26 March 2013

MHRA simplification measures announced following Red Tape Challenge

The Medicines and Healthcare products Regulatory Agency (MHRA) is today announcing a package of simplification proposals. This follows participation in the Cabinet Office Red Tape Challenge exercise last year.

In total 253 MHRA regulations were published in this RTC theme for public comment. 208 (over 80% of these) were consolidated in the Human Medicines Regulations 2012, which is one of the highest in the RTC so far. Published alongside this text is a spreadsheet showing the decision made on every regulation in the RTC.

The challenge process largely validated the European framework within which medicines are regulated, so the majority of proposals being announced are non-statutory. The proposals include process changes for applying for a variation to a licence and a review of MHRA guidance as part of transition of content to Gov.UK by March 2014. The MHRA will bring forward proposals to permit sale of medicines on planes and trains later this year, which will require a change to the law in the autumn. Information on the proposals is at Annex A.

In addition to the measures announced today, a new reclassification process for over-the-counter medicines to switch from prescription to non-prescription status, co-produced with industry, came into force in December 2012 and was announced by the Chancellor in his December autumn statement. MHRA has previously announced a review of sanctions and penalties and continues to lobby on risk-adapted approaches to clinical trials in the EU regulation negotiations.

A number of meetings have been held with business throughout the RTC process. An assessment by MHRA of all 260 RTC proposals was shared with industry who agreed with MHRA's assessment that 47 of the suggestions had already been delivered or did not require regulatory change since these had never been a requirement of legislation. The remaining proposals have been prioritised for implementation. The new Medicines Industry Liaison Group, meeting for the first time on 27 March 2013, will provide a forum for MHRA and business continue to prioritise and consider the impact of the measures being announced.

An announcement on two DH pharmacy-related regulations in this RTC theme will be made later in the year.

Annex A - MAIN AREAS OF PROPOSED REFORM FOLLOWING RTC

MHRA Guidance

1. Many comments were received about how the Agency produces and publishes guidance, and its legal status. Views were wide ranging.

2. As agreed with ministers, during 2013/14, the MHRA website will be integrated with the new government platform GOV.UK. As part of this, the MHRA will carry out a full audit and categorisation of content and remove outdated material by March 2014. Getting industry agreement on the principles, format, delivery mechanisms, and review arrangements for guidance will be key. The MHRA will conduct the review in phases according to the areas of regulation.

Variations processing review

3. Issuing licences is a core medicines licensing process and monthly there are around 4250 variations (amendments) to licences. These range from simple administrative changes to a licence such as change of address of the licence holder, to important public health information such as medicine dosage. This was the most popular theme under the medicines theme of RTC. The main issues raised were whether variations could be triaged and grouped for assessment, possible further worksharing with other Member States and questions around the UK requirement for Summary of Product Characteristic (SmPC) fragments to be submitted with initial and variation submissions. The latter was introduced in order to facilitate efficient handling of concurrent variations for the same product. Some parts of industry like this, whilst others see it as an administrative burden. To change it would require a major IT system change and would impact on assessment processes, but MHRA will consider whether this is feasible.

Extension of "do and tell"

4. Pharmaceutical regulation requires companies to submit data regularly to MHRA and make applications. If companies do not know how long the subsequent regulatory approval will take, the commercial costs can be significant. Timeline certainty is therefore key for industry and a principle of "do and tell" can remove some of these problems. Successful MHRA notification schemes already introduced under the Better regulation of medicines initiative (BROMI) scheme for patient information and pharmacovigilance and for clinical trials are successful examples on which to build.

Sanctions and penalties

5. There are many criminal offences in medicines legislation. The consolidation of medicines legislation project included 64 offence provisions (reduced from c.150) and there remain some in other legislation. During the consolidation exercise and passage of the Health and Social Care Act 2012, DH Ministers committed to a review of medicines sanctions and penalties, including consideration of S56 of the Medicines Act 1968 and dispensing errors.

6. DH, with MHRA, has also identified the need to look at the balance between professional regulation and standards and medicines legislation in safeguarding the public in relation to healthcare professionals' use of medicines. We will explore the respective roles of professional regulation and medicines regulation and consider the

scope to rely more on professional standards rather than legislation to deliver those necessary safeguards.

Fees simplification

7. Industry has asked MHRA to keep as a priority for review the issue of fees charged for assessing applications. In April 2012, during the live phase of the RTC, MHRA introduced a simplification and fees reduction package. On 1 April 2013, subject to parliamentary privilege, MHRA will introduce new burden-reducing legislation to:

Amend legislation to permit sale on planes and trains

8. General Sale List (GSL) medicines, such as painkillers, are widely available to the public through a variety of retail outlets and not just pharmacies, but can only be sold from "premises". Certain medicines such as painkillers can be sold on trains in other countries, such as the USA. Informal consultation with industry has been positive but MHRA needs to consider wider public and legal considerations. If a change were made, it could be done as part of other planned changes to secondary legislation in autumn 2013 and would not require primary legislation.

Inspection benefits for compliant companies

9. As part of the risk-based inspection programme, MHRA will evaluate what the benefits are for compliant companies.

Overall list of proposals MHRA will consider, as discussed with business in 2012.

Some of these proposals will be subject to further consultation ahead of decisions being taken on implementation

No.	RTC theme	Proposed RTC action
1	**Medicines**	**Review of guidance and forms**
2	**Fees**	**Further simplification of fees**
3	**Medicines**	**Review of sanctions & penalties**
4	**Medicines**	**Extend Notification Principle**
5	**Medicines**	**Inspection benefits for compliant companies**
6	**Medicines**	**Tracking Applications as part of repurposing of RamaXL**
7	**Medicines**	**Variations processing review and review of need for SmPC fragments**
8	**Medicines**	**Streamlined Reclassification Process**
9	**Clinical Trials**	**Clinical Trials Renegotiation. UK position to be developed in 2012**
10	**Medicines**	**Amend legislation to permit sale on planes & trains**
11	Blood	Respond to European Commission request for suggestions for technical amendments to the blood directives
12	Clinical Trials	Find out how other MS handle access to medicines until commercially available.
13	Clinical Trials	Discuss with HRA possible cross-Government “nomenclature” for all CT approval documentation
14	Clinical Trials	Produce FAQ to clarify UK law and ICH position on retention of clinical trial documentation
15	Clinical Trials	Include information in clinical trial approval letter on process for queries
16	Fees	Extend iRIS accounting payments system to cover all MHRA charges eg inspections, advice meetings
17	Fees	Include MHRA fee type on RAMA XL IT system
18	Fees	Consider IT change to send inspection invoices for foreign sites directly to the site
19	GLP	Ask OECD working group to consider interpretation of GLP principles
20	Herbals	Revise the current requirement for traditional herbal medicinal products to demonstrate that at least 15 of the 30 years history of use has been within the EU
21	Herbals	Raise in EU Extend scope of THR to non-herbal ingredients
22	Medicines	Allow MA Holder access to Common Technical Document (CTD)
23	Medicines	Review wholesale dealer licence requirements/pack contents for vessels and their suppliers
24	Medicines	IT change for company to enter Summary of PV System information once

25	Medicines	New guidance on Batch specific variations
26	Medicines	Revised guidance on clarification of variation category and grouping
27	Medicines	Consult on revised guidance on MHRA policy on product naming
28	Medicines	Consider lobbing EU on advertising to teenagers for acne products
29	Medicines	Review pre-vetting for advertising to identify the potential for reduction
30	Medicines	Review use of lay language and essential information requirements for adverts
31	Medicines	Review MHRA website navigability in move to .Gov.UK
32	Medicines	Consider with wider Government extension of one year data exclusivity for reclassified medicines to incentivise wider availability
33	Medicines	Develop programme of work to assess balance between medicines regulation and Professional Regulation
34	Medicines	Consult on non-NHS paramedic use of Patient group Directions

Links

1. Link to Red Tape Challenge website.
http://www.redtapechallenge.cabinetoffice.gov.uk/home/index/

2. The Chancellor's Autumn Statement of 5 December 2012 in which he announced the new reclassification procedure and review of guidance is at http://cdn.hm-treasury.gov.uk/autumn_statement_2012_complete.pdf

3. The PM's Life Sciences One year on report of 6 December 2012 is at http://www.bis.gov.uk/assets/biscore/innovation/docs/s/12-1346-strategy-for-uk-life-sciences-one-year-on.pdf

4. The consolidated UK medicines legislation The Human Medicines Regulations 2012 SI 2012/1916 came into force on 14 August 2012. It consolidated large parts of the Medicines Act 1968 and 208 of the regulations published in the RTC medicines live phase. It is available at http://www.legislation.gov.uk/uksi/2012/1916/contents/made