry, all organisations advised that it was likely that prescribers would familiarise themselves with the requirements when they were asked for a cross-border prescription. **All organisations considered the costs associated with the Directive's requirements to be small and insignificant** however they were not able to provide quantitative data (in relation to time and cost) to substantiate their views.

In an attempt to overcome the lack of quantitative evidence, the Agency convened a stakeholder meeting and asked participants for information on cost.

The meeting was attended by DH, the BMA, the British Dental Association (BDA), the Optical Federation (OF), the Royal Pharmaceutical Society (RPS), the Dispensing Doctors Association (DDA), the Nurse and Midwifery Council (NMC) and the National Pharmacy Association (NPA). Representatives were asked to discuss and provide evidence of the demand for and occurrence of cross-border prescriptions and to gauge the costs of familiarisation. **None of the represented organisations envisaged any significant demand for cross-border prescriptions.** As before, stakeholders were not able provide estimates of the likely number of cross-border prescriptions issued in the UK or the cost of having to familiarise themselves with the Directive's requirements.

We have estimated the costs for the 800 private sector GPs. We assumed that all of them will encounter a cross-border prescription per year, forcing them to familiarise themselves with the requirements and spending 15 minutes doing so. We have used hourly wage figures for GPs (between £44.2 and £58.5) from the British Medical Journal and estimated that the **800 independent GPs will incur one-off familiarisation costs between £8,840 and £11,700 (midpoint estimate: £10,270).** The calculations can be found in the Annex. The Agency has been unable to quantify familiarisation costs incurred by the 22,000 consultants because the BMA was unable to estimate the number of impendent cross-border prescriptions issued by them or provide any data to proxy these costs.

The Agency expects some additional familiarisation costs to be incurred by private sector activity of the aforementioned affected individuals but, as already noted, stakeholders

suggested that these will not be significant and are not monetised here due to stakeholder's inability to provide quantitative evidence.

Scale of impacts – on-going costs

On-going private sector costs may be incurred by prescribers who issue private cross-border prescriptions and currently include less than the soon-to-be required total of 16 elements. These prescribers may incur additional time and or costs to comply with the requirements of the proposal. A study commissioned by the European Commission (De Bie et al., 2011; see Annex) suggests that out of the 16 elements described in the Directive to be included in these prescriptions, 9 are already mandatory and 6 are already commonly added by UK prescribers. Additionally, the General Medical Council (GMC) guidance notes that prescribers must include the 9 legally required elements and should also include 4 other elements.

The RPC noted that evidence of compliance with General Medical Council (GMC) guidance will be required to demonstrate that this proposal qualifies as 'low-cost'. The Agency responded to these comments and contacted the GMC. The GMC advised that adherence to their guidance was a requirement for all practicing doctors as part of their continuous professional development and that non-compliance would result in loss of license to practise.

The Agency also contacted the Royal College of General Practitioners (RCGP) to ask them about on-going costs for prescribers. The RCGP advised the Agency that they expect that all 16 elements described in the Directive will already routinely be included in a private prescription, suggesting that no on-going costs would be incurred.

The Agency also contacted the professional bodies representing other prescribing health care professionals. The Royal Pharmaceutical Society (representing pharmacists) advised that only a small number of their prescribers would issue private prescriptions and the Royal College of Nursing considered it highly unlikely that nurse prescribers would be asked for a cross-border prescription.

None of these organisations were able to provide evidence about the number of elements routinely included in cross-border prescriptions or quantitative evidence of on-going costs of compliance with the Directive's requirements.

The Agency expects some additional on-going costs to be incurred by private sector activity of the aforementioned affected individuals but stakeholders suggested that these will not be significant and are not monetised here due to stakeholder's inability to provide quantitative evidence.

The RPC also noted that other impacts on business such as independent pharmacies should be explained further. The Agency notes that the proposal only imposes requirements for 'outgoing' cross-border prescriptions and that there are no requirements for or impacts on UK pharmacists receiving 'incoming' EEA prescriptions.

The UK already has legislation in place to enable recognition of prescriptions from EEA prescribers and the decision to accept the prescription is, and will continue to be, subject to the professional judgement of the pharmacist. An independent pharmacist will only be impacted by the regulation if he were to issue a cross-border prescription for a UK resident.

Annex 2 (contd)

One-in, Two-out status

The proposed measure is **out of scope of One-In, Two-Out** as it seeks to transpose a European Union directive into UK law and no exemptions apply.

Departmental lawyers have confirmed that we are transposing only minimal requirements (i.e. we will not gold-plate) and we will not be implementing early. According to the BIS Better Regulation Framework Manual (July 2013) this measure is therefore out of scope of OITO.

Rationale for Triage rating

The additional work the Agency has undertaken provides a strong steer that this **proposal is 'low-cost' and therefore eligible for the RPC Fast Track**.

Departmental signoff (*SCS*): Gian Marco Currado Date: 31/10/2013

Economist signoff (*senior analyst*): Chris Collinson Date: 31/10/2013

Better Regulation Unit signoff: Date:

Supporting documentation

Matrix Insight Ltd., (2012). Health Reports for Mutual Recognition of Medical prescriptions: State of Play. Available at <http://ec.europa.eu/health/cross_border_care/docs/matrix_mutual_recognition_prescriptions_en.pdf > Accessed 17 July 2013.

De Bie J, Bouvy M, Snoeijs S, van Dijk (2011). The identification and development of a minimum data set for cross-border prescription form items. Utrecht University, Netherlands. Available at <http://www.nivel.nl/sites/default/files/bestanden/Rapport-presform.pdf> Accessed 17 July 2013.

Evidence gathering efforts

The Agency identified doctors, dentists, nurses prescribers, pharmacist prescribers and optometrist prescribers as the affected groups of the proposal. The Agency subsequently contacted all relevant representative professional bodies as well as different parts of government to obtain additional evidence. The table below lists the contacted organisations.

Contacted organisation	**representing…**	**contacted via…**
General Medical Council (GMC)	Doctors	email, phone;
British Medical Association (BMA)	Doctors	email, phone;
Independent Doctors' Federation (IDF)	Doctors	email;
Royal College of General Practitioners (RCGP)	Doctors (GPs)	email;
General Dental Council (GDC)	Dentists	email;
British Dental Association (BDA)	Dentists	email;
Royal Pharmaceutical Society	Pharmacists	email;
General Pharmaceutical Council (GPhC)	Pharmacists	email;
Royal College of Nurses (RCN)	Nurses	email, phone;
Nurse and Midwifery Council (NMC)	Nurses	email;
NHS Business Services Authority (NHSBSA)		phone;
Department of Health (DH)		email, phone;
Represented Organisations at MHRA stakeholder meeting		
Dispensing Doctors' Association (DDA)	Doctors	face-to-face
British Medical Association (BMA)	Doctors	face-to-face
British Dental Association (BDA)	Dentists	face-to-face
Royal Pharmaceutical Society (RPS)	Pharmacists	face-to-face
National Pharmacy Association (NPA)	Pharmacists	face-to-face
Nurse and Midwifery Council (NMC)	Nurses	face-to-face
Department of Health (DH)	Government	face-to-face
Optical Federation (OF)	Optometrists	face-to-face

The Agency initially contacted the main professional bodies representing prescribers and tried to collect data to establish:
1) a baseline 'do-nothing' scenario *and*
2) the costs of implementation of the Directive's requirements (i.e. one-off familiarisation costs and on-going costs);

Here is a detailed account of our engagements:

1. The Agency contacted the General Medical Council (GMC), the General Pharmaceutical Council (GPhC) and the Royal College of Nursing (RCN) and asked specific questions about the familiarisation costs (ie likelihood of prescribers familiarising themselves with the requirements for a cross-border prescription; distribution of impact; time it takes to read through and familiarise with the new requirements) and on-going costs (ie number of elements currently added to cross-border prescriptions, cost and time of adding additional elements; other possible on-going costs) and information on the number of private prescriptions issued by their members and the proportion of time spent doing 'private' vs 'public' (NHS) work.
    a. The GMC was also asked for information on compliance with their guidance and standards for prescribing.

2. The General Dental Council (GDC) was approached through a Department of Health (DH) contact. The Agency sought information on dental prescribing in relation to private cross-border prescriptions (ie number of private cross-border prescriptions, familiarisation costs, ongoing costs, elements routinely included in a prescription).

3. Reminders were sent to the GMC and GPhC. As no reply had been received, the Agency followed up the previous reminder with a call to the GMC advice line. An additional request for information was sent to the GMC guidance and standards team.

4. The Agency also contacted the Royal College of General Practitioners (RCGP) and the Royal Pharmaceutical Society (RPS) and enquired about numbers of private prescriptions, time and cost estimates of producing a private cross-border as oppose to an NHS prescription and the impact of the Directive's requirements. Reminders were sent to the RCGP.

5. The Agency also contacted various teams in the Department of Health's (DH) Medicines, Pharmacy and Industry Group (MPIG) and Northern Ireland by email and telephone. In trying to establish a baseline estimate, the Agency enquired about numbers of private and NHS cross border prescriptions, how many of these prescriptions are actually taken abroad, the number of items currently added to these prescriptions, the time and costs involved of issuing one and expected additional time and costs from the Implementing Directive's requirements.

6. In order to establish the number of total prescribers, the Agency contacted professional regulatory bodies via phone and email and conducted internet searches.

The Agency received a number of responses which are summarised below:

1. The GMC guidance and standards team replied that they could not answer any of the Agency's questions.
    a. The GMC stated that their prescribing guidance applied to all prescriptions and that doctors must be familiar with and keep up to date with guidance and follow the law.

2. The GPhC and RCN were also unable to provide any specific information. No information was forthcoming about the number of private prescriptions. GPhC noted that the numbers of pharmacist prescribers was small and the number of private prescriptions even smaller. RCN noted that it would be highly unlikely for nurse prescribers to be asked for cross-border prescriptions.

3. The GDC could not answer any of the Agency's questions. The Council only noted that only 0.6% of NHS prescriptions are written by dentists and that the GDC does not specify the elements that should be included in a private prescription. The GDC had no data about numbers, time or cost of issuing NHS or private cross border prescriptions.

4. The RCGP advised the Agency that they expect the elements described in the Directive to be included in a private prescription already. With regard to ongoing costs and writing prescriptions, the correspondent indicated that the clinical system he uses offers a choice to issue a NHS or private prescription so there is not a significant increase in time provide the computer can print it out. Handwritten private prescriptions take a considerable amount of extra time of 3 - 10 minutes depending on the number of additional items. The RCGP was not able to offer any estimates in relation to the number of private v public prescriptions or cross-border v normal.

5. The RPS did not have any evidence in relation to our questions and was not able to offer a formal opinion on them.

6. Northern Ireland responded that it does not monitor numbers of private prescriptions and was also not able to offer any other feasible evidence.

7. DH was unable to provide information about time and costs of issuing a prescription. They only noted that 'it is a very small fraction of a consultation'. They stated that the majority of the required elements are already added to existing NHS prescriptions and that no figures are available for numbers of private prescriptions. Moreover, they noted that they do not hold figures for claims for reimbursement of the costs of prescriptions dispensed abroad.

8. With regard to familiarisation costs, responses from all professional bodies suggested that prescribers would familiarise themselves with the requirements when they were asked for a cross-border prescription.

9. DH and the Agency also arranged a meeting for stakeholders to discuss cross-border prescriptions. Attendees included the Department of Health, the British Medical Association, the British Dental Association, the Optical Federation, the Royal Pharmaceutical Society, the Dispensing Doctors Association, the Nurse and Midwifery Council and the National Pharmacy Association. The group did not envisage a significant demand for cross-border prescriptions. The BMA representative noted that under his GP system, there were two elements on the non-exhaustive list were not currently included on prescriptions and that adding them on would not be an onerous task.

Familiarisation costs for independent General Practitioners

Number of private GPs	800
Estimated familiarisation time (minutes)	15
Labour Costs	
Lower bound hourly wage costs GP net	£34.00
Upper bound hourly wage costs GP net	£45.00
Lower bound hourly wage costs GP gross (30% non salary costs)	£44.20
Upper bound hourly wage costs GP gross (30% non salary costs)	£58.50
Total Annual Familiarisation costs	
Lower bound	£8,840.00
Upper bound	£11,700.00
Midpoint estimate	£10,270.00

Source of salary data:
http://careers.bmj.com/careers/advice/view-article.html?id=20000354

Annex 3

Summary of Responses to Consultation MLX 391: Post-Implementation Review of the Human Medicines Regulations 2012

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]

Q1. In your view what best describes the way in which the PV Directive has been implemented in the UK?

	Responses
Significantly less burdensome	1
Less burdensome	0
Proportionate	4
More burdensome	2
Significantly more burdensome	1
Skipped	48

1. There has been no “gold plating”; implementation has not gone beyond the requirements of the Directive and consequential GVP Modules.

2. For the generics sector, the impact can at best be described as neutral. It is noted that work sharing on such materials is encouraged in the GVP module on Risk Management Plans (RMPs) but there are several instances where the originator has declined to participate in such activities.

3. One respondent felt that the PV Directive requires collection of a lot of data that doesn't add value to the benefit:risk assessment of medicines and, in some cases, may even prevent the detection of signals in amongst the amount of data collected.

Q2. 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?

	Responses
Yes	3
No	2
Don't know	5
Skipped	46

4. One respondent commented that the PV Directive requires collection of a lot of data on adverse drug reactions that doesn't add value to the benefit: risk assessment of the medicines. They suggested that a better approach would be to concentrate on data collection in situations where it will help the understanding of benefit: risk of medicines, as well as emphasising to healthcare professionals the importance of reporting and providing follow up information on adverse reactions to pharmaceutical companies when requested. Another respondent commented that the requirement to create and maintain RMPs for generic authorisations, and to prepare and distribute RMM's has caused significant issues for most generic MA holders. It is considered by some general MA holders that the costs associated with producing and disseminating RMMs are a barrier to market entry. A third respondent highlighted there had been unintended consequences, but did not provide any supporting detail.

Q3. How has UK implementation of the PV Directive affected the clarity and understanding of pharmacovigilance requirements?

	Responses
Much clearer	0
Clear	4
No change	3
Unclear	0
Very unclear	0
Skipped	49

5. The Directive, its related guidelines, and its implementation into UK legislation are much more explicit and have reduced the number of areas that were open to interpretation. In addition, the open dialogue that exists between industry associations and the MHRA, and at the broader European level with the EMA, has enabled industry to understand the expectations of the competent authorities, and for these authorities to understand the issues and concerns of industry. However, areas like collection of data in Market Research, guidance for assessment of Patient Support Programmes and capture of off-label and medication error reports, still require additional clarification (particularly for patients and healthcare professionals).

Q4. What effect has UK implementation of the PV Directive had on patient safety?

	Responses
Vastly improved	0
Improved	6
No change	1
Decreased	0
Vastly decreased	0
Skipped	49

6. The majority of respondents to this question thought patient safety had improved as a result of the PV Directive. One respondent considered that it was too early to say if the new legislation has had a positive or negative effect on patient safety; however there may be hidden benefits from increased PV activity resulting in better reporting and awareness of drug safety issues in clinical settings. There has also been some increase in patient awareness.

7. Implementation of the PV Directive has not placed any additional obligations on healthcare professionals and patients; for improvements in patient safety, all stakeholders need to be engaged.

Q5. Is there any potential to refine the UK implementation of the PV Directive to reduce the burden on industry?

	Responses
Yes	3
No	0
Don't know	5
Skipped	48

8. As most MA holders operate in two or more EU countries, the PV Directive and related legislation has harmonised and aligned many pharmacovigilance activities. There is probably limited scope for refining the UK legislation that would not have an adverse impact on the MA Holders pharmacovigilance activities elsewhere in the EU.

9. One area highlighted as an issue, particularly for generic MA holders, was the requirement to create and maintain Risk Management Plans (RMPs) and to prepare and distribute Risk Minimisation Measures (RMMs), as these are not always in the public domain. Even when these are accessible to generic applicants, documents submitted for assessment based on the originator's materials have been assessed in an inconsistent manner, including by the MHRA. This has resulted in some MA holders having two or more RMPs for the same active. It is considered by some generic MA holders that the costs associated with RMM are a barrier to market entry.

10. In relation to the distribution of DHPCs and RMM it was suggested that to reduce costs for industry and ensure a single message is delivered to healthcare professionals work-sharing by all MA Holders, generic and originator could be mandated.

11. One respondent asked for clearer guidance and a pragmatic approach on the definition of off-label. They considered the improved collection of pharmacovigilance data on off-label use of medicines would help generate a better understanding of the benefit:risk profile, which would ultimately help patients.

12. There was a comment that the Yellow card system needs improving, but no specific suggestion on what form the improvements might take.

Q6. How does the way in which the PV Directive has been implemented in the UK compare to implementation by other EU member states?

	Responses
More burdensome	1
Burdensome	0
In line with other members states	2
Less burdensome	1
Significantly less burdensome	1
Skipped	51

13. Implementation has been in line with other member states. Alignment of the UK with other EU member states is important as most pharmaceutical companies need to comply with international regulations as well as those in the UK. At the time of implementation, the UK was already recognised as one of the leading member states with regards to the pharmacovigilance systems in place.

14. If was noted that the implementation of the PV Directive has not resulted in any 'gold plating', unlike in other EU member states. For example, there is no requirement for a local QPPV. In some EU countries, there is not only such a requirement but the local QPPV must be medically qualified, e.g. a physician or pharmacist. Such a requirement can add significantly to costs but also to procedures where the local QPPV as well as the EEA QPPV needs to have oversight of national activities.

Q7. Have there been additional benefits or cost arising from UK implementation of the PV Directive?

	Responses
Yes	0
No	3
Don't know	3
Skipped	50

15. The impact of the UK implementation of the PV directive for most generic MA holders has been neutral. The reduced requirement for some activities has been counterbalanced by the need to conduct new activities.

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

Q8. Are you aware of any cases where the UK has not recognised prescriptions from other European Economic Area (EEA) countries[2] and vice versa?

	Responses
Yes	2
No	2
Don't know	3
Skipped	49

16. One respondent reported that the additional prescription requirements placed on EEA prescriptions (e.g. prescriber email address and phone number with international prefix) has often meant that even though it may be clear what medication the prescriber intended the patient to have, the prescription must be refused. In addition, prescriptions for brands which are unavailable in the UK has resulted in a refusal to dispense. In some cases patients and overseas prescribers believe that a fax or email prescription is a legally valid document which again results in a refusal to dispense and can be time-consuming to explain to the patient.

Q9. What effect has cross border recognition of prescriptions had on patients?

	Responses
Very beneficial	0
Beneficial	4
No effect	0
Detrimental	1
Very Detrimental	0
Skipped	51

17. The regulations around cross border prescriptions improve access to medicines for patients, especially visitors, with prescriptions from other European Economic Area (EEA) countries.

18. Patients travelling from the Republic of Ireland (ROI) to Northern Ireland to have their prescriptions dispensed in the UK will generally save money as the cost of their medicine is cheaper in the UK compared with the ROI. In an economic sense this could be seen as beneficial for the EEA patients.

[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

Q10. What effect has cross border recognition of prescriptions had on pharmacists?

	Responses
Very beneficial	0
Beneficial	1
No effect	1
Detrimental	3
Very Detrimental	0
Skipped	51

19. It was acknowledged by two respondents that there are some issues that arise with the dispensing of EU prescriptions including in some cases increased work load for pharmacists.

20. There is a thriving cross border movement of prescriptions coming from the Republic of Ireland into the UK via Northern Ireland. Patients will travel to have their prescriptions dispensed by NI pharmacies. It could be anticipated that this has resulted in increased business/trade in NI pharmacies.

21. It is currently unclear what implications the United Kingdom's decision to withdraw from the European Union will have on cross border prescriptions. Pharmacists, prescribers and patients will all benefit from up to date guidance on this matter as soon as it is clearer what the implications will be.

Q11. What effect has cross border recognition of prescriptions had on healthcare professionals (other than pharmacists)?

	Responses
Very beneficial	0
Beneficial	2
No effect	0
Detrimental	3
Very detrimental	0
Skipped	51

22. It was acknowledged by some respondents that it does create an increased workload for prescribers; where prescriptions are written for medicines not available in the UK, or are not written in English, the patients generally have to be referred to a GP/prescriber for a UK prescription to be provided, which can result in an additional workload.

Q12. What level of understanding do pharmacists have of cross border prescriptions?

	Responses
Very good	0
Good	2
Neither good nor bad	2
Bad	1
Very bad	0
Skipped	51

23. The majority of respondents felt that there is good recognition amongst pharmacists of their ability to receive and dispense EU prescriptions. All pharmacists can access the regulations to confirm detail required for a valid prescription, should they need to do so. In general, those in pharmacies with a high level of EEA patients will have a greater working knowledge of the cross-border process, as they deal with it more frequently in their daily practice than those with few EEA patients.

24. One respondent felt that many pharmacists are still unsure about whether they are allowed to dispense prescriptions from other EEA countries. It can also prove particularly complicated for a pharmacist in the United Kingdom to ascertain validity of a prescription from another EEA country and the validity of the prescriber, as EEA prescriptions do not come in any consistent form and are often in different languages.

25. The Royal Pharmaceutical Society has published guidance to raise awareness and respond to queries from pharmacists about this topic.

Q13. What level of understanding do healthcare professionals (other than pharmacists) have of cross border prescriptions?

	Responses
Very good	1
Good	0
Neither good nor bad	1
Bad	2
Very bad	1
Skipped	51

26. It was felt that knowledge and understanding of cross border prescriptions is still limited amongst some healthcare professions.

Q14. Are you aware of any difficulties that cross border prescriptions have caused for patients?

	Responses
Yes	3
No	1
Don't know	3
Skipped	49

27. There have been cases where the prescription has not been dispensed due to incomplete information or where the prescription has been for brands which are unavailable in the UK.

28. Where prescriptions have been written for medication not available in the UK, or are not written in English, the pharmacist will generally have to refer patients to a GP for a UK prescription to be provided, which can result in delay, inconvenience and additional cost for the patient.

29. There is a reported death from the misuse of drugs associated with an EEA prescription issued remotely in the Czech Republic for a patient based in the UK.

Q15. Are you aware of any difficulties that cross border prescriptions have caused for pharmacists?

	Responses
Yes	4
No	1
Don't know	3
Skipped	48

30. Cross border prescriptions have resulted in an increased workload for pharmacists. EEA prescriptions do not come in any consistent form, are often in different languages, which could potentially introduce patient safety risks, and it is not always clear whether or not the pharmacy should charge for the prescription. Verification can be time consuming and result in extra work for pharmacists.

31. Different countries have different prescription legal requirements, and EU prescribers are not always aware of what they are required to write on a prescription for this to be valid across the EEA. Where prescriptions are written for medicines not available in the UK, or are not written in English, patients generally have to be referred to a GP/prescriber for a UK prescription to be provided.

32. Difficulties arise both to patients and pharmacists, particularly in cases where the EEA prescription is being presented out of hours such as late evenings or weekends and may lead to delays in being able to supply the medication.

Q16. Are you aware of any difficulties that cross border prescriptions have caused for healthcare professionals (other than pharmacists)?

	Responses
Yes	2
No	2
Don't know	3
Skipped	49

33. Two respondents suggested that there is an increased workload for prescribers; scripts written for medicines not available in the UK, or are not written in English, generally must be referred to a GP/prescriber for a UK prescription to be provided, which can result in an additional workload for the prescriber.

Q17. Is there any opportunity to reduce burdens on business as a result of cross border prescriptions?

	Responses
Yes	2
No	2
Don't know	3
Skipped	49

34. Two respondents made suggestions on ways to reduce burdens on business. Firstly, there should be a requirement for prescriptions to be written in the language of the country in which they are to be dispensed, or the provision of a pharmaceutical translation service would help resolve the issues.

35. And secondly, EEA countries should develop the ability to check prescriber registers online and introduce a consistent prescriptions format (or at the very least consistent prescription particulars) across the EEA.

Q18. In your view, what best describes how the requirements to recognise cross border prescriptions have been implemented in the UK?

	Responses
More burdensome	0
Burdensome	3
In line with other member states	1
Less burdensome	0
Significantly less burdensome	0
Skipped	52

36. Two respondents considered that the guidance currently available on cross-border prescriptions provides the necessary information for a pharmacist to recognise a valid prescription, but it is not written in a user friendly format, and therefore takes a significant time to read and understand especially for someone not previously familiar with the process.

37. One respondent indicated that while the volume of prescriptions from the EEA is low but when they are presented the burden of checking the validity of the prescription is excessive.

Q19. How has the recognition of cross border prescriptions in the UK been implemented in the UK compared to other EU member states?

	Responses
More burdensome	0
Burdensome	0
In line with other member states	2
Less burdensome	0
Significantly less burdensome	0
Skipped	54

Q20. Have there been additional benefits or costs arising from cross border recognition of prescriptions?

	Responses
Yes	2
No	0
Don't know	3
Skipped	51

38. The introduction of cross border prescriptions has been generally beneficial for patients. Patients travelling to UK from other EEA countries in possession of a valid prescription, can obtain supplies in UK Pharmacies during travel and vacations.

39. There are an increased number of patients travelling abroad for surgical and medical treatment. These patients appreciate the convenience of obtaining supplies of their medication on return, often at a reduced cost compared to the country of issue.

40. Costs are increased due to the problems associated with checking prescription validity. However, some of this can be reclaimed from the patient due to the private nature of the transaction. There is likely to have been financial benefit to some NI pharmacies due to the increase in cross border trade from the ROI.

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

41. Section 10 (7) of the Medicines Act 1968 provided an exemption in UK law for the requirement for a pharmacist in a registered pharmacy to hold a Wholesale Dealer's Licence if the pharmacy undertook wholesale trading in medicines in certain circumstances.

42. 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:

    a. 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).

    b. Preserve continued supplies of medicines above all other concerns.

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

Q21. Since the repeal of Section 10(7) to what extent have supplies of medicines met the needs of patients?

	Responses
Completely met	1
Met	3
No change	3
Weakened	8
Greatly weakened	2
Skipped	39

Q22. How has the repeal of Section 10(7) affected regulatory cost and administrative burden, particularly for the NHS?

	Responses
More burdensome	12
Burdensome	4
Neither more or less burdensome	2
Less burdensome	1
Significantly less burdensome	0
Skipped	37

Q23. How has the repeal of Section 10(7) affected the continued access to supplies of medicines?

	Responses
Improved a lot	0
Improved	1
No change	2
Worsened	13
Worsened a lot	3
Skipped	37

Q24. How has the repeal of Section 10(7) affected pharmacists?

	Responses
Very beneficial	0
Beneficial	0
No change	0
Detrimental	14
Very detrimental	1
Skipped	41

Q25. How has the repeal of Section 10(7) affected healthcare professionals (other than pharmacists)?

	Responses
Very beneficial	0
Beneficial	0
No change	5
Detrimental	10
Very detrimental	1
Skipped	40

Q26. Have there been any unintended consequences that you are aware of arising from the repeal of Section 10(7)?

	Responses
Yes	17
No	0
Don't know	3
Skipped	36

43. One respondent felt that supplies of medicines to patients have not been affected, due to the work carried out by pharmacists and prescribers to ensure uninterrupted supply. Another three respondents said that in most cases organisations have worked together to maintain the same quality of service.

44. There were 21 responses which in summary expressed the following concerns about the repeal of Section 10(7):

- There is administrative burden and costs associated with obtaining a wholesale dealers licence. This is often passed onto customers. Where the customer is the NHS it was felt that this was a poor use of resources. There are also costs associated with inspection and obtaining a controlled dugs licence.

- Repeal of Section 10(7) has hindered supply arrangements within NHS settings; including movement of stock around ambulance trusts and neighbouring NHS Trusts.

- It was felt that it has inhibited local supply arrangements between NHS organisations where supplying pharmacy has not been willing to purchase a licence for small scale activity,

- It has made it unduly onerous to obtain stocks due to minimum order qualities and values specified by suppliers. In particular, this has caused problems for some community pharmacists.

- There have been occasions where pharmacies have had to reject signed orders from prescribers for medication and refer them to a WDA holder. While this may not have affected patients directly time associated with processing these orders could have impacted on patient care if supplies were not made in time.

- Some organisations have had to find new suppliers sometimes remote of their location to maintain supplies. In several cases healthcare professionals no longer have the convenience of having an account with a local pharmacy.

- The extension of controlled drug licensing to include controlled drugs within the same NHS entity has caused confusion.

- Hospices highlighted concerns regarding supply of medication; in particular, controlled drugs from pharmacies. Pharmacies are now required to hold a wholesale dealer's licence if the pharmacy wholesales medicine and a controlled drug licence issued by the Home Office. This has resulted in pharmacies withdrawing from contracts to supply medicines and others have passed costs onto hospices. As a result, hospices have had additional costs in retendering. Hospices are having to get medicines from pharmacies that are geographically further away leading to delays in obtaining medicines and increased costs. Hospices commented that they have lost their existing supply arrangements.

- There is a huge amount of work required to update Standard Operating Procedures (SOPs). Other burdens include financial arrangements and service level agreements. There is a requirement for pharmacies to employ staff with the necessary skill set required in pharmacies to do this.

- There is some duplication. NHS trusts now have Home Office as well as CQC requiring reports on controlled drug incidents and a responsibility to both organisations. The requirements to both are not necessarily aligned. Pharmacists are required to register with the General Pharmaceutical Council, MHRA and the Home Office. The standards of these regulators are all similar and feel that one regulator could oversee the whole process.

- Pharmacists spend additional time complying with “green book” code for wholesale dealers licensing requirements.

- Community pharmacists used an exemption in times of medicines shortages where a neighbouring pharmacist required stock for a particular patient need. This practice has become more difficult as a result.

Q27. Are there any opportunities to reduce burden on pharmacists as a result of the repeal of Section 10(7)?

	Responses
Yes	10
No	4
Don't know	4
Skipped	38

45. The following suggestions to reduce burden on pharmacists were highlighted by ten respondents:

- Better communication of the regulatory change to healthcare professionals and updated guidance.

- Further clarity on requirements for a wholesale dealer’s licence. In particular, for Doctors bags; what constitutes supplies on an occasional basis, criteria in guidance on what is considered to be small supplies, and what costs can be added but still be fall into the category not for profit.

- The need for a wholesale dealers licence remains unclear in some sectors of the NHS.

- It is becoming more common for NHS Trusts to outsource their pharmacy departments to a third party in a drive to deliver savings on medicines and enabling trust staff to focus on patient care.

- Look at introducing exemptions from the need for a wholesale dealers licence for supplies between ambulance trusts and to cover activities between the trust and other legal entities and for NHS Trust supply to hospices.

- Consider the opportunity to revisit the repeal of Section 10(7) post-Brexit; in particular, the requirement for a wholesale dealers licence to support NHS to NHS supply for the management of NHS patients.

46. In addition, two respondents answered the question more broadly. One suggested reconsidering the requirement for community pharmacists to hold wholesale dealer's licence from MHRA and a separate Home Office licence for wholesale of controlled drugs. Another commented that the drive to named patient supply has resulted in wastage of medicines. Many pharmacies are left with pre-ordered stock that they will not use. Pharmacies can no longer sell unwanted stock to another pharmacy with patients that require the medication.

Q28. 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]

	Responses
Significantly less burdensome	0
Less burdensome	1
In line with other member states	1
Burdensome	4
More burdensome	9
Skipped	41

47. Three respondents felt that the implementation of articles 77(1) and 77(2) disrupted a system which worked well and everyone in the supply chain has been affected to a greater or lesser extent with additional bureaucracy. They questioned whether there have been any benefits.

48. Whilst it is reasonable to restrict wholesale dealing when being carried out commercially and for profit, it has not been helpful to extend this to hospitals and community pharmacies who supply medicines to hospices as stock. This supply is only an extension of the patient-specific items in process and intent but has been treated differently without a sound basis for any benefit to patient safety.

49. One respondent commented that the change in the law was not sufficiently publicised.

Q29. 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 EU?

	Responses
Significantly less burdensome	0
Less burdensome	2
In line with other member states	3
Burdensome	1
More burdensome	0
Skipped	50

50. One respondent suggested that whilst the existing supply arrangements are probably not unique to UK healthcare, there appeared to be no effort to adopt whatever "work arounds" were in place in other countries. Rather, it appeared that through a desire to implement the articles in the UK, a rigid and less pragmatic way was chosen than might otherwise have been the case.

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

Q30. How effective have the 2012 Regulations been in consolidating medicines legislation in a rationalised form?

	Responses
Very effective	0
Effective	6
Don't know	5
Ineffective	6
Very ineffective	0
Skipped	39

51. Respondents considered, on balance, that the Human Medicines Regulations 2012 are easier to follow and understand in their consolidated form and it is useful to have a single point of reference. They considered the consolidation had been effective in reducing the number of regulations and statutory instruments.

52. One respondent commented that although the HMR consolidated many of the statutory instruments and now incorporates much of what was in the Medicines Act, key Sections of the Medicines Act 1968 remain in force and were not transposed into the HMR. Further consolidation would be helpful to ensure that legislation which remains in the Medicines Act is not overlooked.

53. One respondent said for healthcare professionals who may access the legislation on a very infrequent basis, the rationalised form is still very complicated to read and understand.

54. One respondent highlighted that what was previously the Section 9 exemption for Doctors has been reworded and is now less clear in terms of what can be undertaken "under the supervision of a doctor".

55. A respondent from the ambulance service commented that nurses working in ambulance services are not permitted the same exemptions from legislation as paramedics in Schedule 17 and as a result there are two professional groups doing the same job, one with an exemption and another requiring Patient Group Directions (PGDs). There were also issues around the movement of controlled drugs around an NHS trust. The regulations do not address administration of non parenteral (non injectable) Patient Only Medicines (POMs). It was felt that the regulations have provided an unwelcome distraction from the business of supplying urgent and emergency care.

56. The HMR 2012 regulations allow emergency supplies of medicines to be made at the request of a prescriber or by a patient. Currently the pharmacist must interview the patient and it is not possible for a pharmacy to supply a medicine at the request of a patient's representative (e.g. a parent, spouse, or carer) even though it may be in the patient's best interests. This is a barrier to care and pharmacists should be empowered to use professional judgement in these situations to make an emergency supply and act in the patient's best interests if needed and appropriate.

57. One respondent highlighted an inconsistency between the Human Medicines Regulations 2012 as amended and the Misuse of Drugs Regulations 2001 as amended in the definition of 'appropriate date' for health prescriptions, and prescriptions which are not health prescriptions. The HMR 2012 differentiates between the two, whilst the Misuse of Drug Regulations 2001 does not.

Q31. Have there been in your view any unintended or unforeseen consequences arising from the coming into force of the 2012 Regulations?

	Responses
Yes	11
No	3
Don't know	5
Skipped	37

58. The 2012 made unannounced changes to the law, for example in relation to the labelling of dispensed medicines, and later changed the law back again. No publicity was given to the changes.

59. As a result of the Regulations there has been a reduction in competition leading to increase in charges for medicines and the services to provide them which are being passed on to care providers. There are significant omissions on exemption list for paramedics e.g. tranexamic acid

60. Some hospices commented that supply arrangements have been lost due to the additional need for a Home Office License for controlled drugs which is both expensive and an additional burden on stretched services. In addition, the controlled drug licensing and mandatory requisition debacle with impact of mandatory requisitioning is unclear.

Q32. Are there any opportunities to reduce burden on industry as a result of the 2012 Regulations?

	Responses
Yes	5
No	1
Don't know	13
Skipped	37

61. One respondent suggested that the regulations should include an exemption for NHS Trusts.

62. There is an opportunity to decriminalise dispensing errors made by pharmacists and pharmacy staff. Fitness to practise cases are more proportionate and less costly for the public than prosecutions.

63. Keeping a constantly updated version of the regulations online and highlighting the changes in that version would be helpful.

64. One respondent asked that the interpretation of EU legislation in order that Pharmacies no longer need licences to supply to Hospices is reconsidered.

Q33. Have there been any unintended impacts on groups sharing protected characteristics as defined in the Equality Act 2010 arising from the implementation of these regulations?

	Responses
Yes	2
No	3
Don't know	12
Skipped	39

65. Two respondents indicated the 2012 regulations had resulted in unintended impacts on groups sharing protected characteristics. One respondent suggested the unintended impact had been on all groups, not just those with protected characteristics. The other respondent named a particular group of healthcare professionals rather than a particular group sharing protected characteristics.

Annex 3 (contd)

List of organisations/Individuals that responded to the consultation:

Association British Pharmaceutical Companies

Celesio UK

Charles Russell Speechleys LLP

Community Pharmacy Scotland

Community Pharmacy Wales

Company Chemists Association

Dr Reddy's

General Pharmaceutical Council

Health Northern Ireland

National Pharmacy Association

NHS Specialist Pharmacy Service (East of England and Northamptonshire)

NHS Specialist Pharmacy Service (NHS London Procurement Service)

Proprietary Association of Great Britain

Royal College of Anaesthetists

St Christopher's Hospice

The Royal Pharmaceutical Society

The Association of Anaesthetists of GB and NI

In addition, the following responses were received:

Pharmacy Business

Pharmacists (8 responses)

Pharmacist group

Association of Supportive and Palliative Care Pharmacy

Pharmacist

Hospice

Doctor or other Healthcare Professional

Marketing Authorisation Holders (2 responses)

Wholesaler

Trade Body

Note: Respondents who asked for their responses to remain confidential, or did not indicate a name, or category of business, are not included in this list. Their responses were still included in the analysis.

Annex 4

POST IMPLEMENTATION REVIEW OF HUMAN MEDICINES REGULATIONS 2012

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
			PARTS					
Falsified Medicines Directive (FMD)	The Human Medicines (Amendment) Regulations 2013	2013 No. 1855	Part 3 - Chapters 1, 3 and 4	Grant etc of licences, Conditions for holding a manufacturer's licence and Conditions for holding a wholesale dealer's licence	Falsified Medicines - Chapter 1 – provides definition of 'Manufacture' in relation to active substances Chapter 3 (reg 45A) – insertion of conditions relating to Brokering Chapter 4 (reg 45M) – insertion of conditions relating to importation, manufacture or distribution of active substances	The general objective of EU pharmaceutical legislation is to give concrete form of the Treaty's objective of free movement of goods for medicinal products while ensuring a high level of protection of human health. Against this background, the general objective is defined as maximising the protection of the legal supply chain in the EU against infiltration of counterfeit medicinal products, ie that for all practical purpose the possibility that medicinal products purchased in the legal supply chain in the EU are counterfeit can be practically ruled out.	2013	The FMD came into force in 2011 (Directive 2011/24/EU) and was largely transposed into UK legislation in 2013. However some measures such as the common logo and safety features had a longer implementation time. Measures relating to the common logo were implemented in 2015 and the safety feature requirements need to be implemented by February 2019. As the Directive has not been fully implemented, it is considered too early to draw conclusions as to whether its objectives have been met and remain proportionate.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
Pharma-coviglance (PV)	The Human Medicines Regulations 2012	2012 No. 1916	Part 11	Pharmacovigilance	Pharmacovigilance Requirements (Directive 2010/84/EU)	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.
FMD	The Human Medicines (Amendment) Regulations 2013	2013 No. 1855	Part 12A	Sale of Medicines to the Public at a Distance	Falsified Medicines - Insertion of regs 256A – N which details conditions for the sale of medicines to the public at distance	The general objective of EU pharmaceutical legislation is to give concrete form of the Treaty's objective of free movement of goods for medicinal products while ensuring a high level of protection of human health. Against this background, the general objective is defined as	2013	The FMD came into force in 2011 (Directive 2011/24/EU) and was largely transposed into UK legislation in 2013. However some measures such as the common logo and safety features had a longer implementation time. Measures relating to the common logo were implemented in 2015 and the safety feature requirements need to be implemented by February 2019. As the Directive has not been fully

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						maximising the protection of the legal supply chain in the EU against infiltration of counterfeit medicinal products, ie that for all practical purpose the possibility that medicinal products purchased in the legal supply chain in the EU are counterfeit can be practically ruled out.		implemented, it is considered too early to draw conclusions as to whether its objectives have been met and remain proportionate.
			REGULATIONS					
FMD	The Human Medicines (Amendment) Regulations 2013	2013 No. 1855	(i) 18(6)(a)	Grant etc of licences- Wholesale dealing in medicinal products. wholesale	Falsified Medicines – a wholesale dealers license does not authorise distribution of a medicinal product unless an MA or equivalent is in place but this does not apply under certain conditions	The general objective of EU pharmaceutical legislation is to give concrete form of the Treaty's objective of free movement of goods for medicinal products while ensuring a high level of protection of human health. Against this background, the general objective is defined as maximising the protection of the legal supply chain in the EU against infiltration of counterfeit medicinal products, ie that for all practical purpose the possibility that medicinal products purchased in the legal supply chain in the EU are counterfeit	2013	The FMD came into force in 2011 (Directive 2011/24/EU) and was largely transposed into UK legislation in 2013. However some measures such as the common logo and safety features had a longer implementation time. Measures relating to the common logo were implemented in 2015 and the safety feature requirements need to be implemented by February 2019. As the Directive has not been fully implemented, it is considered too early to draw conclusions as to whether its objectives have been met and remain proportionate.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						can be practically ruled out.		
FMD	The Human Medicines (Amendment) Regulations 2013	2013 No. 1855	(ii) 20(1)	Grant etc of licences-Mixing of medicines	Exemption from need to have a manufacturing licence by certain healthcare professionals	The general objective of EU pharmaceutical legislation is to give concrete form of the Treaty's objective of free movement of goods for medicinal products while ensuring a high level of protection of human health. Against this background, the general objective is defined as maximising the protection of the legal supply chain in the EU against infiltration of counterfeit medicinal products, ie that for all practical purpose the possibility that medicinal products purchased in the legal supply chain in the EU are counterfeit can be practically ruled out.	2013	The FMD came into force in 2011 (Directive 2011/24/EU) and was largely transposed into UK legislation in 2013. However some measures such as the common logo and safety features had a longer implementation time. Measures relating to the common logo were implemented in 2015 and the safety feature requirements need to be implemented by February 2019. As the Directive has not been fully implemented, it is considered too early to draw conclusions as to whether its objectives have been met and remain proportionate.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
FMD	The Human Medicines (Amendment) Regulations 2013	2013 No. 1855	(iii) 37(4)(b), (5), (6), (11) and (12)	Conditions for holding a manufacturer's licence - Manufacturing and assembly	Falsified Medicines – manufacturers, importers or distributors of active substances to be licensed with competent authority unless the active substance is imported from a third country; licence holder ascertaining and ensuring good manufacturing practice is applied; licence holder must maintain staff, premises and equipment in accordance with manufacturers licence and MA's (or equivalent), licence holder to immediately inform competent authority if suspects any medicinal product to be falsified. Regulations 37(12) doesn't exist any more.	The general objective of EU pharmaceutical legislation is to give concrete form of the Treaty's objective of free movement of goods for medicinal products while ensuring a high level of protection of human health. Against this background, the general objective is defined as maximising the protection of the legal supply chain in the EU against infiltration of counterfeit medicinal products, ie that for all practical purpose the possibility that medicinal products purchased in the legal supply chain in the EU are counterfeit can be practically ruled out.	2013	The FMD came into force in 2011 (Directive 2011/24/EU) and was largely transposed into UK legislation in 2013. However some measures such as the common logo and safety features had a longer implementation time. Measures relating to the common logo were implemented in 2015 and the safety feature requirements need to be implemented by February 2019. As the Directive has not been fully implemented, it is considered too early to draw conclusions as to whether its objectives have been met and remain proportionate.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
FMD	The Human Medicines (Amendment) Regulations 2013 The Human Medicines (Amendment) Regulations 2016	2013 No. 1855 and 2016 No. 186	(iv) 43(5), (6)(a) [and (d)], 7(c)(iii) and (vii), (8) and (10) to (14)	Conditions for holding a wholesale dealer's licence - Obligations of licence holder	43(5) and (6(a)) – licence holder must not sell or supply a medicinal product unless there is an MA (or equivalent) and the sale or supply is in accordance with said MA (or equivalent); unless a special medicinal product. [6(d) or distribution to a person in a 3rd country] 7(c) – 14 - Falsified Medicines – license holder must keep records of the date of brokering and batch number of medicinal products bearing safety features; licence holder importing medicinal product for which they do not hold an MA (or equivalent) from another EEA state must notify the MA holder or competent authority of intention to import said product and	The general objective of EU pharmaceutical legislation is to give concrete form of the Treaty's objective of free movement of goods for medicinal products while ensuring a high level of protection of human health. Against this background, the general objective is defined as maximising the protection of the legal supply chain in the EU against infiltration of counterfeit medicinal products, ie that for all practical purpose the possibility that medicinal products purchased in the legal supply chain in the EU are counterfeit can be practically ruled out.	2016	The FMD came into force in 2011 (Directive 2011/24/EU) and was largely transposed into UK legislation in 2013. However some measures such as the common logo and safety features had a longer implementation time. Measures relating to the common logo were implemented in 2015 and the safety feature requirements need to be implemented by February 2019. As the Directive has not been fully implemented, it is considered too early to draw conclusions as to whether its objectives have been met and remain proportionate.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
					pay a fee to the EMA; Licence holder must verify that medicinal products are not falsified by checking safety features on outside packaging; Licence holder must maintain a quality system and inform licencing of any products they suspect to be falsified; Licence holder must verify broker fulfils requirements that broker is validly registered, has permanent UK address (if applicable) and complies with good distribution practices			
FMD	The Human Medicines (Amendment) Regulations 2013	2013 No. 1855	(v) 44(1) to (6)	Conditions for holding a wholesale dealer's licence - Requirement for wholesale dealers to deal only with specified persons.	Falsified Medicines – licence holder must deal with only specific persons who comply with practices of good manufacturing / good distribution and hold respective licence.	The general objective of EU pharmaceutical legislation is to give concrete form of the Treaty's objective of free movement of goods for medicinal products while ensuring a high level of protection of human health. Against this	2013	The FMD came into force in 2011 (Directive 2011/24/EU) and was largely transposed into UK legislation in 2013. However some measures such as the common logo and safety features had a longer implementation time. Measures relating to the common logo were implemented in 2015 and the safety feature requirements need to be

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						background, the general objective is defined as maximising the protection of the legal supply chain in the EU against infiltration of counterfeit medicinal products, ie that for all practical purpose the possibility that medicinal products purchased in the legal supply chain in the EU are counterfeit can be practically ruled out.		implemented by February 2019. As the Directive has not been fully implemented, it is considered too early to draw conclusions as to whether its objectives have been met and remain proportionate.
PV	The Human Medicines Regulations 2012	2012 No. 1916	(vi) 59,	In the original HMRs though amended by 2014/1878 to incorporate parallel import licences.	Pharmacovigilance - Conditions for the granting an marketing authorisation or parallel import licence and general conditions that apply to such licences.	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						numbers of adverse drug reactions in the general population.		
PV	The Human Medicines Regulations 2012	2012 No. 1916	(vii) 60(3)(b), (9) and (10)	In original HMRs - Exceptional circumstances for granting of a UK MA.	Pharmacovigilance – granting of an MA in exceptional circumstances including where applicant is unable to provide comprehensive data on safety	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
PV	The Human Medicines Regulations 2012	2012 No. 1916	(viii) 61,	In original HMRs - Consideration of application - Conditions of UK marketing authorisation: new obligations post-authorisation	Pharmacovigilance - Post MA obligations for safety and/or efficacy reporting studies	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.
PV	The Human Medicines Regulations 2012	2012 No. 1916	(ix) 63,	In original HMRs - Consideration of application - Frequency of periodic safety update reports	Pharmacovigilance – Frequency of post MA periodic safety report updates	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.		
PV	The Human Medicines Regulations 2012	2012 No. 1916	(x) 64(4)(b), (d) and (e), (5)(a) and (6)(c),	In original HMRs - Consideration of application - Duties of licensing authority in connection with determination	Pharmacovigilance – Licensing authority to make public packaging leaflet, conditions imposed on MA and produce assessment report on data submitted as part of licensing application	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						reactions in the general population.		
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xi) 65(2),	In original HMRs - Validity of UK marketing authorisation - Validity of UK marketing authorisation	Pharmacovigilance – requirement to make further application for renewal of MA	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xii) 66(5) and (6),	In original HMRs - Validity of UK marketing authorisation - Application for renewal of authorisation	Pharmacovigilance – application for MA renewal to be made 9 months prior to expiration and to contain data on adverse incidents and periodic updated safety reports	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
PV	The Human Medicines (Amendment) Regulations 2013	2013 No. 1855	(xiii) 68(2)(a) and (b), (5) and (12A)	In original HMRs though amended by 2014/1878 to reflect insertion of parallel licences. Revocation, variation and suspension of marketing authorisation - Revocation, variation and suspension of UK marketing authorisation.	Pharmacovigilance – revocation, variation or suspension of MA on grounds of harmful, effects do not outweigh risks or post MA obligations not fulfilled. 12A - Falsified Medicines – does not exist within Amendment 2013 No 1855 There is an 11A – revocation, variation and suspension of MA if manufacture not carried out in compliance with schedule 8 – description of methods of manufacturing and control methods employed.	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population. The general objective of EU pharmaceutical legislation is to give concrete form of the Treaty's objective of free movement of goods for medicinal products while ensuring a high level of protection of human health. Against this background, the general objective is defined as	2013	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						maximising the protection of the legal supply chain in the EU against infiltration of counterfeit medicinal products, ie that for all practical purpose the possibility that medicinal products purchased in the legal supply chain in the EU are counterfeit can be practically ruled out.		
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xiv) 69(2)(a) and (b), (5) and (10),	In original HMRs though amended by 2014/1878 to reflect insertion of parallel licences. Revocation, variation and suspension of marketing authorisation - Suspension of use etc of relevant medicinal product	Pharmacovigilance – suspension of use etc of medicinal product on grounds of harmful, effects do not outweigh risks or under General Power to Suspend, Revoke or Vary license (Reg 29)	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						reactions in the general population.		
PV	The Human Medicines (Amendment 2) Regulations 2013	2013 No. 2593	(xiva) 73(5A) to (5C)	Obligations of holder of marketing authorisation - Obligation to notify placing on the market etc.	Pharmacovigilance – Holder of UK MA must notify licensing authority if they request cancellation or do not apply for renewal of authorisation or if they withdraw the product. The holder must provide reasons for the action and also inform the EMA.	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.	2013	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xv) 75(2)(b) and (c),	In original HMRs though amended by 2014/1878 to reflect insertion of parallel licence. Obligations of holder of marketing authorisation - Obligation to provide information relating to safety etc.	Pharmacovigilance – post MA provision of any new information to the licensing authority related to clinical trials or other studies, and data on use outside of the MA	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xvi) 76,	In original HMRs though amended by 2014/1878 to reflect insertion of parallel licence. Obligations of holder of marketing authorisation - Obligation in relation to product information	Pharmacovigilance – post MA product information to be kept up to date with current scientific knowledge	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.		
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xvii) 79,	Offences relating to specific requirements - Failure to provide information on marketing authorisation to EMA	Pharmacovigilance – it is an offence to fail to submit required information to the EMA in relation to any medicinal products with an MA	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						reactions in the general population.		
PV	The Human Medicines (Amendment 2) Regulations 2013	2013 No. 2593	(xviia) 82(1)(c)	In original HMRs. Offences relating to EU marketing authorisations - EU marketing authorisations: failure to notify placing on market etc.	Pharmacovigilance – introduction of offence for failing to notify the EMA of suspending of marketing the product	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.	2013	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xviii) 85,	In original HMRs. Offences relating to EU marketing authorisations - EU marketing authorisations: failure to update product information	Pharmacovigilance – it is an offence to fail to ensure product information is kept up to date with current scientific knowledge	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xix) 86,	In original HMRs. Offences relating to EU marketing authorisations - EU marketing authorisations: breach of pharmacovigilance condition etc.	Pharmacovigilance – it is an offence to hold an EU MA and breach the Pharmacovigilance conditions	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.		
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xx) 97,	In original HMRs though amended by 2014/1878 to reflect insertion of parallel licence. General provisions relating to offences - Breach of pharmacovigilance condition	Pharmacovigilance – it is an offence for an MA holder with an MA subject to a condition (in reg 59, 60 or 61 above) to fail to comply with said condition	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						reactions in the general population.		
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xxi) 105(3)(b),	In original HMRs. Application for certificate of registration and consideration of application - Conditions of certificate of registration	Pharmacovigilance – granting of a certificate of registration in exceptional circumstances where applicant is unable to provide comprehensive data on safety	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xxii) 107(2),	In the original HMRs. Application for certificate of registration and consideration of application - Validity of certificate of registration	Pharmacovigilance – requirement, on grounds relating to pharmacovigilance, to make one further application for renewal of certificate of registration	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xxiii) 108(5),	In original HMRs. Application for certificate of registration and consideration of application - Application for renewal of certificate	Pharmacovigilance – application for a certificate of registration renewal to be made 9 months prior to expiration	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.		
FMD	The Human Medicines (Amendment) Regulations 2013	2013 No. 1855	(xxiv) 110(8A)	Revocation, variation and suspension of certificate of registration - Revocation, variation and suspension of certificate of registration.	Falsified Medicines – revocation, variation and suspension of certificate of registration if manufacture and control of product is not in compliance with provision of a dossier describing how the homoeopathic stock or stocks are obtained and controlled, and a manufacturing and control file for each pharmaceutical form and description of method of dilution and potentisation	The general objective of EU pharmaceutical legislation is to give concrete form of the Treaty's objective of free movement of goods for medicinal products while ensuring a high level of protection of human health. Against this background, the general objective is defined as maximising the protection of the legal supply chain in the EU against infiltration of counterfeit medicinal products, ie that for all practical purpose the possibility that medicinal products purchased in the legal supply chain in the EU are counterfeit	2013	The FMD came into force in 2011 (Directive 2011/24/EU) and was largely transposed into UK legislation in 2013. However some measures such as the common logo and safety features had a longer implementation time. Measures relating to the common logo were implemented in 2015 and the safety feature requirements need to be implemented by February 2019. As the Directive has not been fully implemented, it is considered too early to draw conclusions as to whether its objectives have been met and remain proportionate.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						can be practically ruled out.		
PV	The Human Medicines (Amendment 2) Regulations 2013	2013 No. 2593	(xxiva) 113(3A)	Obligations of holder of certificate of registration - Obligation to notify placing on the market etc.	Pharmacovigilance – holder of a certificate of registration must provide a reason to the licensing authority when withdrawing a product from the market	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.	2013	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xxv) 115(2)(b) and (c),	In original HMRs. Obligations of holder of certificate of registration - Obligation to provide information relating to safety etc.	Pharmacovigilance – post certificate of registration provision of any new information to the licensing authority related to clinical trials or other studies, and data on use outside of the certificate of registration	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xxvi) 132(2),	In original HMRs. Validity of traditional herbal registration - Validity of traditional herbal registration	Pharmacovigilance – requirement, on grounds relating to pharmacovigilance, to make one further application for renewal of traditional herbal registration	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.		
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xxvii) 133(5) and (6),	In original HMRs. Validity of traditional herbal registration - Application for renewal of registration	Pharmacovigilance – post traditional herbal registration provision of any new information to the licensing authority related to clinical trials or other studies, and data on use outside of the traditional herbal registration	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						reactions in the general population.		
FMD	The Human Medicines Regulations 2013	2013 No. 1855	(xxviii) 135(10A)	Revocation, variation and suspension of traditional herbal registration - Revocation, variation and suspension of traditional herbal registration.	Falsified Medicines – revocation, variation and suspension of traditional herbal registration if manufacture not carried out in accordance with schedule 12 – description of methods of manufacturing and control methods employed.	The general objective of EU pharmaceutical legislation is to give concrete form of the Treaty's objective of free movement of goods for medicinal products while ensuring a high level of protection of human health. Against this background, the general objective is defined as maximising the protection of the legal supply chain in the EU against infiltration of counterfeit medicinal products, ie that for all practical purpose the possibility that medicinal products purchased in the legal supply chain in the EU are counterfeit can be practically ruled out.	2013	The FMD came into force in 2011 (Directive 2011/24/EU) and was largely transposed into UK legislation in 2013. However some measures such as the common logo and safety features had a longer implementation time. Measures relating to the common logo were implemented in 2015 and the safety feature requirements need to be implemented by February 2019. As the Directive has not been fully implemented, it is considered too early to draw conclusions as to whether its objectives have been met and remain proportionate.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
PV	The Human Medicines (Amendment 2) Regulations 2013	2013 No. 2593	(xxviiia) 142(5A) to (5C)	Obligations of holder of traditional herbal registration - Obligation to notify placing on the market etc.	Pharmacovigilance – the holder of a traditional herbal registration must notify the licensing authority if they request cancellation or do not apply for renewal of the registration or if they withdraw the product. The holder must provide reasons for the action and also inform the EMA.	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.	2013	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.
Cross Border	The Human Medicines (Amendment) Regulations 2014	2014 No. 490	(xxviiib) 213(3)	Part 12 Chapter 1 - Interpretation	Prescriptions / Cross Border - any substance or product specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations 2001 or in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations (Northern Ireland)	A full impact assessment has not been produced for Cross Border / Prescription recognition across Member States as no, or no significant, impact on private, public or voluntary sectors was foreseen.	2014	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
					2002(3) shall be a product subject to special medical prescription			
Sale and supply of medicines	The Human Medicines (Amendment) Regulations 2016	2016 No 186	[(xxviiiba) 214(5c)]	Independent prescribing	Therapeutic radiographer exemptions listed as appropriate practitioners in relation to prescription only medicines as specified	DH impact assessment. Allows radiographers to supply POMs and special medical prescriptions listed.	2016	The amendments made to the Human Medicines Regulations 2012 by these provisions have been in force for just over a year, and they are therefore not included as part of the post-implementation review as it is too early to assess whether the objectives of the legislation have been met and remain proportionate.
Cross Border	The Human Medicines (Amendment) Regulations 2014	2014 No. 490	(xxviiic) 217A	Prescription only medicines - Requirements for prescriptions to be dispensed in an EEA state other than the UK	Prescriptions / Cross Border – insertion of conditions that are required for prescriptions that are to be dispensed within an EEA state other than the UK	A full impact assessment has not been produced for Cross Border / Prescription recognition across Member States as no, or no significant, impact on private, public or voluntary sectors was foreseen.	2014	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.
Cross Border	The Human Medicines (Amendment) Regulations 2014	2014 No. 490	(xxviiid) 218(2)(b) and (c), (3) and (5)	Prescription only medicines - Requirements for prescriptions: EEA health professionals.	Prescriptions / Cross Border – EEA health professional is legally entitled to issue prescription in the EEA state where it will be used; prescription is to be signed in ink by prescribing EEA health	A full impact assessment has not been produced for Cross Border / Prescription recognition across Member States as no, or no significant, impact on private, public or voluntary sectors was foreseen.	2014	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
					professional; prescription must contain particulars including patients details and information about medicine being prescribed Could not see 218(2)(c) in Amendment 2014 No:490			
Cross Border	The Human Medicines (Amendment) Regulations 2014 and Human Medicines (Amendment) Regulations 2015	2014 No. 490 and 2015 No. 903	[(xxviiie) 219 and 219A]	Prescription only medicines - Electronic prescriptions. .	Prescriptions / Cross Border – electronic prescription to be signed by advanced electronic signature when authorised by an appropriate practitioner other than an EEA health professional; and to be signed by an electronic signature when authorised by an EEA health professional. 219A applies to a prescription that is not a health prescription for a product subject to	A full impact assessment has not been produced for Cross Border / Prescription recognition across Member States as no, or no significant, impact on private, public or voluntary sectors was foreseen.	2014	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
					a special medical prescription.			
Sale and supply of medicines	The Human Medicines (Amendment) Regulations 2016	2016 No. 186	[(xxviiiea) 223(3)(b)]	Exemptions for Doctors and Dentists	Minor amendments to wording	Minor change.	2016	The amendments made to the Human Medicines Regulations 2012 by these provisions consist of changes which were considered too minor to be included in the public consultation associated with the post-implementation review. MHRA working group consideration of these provisions concluded that they remain appropriate for meeting the objectives of the legislation.
Sale and supply of medicines	The Human Medicines (Amendment) Regulations 2012 and The Human Medicines (Amendment) Regulations 2016	2015 No 323 and 2016 No. 186	[(xxviiif) 229(1)(db)and(dc)[and (2)]	Sale and Supply of prescription only medicines	Exemption for supply of medicinal products by national health service bodies. Regs 214(1), 220 and 221 do not apply in accordance with written directions of a doctor, dentist, nurse, independent prescriber, optometrist or pharmacist or PGD. [229(1) (2) adds optometrist physiotherapist, podiatrist and therapeutic	Para (1) (db) (dc) wording omitted from the original regs inserted in 2015. Para (2) physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber inserted in 2016. DH lead on policy.	2015 and 2016	The amendments made to the Human Medicines Regulations 2012 by these provisions consist of changes which were considered too minor to be included in the public consultation associated with the post-implementation review. MHRA working group consideration of these provisions concluded that they remain appropriate for meeting the objectives of the legislation.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
					radiographer independent prescriber]			
Sale and supply of medicines	The Human Medicines (Amendment) Regulations 2013 The Human Medicines (Amendment) Regulations 2015	2013 No. 235 and 2015 No. 503	[xxviiifa) 233(1)(a) (ivd) and (ive)]	Sale and supply of prescription only medicines under a PGD	Exemption for supply etc under a PGD by person conducting a retail pharmacy business. (ivd) and (ive) added PHE and PHA (NI equivalent) to list of organisations.	PHE and NI equivalent added to the list of bodies that can authorise PGDs.	2013 and 2015	The amendments made to the Human Medicines Regulations 2012 by these provisions consist of changes which were considered too minor to be included in the public consultation associated with the post-implementation review. MHRA working group consideration of these provisions concluded that they remain appropriate for meeting the objectives of the legislation.
Sale and supply of medicines	The Human Medicines (Amendment) Regulations 2015	2015 No. 1503	[(xxviig) 234(2) (e)]	Sale and supply of prescription only medicines under a PGD	Exemption for supply etc of products under a PGD to assist police etc.234(2) (e)] adds helicopter search and rescue to the list of organisations	A full impact assessment has not been produced as no, or no significant, impact on private, public or voluntary sectors was foreseen. Maritime and Coastguard Agency providers of search and rescue operations added to the list of groups able to use PGDs.	2015	Legislation meets the objectives of the Maritime and Coastguard Agency (MCA) by enabling search and rescue paramedics access to the same range of medicines as their counterparts in similar settings such as armed forces and NHS. MHRA working group consideration of these provisions concluded that they remain appropriate for meeting the objectives of the legislation.
Sale and supply of medicines	The Human Medicines (Amendment) Regulations 2012	2016 No 186	[(xxviiih) 248(1)(a) and (2)(a)	Exemption for certain collection and delivery arrangements	Supply of medicinal products on premises that are not a registered pharmacy (1)(a) where supply is in accordance with a prescription (2)(a)	Physiotherapist podiatrist therapeutic radiographer independent prescriber added in 2016. DH lead on policy.	2016	The amendments made to the Human Medicines Regulations 2012 by these provisions have been in force for just over a year, and they are therefore not included as part of the post-implementation review as it is too early to assess whether the objectives of the legislation have been met and remain proportionate.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
					arrangement for collection and delivery of a prescription to premises other than a registered pharmacy [248 (1)(a) and (2)(a) physiotherapist podiatrist therapeutic radiographer independent prescriber added]			
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xxix) 266(4) and (5),	Requirements for packaging and package leaflets relating to medicinal products - Language requirements etc.	Pharmacovigilance –exemptions from obligations regarding packaging and packaging leaflet for medicinal products under certain grounds	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						reactions in the general population.		
PV	The Human Medicines (Amendment) Regulations 2013	2013 No. 1855	(xxx) 327(2)(g) and insofar as the provision relates to active substances paragraphs (1)(c)(iii), (iv) and (viii), (2)(a) to (f), (3), (4) and (6)	Part 16 - Powers of inspection, sampling and seizure	Pharmacovigilance – an inspector may inspect information and documents relating to safety of medicinal products including pharmacovigilance obligations; 1(c)(iii) – (6) Falsified Medicines – 1(c) is incorrectly stated as 4(c) – an inspector, in relation to an application under Parts 3 or 5 to 8, may inspect info and documents relating to a brokering registration, registration as an importer, manufacturer or distributor of active substances and article 126(a) authorisation; 2(a) to (f), 3, 4 and	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population. The general objective of EU pharmaceutical legislation is to give concrete form of the	2013	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
					6 – inclusion of active substance as opposed to just medicinal product	Treaty's objective of free movement of goods for medicinal products while ensuring a high level of protection of human health. Against this background, the general objective is defined as maximising the protection of the legal supply chain in the EU against infiltration of counterfeit medicinal products, ie that for all practical purpose the possibility that medicinal products purchased in the legal supply chain in the EU are counterfeit can be practically ruled out.		
FMD	The Human Medicines Regulations 2012	2012 No. 1916	(xxxi) 330(1) and (2)	Part 16 - Analysis of samples: other cases.	Falsified Medicines – inclusion of active substances (as opposed to just medicinal products) purchased and submitted for analysis by someone other than an inspector or person authorised by the enforcement authority	The general objective of EU pharmaceutical legislation is to give concrete form of the Treaty's objective of free movement of goods for medicinal products while ensuring a high level of protection of human health. Against this background, the general objective is defined as maximising the protection of the legal supply chain in the EU against infiltration of	2012	The FMD came into force in 2011 (Directive 2011/24/EU) and was largely transposed into UK legislation in 2013. However some measures such as the common logo and safety features had a longer implementation time. Measures relating to the common logo were implemented in 2015 and the safety feature requirements need to be implemented by February 2019. As the Directive has not been fully implemented, it is considered too early to draw conclusions as to whether its objectives have been met and remain proportionate.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						counterfeit medicinal products, ie that for all practical purpose the possibility that medicinal products purchased in the legal supply chain in the EU are counterfeit can be practically ruled out.		
PV	The Human Medicines Regulations 2012	2012 No. 1916	(xxxii) 331	Part 16 - Findings and report of inspections	Pharmacovigilance – if following an inspection it has been found that pharmacovigilance requirements have not been complied with this must be brought to the attention of the MA or traditional herbal registration holder. After every inspection the enforcement authority must report on activities relating to Pharmacovigilance requirements	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
Repeal of Section 10(7)	The Human Medicines Regulations 2012	2012 No. 1916	(xxxiii) regulation 349 insofar as it repeals Section 10(7) of the Medicines Act 1698;	Part 17 - Transitional provisions, savings, amendments, repeals and revocations Repeal of pharmacy wholesale dealing in Section 10(7) of the Medicines Act 1968	Section 10(7) exempted pharmacies in the UK from requiring a wholesale dealers license which was incompatible with European legislation	The policy objectives are to create a regime which brings the UK into compliance with EU legislation, whilst taking 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). A repeal of the 10(7) exemption without any mitigating solutions would cause serious problems in terms of supplies of medicines for patient care, extra regulatory cost and administrative burden, particularly for the NHS, and the policy seeks to preserve continued medical supplies above all other concerns.	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.
			SCHEDULES					
FMD	The Human Medicines (Amendment) Regulations 2013	2013 No. 1855	Schedule 5 paragraphs 1(1)(b) to (d), (2)(b) to (d), 3(11)(b)(vi) to (viii), 5(2)(f) to (h)	Review upon oral representations	Falsified Medicines – inclusion of provisions for brokers registration, active substances registration and the removal from list	The general objective of EU pharmaceutical legislation is to give concrete form of the Treaty's objective of free movement of goods for medicinal products while ensuring a high level of protection of human	2013	The FMD came into force in 2011 (Directive 2011/24/EU) and was largely transposed into UK legislation in 2013. However some measures such as the common logo and safety features had a longer implementation time. Measures relating to the common logo were implemented in 2015 and the safety

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
					for review upon oral representation	health. Against this background, the general objective is defined as maximising the protection of the legal supply chain in the EU against infiltration of counterfeit medicinal products, ie that for all practical purpose the possibility that medicinal products purchased in the legal supply chain in the EU are counterfeit can be practically ruled out.		feature requirements need to be implemented by February 2019. As the Directive has not been fully implemented, it is considered too early to draw conclusions as to whether its objectives have been met and remain proportionate.
FMD	The Human Medicines (Amendment) Regulations 2013	2013 No. 1855	Schedule 7A	Qualified persons	Falsified Medicines – information to be provided when applying for registration as a importer, manufacturer or distributor of active substance	The general objective of EU pharmaceutical legislation is to give concrete form of the Treaty's objective of free movement of goods for medicinal products while ensuring a high level of protection of human health. Against this background, the general objective is defined as maximising the protection of the legal supply chain in the EU against infiltration of counterfeit medicinal products, ie that for all practical purpose the possibility that medicinal products purchased in	2013	The FMD came into force in 2011 (Directive 2011/24/EU) and was largely transposed into UK legislation in 2013. However some measures such as the common logo and safety features had a longer implementation time. Measures relating to the common logo were implemented in 2015 and the safety feature requirements need to be implemented by February 2019. As the Directive has not been fully implemented, it is considered too early to draw conclusions as to whether its objectives have been met and remain proportionate.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						the legal supply chain in the EU are counterfeit can be practically ruled out.		
PV	The Human Medicines (Amendment) Regulations 2013	2013 No. 1855	Schedule 8 paragraphs 9A, 12, 13, 19 and 23	Material to accompany an application for a UK marketing authorisation	Paras 12,13,19 & 23 - Pharmacovigilance – summary of pharmacovigilance system; risk management plan; summary of product characteristics and package leaflet where an application for authorisation is under consideration in a member state(s); medicinal products included in the central EU list of products that require additional monitoring. 9A - Falsified Medicines – written confirmation that manufacturer has verified compliance of the manufacturer of	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population. The general objective of EU pharmaceutical legislation is to give concrete form of the Treaty's objective of free	2013	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
					active substance with the principles of good manufacturing practice	movement of goods for medicinal products while ensuring a high level of protection of human health. Against this background, the general objective is defined as maximising the protection of the legal supply chain in the EU against infiltration of counterfeit medicinal products, ie that for all practical purpose the possibility that medicinal products purchased in the legal supply chain in the EU are counterfeit can be practically ruled out.		
PV	The Human Medicines (Amendment) Regulations 2014	2014 No. 490	Schedule 12 paragraph 21	Material to accompany an application for a traditional herbal registration	Pharmacovigilance – medicinal products included in the central EU list of products that require additional monitoring.	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended	2014	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
						effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.		
Sale and supply of medicines	The Human Medicines (Amendment) Regulations 2015	2015 No. 323	Schedule 16 Part 2 entries relating to PHE and PHA and Part 3 search and rescue	Patient Group Directions	PHE and PHA (NI equivalent) added to the list of persons on whose behalf a PGD must be signed	A full impact assessment has not been produced. PHE and NI equivalent added to the list of bodies that could authorise PGDs. (See Sale and Supply of Medicines amendments in 2013 and 2015 above)	2015	The amendments made to the Human Medicines Regulations 2012 by these provisions consist of changes which were considered too minor to be included in the public consultation associated with the post-implementation review. MHRA working group consideration of these provisions concluded that they remain appropriate for meeting the objectives of the legislation.
Sale and supply of medicines	The Human Medicines (Amendment) Regulations 2013, 2014, 2015 and 2016	2013 No, 2593, 2014 No. 490 and No. 1878, 2015 No. 1503 2016 No. 186	Schedule 17, Part 1 items 12 and 13, Part 2 items 4a, 11 and 12, Part 4 items 11 to 13 and Part 5 items 7a and 18	Exemptions from medicine legislation for sale and supply of medicines	Prescriptions - Part 1 items 12 and 13 exemptions for persons selling supplying POM in schools for use in emergencies; exemptions for orthoptists. Part 4 Exemptions to allow sale of General Sale List products on planes and trains and exemptions for registered orthoptists. Part 5 exemptions for	A full impact assessment has not been produced as no, or no significant, impact on private, public or voluntary sectors was foreseen. Allows the use of asthma inhalers by schools in an emergency. Lists exemptions for orthoptists to supply certain POMs. Allows the sale and supply of GSL medicines on planes and trains. Allows supply of naloxone to persons engaged in the provision of drug	See note in 'Policy Objective' column	Regulations implement DH policy to widen supply of salbutamol inhalers and naloxone in emergencies. DH has issued guidance. There is no evidence of unforeseen consequences. DH has agreed that salbutamol inhalers are out of scope for this review. Legislation to add exemptions for optometrists has been in force for just over a year. A decision was made by a MHRA working group that it is too early to assess whether the objectives have been met/remain proportionate. The amendment to allow sale of GSL medicines on planes and trains has achieved its stated objective of

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
					persons employed in the provision of drug treatment services and for employees of schools to administer named medicines in an emergency.	treatment services for use in an emergency. **NOTE** - Sale of GSL products on Trains and Planes 2013.Salbutamol inhalers added Oct 2014 Naloxone added October 2015 Optometrists added April 2016		widening access of GSL medicines to the public.
Sale and supply of medicines	The Human Medicines (Amendment) Regulations 2015	2015 No. 323	Schedule 22 entries relating to PHE, PHA and search and rescue	Patient Group Directions	Reg 249 prevents a person from selling a prescription only medicine or pharmacy medicine to any one who does not fall into a class specifies in Schedule 22. Entries relating to PHE, PHA and search and rescue added to the list in Schedule 22	PHE and NI equivalent added to the list of bodies that could authorise PGDs. UK Search and Rescue added to the list of groups able to use PGDs.(See Sale and Supply of Medicines amendments in 2013 and 2015 above).	2015	The amendments made to the Human Medicines Regulations 2012 by these provisions consist of changes which were considered too minor to be included in the public consultation associated with the post-implementation review. MHRA working group consideration of these provisions concluded that they remain appropriate for meeting the objectives of the legislation.

Reg area	Legal instrument	SI No	Provisions specified for review in Regulation 346	Policy area	Regulation	Policy Objective	Year	Post-implementation review outcome - August 2017
Sale and supply of medicines	The Human Medicines Regulations (Amendment) Regulations 2016	2016 No 186	Schedule 23 para 1(a)(vii) to (ix)	Particulars in pharmacy records	Pharmacists, podiatrists, physiotherapists and therapeutic radiographers added to list of healthcare professional	Physiotherapist, podiatrist therapeutic, radiographer, and independent prescriber added in 2016.	2016	The amendments to the Human Medicines Regulations 2012 to add physiotherapists, podiatrists and therapeutic radiographers to the list of independent prescribers has been in force for just over a year. They are therefore not included as part of the post-implementation review as it is too early to assess whether the objectives of the legislation have been met and remain proportionate.
PV	The Human Medicines Regulations 2012	2012 No. 1916	Schedule 27 paragraphs 14 and 15	Package leaflets	Pharmacovigilance – package leaflets must include the yellow card reporting note and the date on which the package leaflet was last revised	The policy aims to remove unjustified costs placed upon industry by regulators under the current European legal framework, through the use of work-sharing and harmonised processes. The policy also aims to ensure that pharmacovigilance resource is expended (in both the pharmaceutical industry and the MHRA) in a targeted way at areas of greatest risk to patients. The intended effect is to alleviate burdens upon industry whilst at the same time maintaining public health, and reducing the numbers of adverse drug reactions in the general population.	2012	The conclusions of the post-implementation review in relation to these provisions are summarised in the research and analysis Section of the final review report, and detailed in Annex 3 of the final review report.

Annex 5

Title: Post-implementation Review of the Human Medicines Regulations 2012 **PIR No:** Click here to enter text. **Original IA/RPC No:** Click here to enter text. **Lead department or agency: MHRA** **Other departments or agencies:** **Department of Health** Contact for enquiries: Paul McCormack, MHRA Policy Division, T. 0203 080 6965.	Post Implementation Review **Date:** Click here to enter a date. **Type of regulation: EU** **Type of review: Statutory** **Date measure came into force:** **14/08/2012 (31/03/2014 for Cross Border recognition of prescriptions)** **Recommendation: Keep** **RPC Opinion:** Choose an item.

1. What were the policy objectives of the measure? (Maximum 5 lines)

The Human Medicines Regulations 2012 consolidated medicines legislation in one place and were designed to create shorter, simplified law that was easier to understand and apply. In addition, the 2012 Regulations were designed to:

i) implement national requirements of EU pharmacovigilance (PV) legislation, Directive 2010/84/EU;

ii) implement Directive 2012/52/EU to address problems associated with cross border recognition of prescriptions; and,

iii) repeal Section 10(7) of the Medicines Act 1968 (which exempted a pharmacist in a registered pharmacy from holding a Wholesale Dealer's licence in certain circumstances) in order to comply with Articles 77(1) and 77(2) of Directive 2001/83/EC (which required anyone undertaking wholesale dealing activities to hold an authorisation), whilst also taking account of the UK's National Health Service.

2. What evidence has informed the PIR? (Maximum 5 lines)

MHRA ran a public consultation exercise from 15 June to 6 July 2017 seeking views on the implementation of the PV Directive, recognition of cross border prescriptions, and repeal of Section 10 (7), as part of a consultation of all of the provisions of the Human Medicines Regulations 2012 within scope of a wider Post-implementation Review under Regulation 346. The consultation attracted over 60 responses.

The EC report on PV related activities (2012 to 2014) statistics on the work of the Pharmacovigilance Risk Assessment Committee (PRAC) and also information collected for the Strengthening Collaboration and Operation of Pharmacovigilance in Europe (SCOPE) joint action project led by MHRA. The PV legislation requires audits of all National Competent Authorities and MHRA is noted to be a 5 star regulator through benchmarking.

3. To what extent have the policy objectives been achieved? (Maximum 5 lines)

PV Directive: Work-sharing across the EU has led to safety changes being introduced in a consistent, timely and transparent manner; some administrative burden reductions for industry have been introduced and others are on-going; and, information is more readily available to patients through web-portals and patient organisations have been involved in decision-making.

Cross border prescriptions: The measure has improved access to medicines for patients. The PIR consultation has identified, however, that the measure has increased the workload of some pharmacists and healthcare professionals. To help mitigate that burden, MHRA plans to review the guidance currently available to pharmacists and healthcare professionals on processing cross border prescriptions with a view to publishing revised guidance to aid awareness and understanding.

Repeal of Section 10(7): Over 20 responses to the public consultation expressed concern about the impact of the measure on the NHS supply chain. Medicine supply problems can occur for a number of reasons, however, such as manufacturing problems, difficulties in obtaining raw materials or regulatory issues. The Department of Health (DH) monitors supply shortages that may occur. Both MHRA and DH work with licensed pharmaceutical manufacturers and distributors to mitigate supply shortages. In addition, the DH, MHRA and Home Office have held joint meetings with representatives from hospices and NHS ambulance trusts since the repeal of Section 10(7) to discuss supply arrangements for medicines. There have been no reports of patients not receiving their medicines because of the repeal of Section 10(7).

Further provisions in the Human Medicines Regulations within scope of the PIR: Respondents to the public consultation were generally supportive of the 2012 consolidation.

Sign-off for Post Implementation Review: Chief economist/Head of Analysis and Minister

I have read the PIR and I am satisfied that it represents a fair and proportionate assessment of the impact of the measure.

Signed: Click here to enter text. Date: Click here to enter a date

Further information sheet (Post-implementation review of the Human Medicines Regulations 2012)

Please provide additional evidence in subsequent sheets, as required.

4. What were the original assumptions?(Maximum 5 lines)

PV Directive: The EC Impact Assessment assumed that the changes to legislation would (i) clarify roles and responsibilities, (ii) rationalise EU decision-making on drug safety issues, (iii) strengthen medicines safety transparency and communication, (iv) strengthen companies' pharmacovigilance systems, (v) ensure proactive and proportionate collection of safety data, and vi) provide for greater involvement of relevant stakeholders in pharmacovigilance. The recent PIR consultation suggests these original assumptions remain valid.

Cross border prescriptions: that the proposals would be a low cost regulatory measure. Stakeholders did not envisage significant demand for cross-border prescriptions. The recent PIR consultation suggests these original assumptions remain valid.

Repeal of Section 10(7): Assumptions were made about the number of healthcare practices that obtained medicines from pharmacies, based on NHS data for England; the behaviour of the pharma sector with respect to restricting supplies of branded medicines; the efficiency of stock control by pharmacies and a potential increase in the number of wholesalers supplying small quantities of stock to healthcare practices. The recent PIR consultation suggests these original assumptions remain valid.

5. Were there any unintended consequences? (Maximum 5 lines)

PV Directive: the additional burden imposed by the requirement for Risk Management Plans (RMPs) for all generics marketing authorisation (MA) applications is an area where the requirement may be disproportionate to the risk – the UK negotiating position was that RMPs should not be required for all generic MAs but rather dependent on risk and the need for specific risk management.

Cross border prescriptions: None have been identified.

Repeal of Section 10(7): Home Office legislation on licences for Controlled Drugs provided an exemption that relied upon Section 10(7). Hence the repeal of Section 10(7) resulted in the need for more HO Licences – but a “grace period” was provided for healthcare organisations.

Further information sheet (Post-implementation review of the Human Medicines Regulations 2012) (contd)

6. Has the evidence identified any opportunities for reducing the burden on business? (Maximum 5 lines)

PV Directive: Taking a more risk proportionate approach with regards to the need for and the evaluation of RMPs for generics would be an important opportunity for further reducing the burden on both industry and regulators. In the light of the evidence gathered in the PIR, MHRA is considering the options for remediation, for example further encouraging work sharing between generic MA holders.

Cross border prescriptions: the PIR public consultation has highlighted some practical issues associated with the processing of EU generated prescriptions, for example inconsistent formatting, incomplete information, prescriptions for medication not available in the UK. These practical issues may result in increased burdens on some prescribers arising from cross border prescriptions not being processed. MHRA plans to review the guidance currently available to pharmacists and healthcare professionals on processing cross border prescriptions, with a view to publishing revised guidance to aid awareness and understanding, and thereby reduce burdens on all healthcare professionals involved in such work.

Repeal of Section 10(7): The PIR public consultation has identified that concerns remain about the impact on the maintenance of essential medical supplies, particularly in the NHS. MHRA proposes to consider these concerns and decide what further action might be appropriate, such as revised guidance to aid common understanding about the operation of the repeal of Section 10(7) and to reflect that more NHS Trusts now outsource their pharmacy departments to a third party.

Further information sheet (Post-implementation review of the Human Medicines Regulations 2012) (contd)

7. For EU measures, how does the UK's implementation compare with that in other EU member states in terms of costs to business? (Maximum 5 lines)

PV Directive: Evidence gathered during the PIR suggests that the PV directive has been transposed into UK law in a proportionate way with no 'gold plating' and minimal burden on business whilst at the same time ensuring a harmonised approach with other EU member states. PV Directive implementation has been discussed and agreed at EU level. The new processes and procedures have been overseen by a task force composed of member states and EMA that has ultimately reported through to Heads of Medicines Agencies. The MHRA led SCOPE project has also ensured sustainability for the future; this project published outcomes in February/March 2017 – see: http://www.scopejointaction.eu/

Cross border prescriptions: Evidence gathered during the PIR suggests that the prescriptions measure has been transposed into UK law in a proportionate way with no 'gold plating' and minimal burden on business whilst at the same time ensuring a harmonised approach with other EU member states.

Repeal of Section 10(7): All wholesalers in the EU must be licensed and listed in the EUDRAGMDP system with a GDP certificate of compliance. There was no gold plating in the UK implementation of the EU requirements for wholesalers. The EMA GMDP Inspectors' Working Group provides for a consistent approach. Evidence gathered during the PIR suggests that articles 77(1) and 77(2) have been transposed into UK law in a proportionate way with no 'gold plating' whilst at the same time ensuring a harmonised approach with other EU member states.

Opinion: post-implementation review
Origin: EU
RPC reference number: RPC17-DH-MHRA-4144(1)
Date of review: August 2017

Regulatory Policy Committee

Human Medicines Regulations 2012

Department of Health/ Medicines & Healthcare products Regulatory Agency

RPC rating: fit for purpose

Description of proposal

The Human Medicines Regulations 2012 consolidated medicines legislation in one place and were designed to create shorter, simplified law that was easier to understand and apply. In addition, the 2012 Regulations were designed to:

i) implement national requirements of EU pharmacovigilance (PV) legislation, Directive 2010/84/EU;
ii) implement Directive 2012/52/EU to address problems associated with cross border recognition of prescriptions;
iii) repeal Section 10(7) of the Medicines Act 1968 (which exempted a pharmacist in a registered pharmacy from holding a Wholesale Dealer's licence in certain circumstances) in order to comply with Articles 77(1) and 77(2) of Directive 2001/83/EC (which required anyone undertaking wholesale dealing activities to hold an authorisation), whilst also taking account of the UK's National Health Service.

The post-implementation review (PIR) fulfils a five-year statutory review of these changes.

Impacts of proposal

The Agency has sought to obtain a range of evidence to inform its PIR on the measures. In doing so, it explains that it received 60 responses to its consultation held between June and July 2017. Responses generally suggested that the policy objectives had been achieved. In particular respondents felt that:

- The consolidation of legislation had been net beneficial to business;
- The PV Directive had reduced administrative burdens and made information more readily available for decision-making on drug safety;
- On cross border prescriptions, the measure had created an improvement in access to medicines for patients, though some healthcare professionals felt

this had led to an increase in workload. The Agency intends to mitigate this through a review of guidance to aid awareness and understanding.

- On the repeal of section 10(7) of the Medicines Act, concerns were raised of an impact on the NHS supply chain that could lead to supply shortages, though the PIR notes that both the Department and Agency undertake monitoring of the supply in order to mitigate this risk.

Overall, the Agency argues that:

- the evidence gathered broadly supports the original assumptions it had made about the measure; and
- that the consolidation of regulations has led to a more consistent, simpler and more transparent system with reduced costs to business, while the additional elements were transposed with the minimal burden on business and no evidence of gold plating of requirements.

It therefore argues that its original estimates of costs and benefits remain broadly valid as shown in the table below:

Impact Assessment	**Total Costs** (best estimate, present value unless otherwise stated)	**Total Benefits** (best estimate, present value unless otherwise stated)	**Net Benefit Present Value** (best estimate)
Consolidation of UK medicines legislation	£2.4m	£11.5m	£9.0m
Pharmacovigilance Directive	£65.9m	£48.9m	Minus £17.0m
Repeal of Section 10(7)	£28.3m	Unquantifiable **	Minus £28.3m
Cross border prescriptions	£10.27m (midpoint estimate)	n/a	n/a

Regulatory Policy Committee

Quality of submission

The Agency has provided proportionate evidence from consultation to support the retention of the measures with some amendments such as guidance changes. It argues that the objectives of the various changes have been achieved with minimal impact on business. However, the analysis could have been made more robust by the appropriate use of relevant data or statistics to assess whether the success criteria have been met, or to revisit original cost/benefit assumptions. This is of particular note given that the Agency argues that a light touch PIR is appropriate to a package whose NPV totals about £35 million.

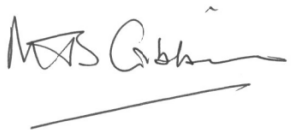
The PIR clearly identifies and discusses the unintended consequences of the measures (e.g. criminal market in para 38) and suggests approaches to addressing these through mitigation to reduce the burdens on business.

Finally, the PIR would have benefited from a brief discussion on implementation of the regulations in other member states, to provide a comparison and to note any lessons that could be learned for UK implementation.

Departmental recommendation	Retain

RPC assessment

Is the evidence in the PIR sufficiently robust to support the departmental recommendation?	Yes



Michael Gibbons CBE, Chairman