Business function	Description	Target publications date
Devices		
Brexit overview for Devices	Introduction to guidance	25/02/2019
The legislation	How devices are regulated before and after 29 March 2019	25/02/2019
The role of the MHRA	In relation to Devices for no deal	25/02/2019
Role of those manufacturing and supplying devices	UK authorised representative (AR), plus need for EU AR; UK RP responsibilities (including AITS)	25/02/2019
Determining whether your product is a device	Information on current webpage remains relevant until 29 March 2019	25/02/2019
Classification	Information on current webpage remains relevant until 29 March 2019	25/02/2019
Clinical investigations and performance evaluations	Information on current webpage remains relevant until 29 March 2019	25/02/2019
CE marking your device	Information on current webpage remains relevant until 29 March 2019	25/02/2019
Conformity assessment	Information on current webpage remains relevant until 29 March 2019	25/02/2019
Labelling requirements		25/02/2019
Registrations	Information on current webpage remains relevant until 29 March 2019	25/02/2019
Post-market surveillance and vigilance	Information on current webpage remains relevant until 29 March 2019	25/02/2019
Inspection and Assurance		
Clinical trial supplies	Publish IMP 'countries on a list' guidance - linked to legislative requirement	01/03/2019
Clinical trial supplies	Guidance on IMP supply process from EEA (Sponsor and QP responsibilities)	01/03/2019
GMP certificates	Letters to re-issue GMP certificates to UK sites	18/01/2019
Blood Establishment	Blood Establishment guidance	01/02/2019
Continuity of supply of investigational medicines	IMP supply process from EEA. Sponsor and QP focussed	18/02/2019
Whitelist system	Publish 'Countries on a list' - QP certification, QC testing and inspections - linked to legislative requirement	25/02/2019
Whitelist system	Publish 'Countries on a list' - QC testing and inspections - linked to legislative requirement	25/02/2019

Whitelist system	Publish 'Countries on a list' - API GMP - linked to legislative requirement	25/02/2019
Unlicensed imports	Stakeholder guidance on unlicensed medicines supply	01/03/2019
Varying wholesale (WDA) authorisations (Process licence submissions)	Comms and guidance required for new WDA / RP-I process and requirement (importation from EEA)	01/03/2019
Varying wholesale (WDA) authorisations (Process licence submissions)	Publish guidance on variations and applications for WDA holders	01/03/2019
New WDA(H) application form (Process licence submissions)	New application / variation forms (for new applicants and when naming RPIs on amended WDA(H))	01/03/2019
GMP certificates	Publish compliance statements for APIs (Written Confirmations)	01/03/2019
Variations to MAs	QPPV / PSMF variations guidance	15/03/2019
Update all PcL application forms to remove EU references	Update application forms for existing licence types (remove EU references if necessary)	29/03/2019
Compliance actions	Publish, on MHRA website, copies of GMP (Parts I-IV), and formalised risk assessment re excipients, and GDP – regulation C17(3)	29/03/2019
Licensing		
Centrally Authorised MAs	Guidance on final technical details for submitting a baseline and for handling applications pending on exit day.	01/03/2019
Initial MAs	Guidance on handling of pending MRDC initial applications on exit day	01/03/2019
Variations	Guidance on handling of variations including those MR variations that are pending on exit day	01/03/2019
Initial MAs	Guidance on ongoing referrals at exit day	01/03/2019
Orphan Products	New guidance explaining that UK incentives and that compliance with orphan criteria will be determined at the time of marketing authorisation.	06/03/2019
Initial MAs	To define the new MA processes required for targeted assessment , accelerated assessment.	06/03/2019

Initial MAs	Requirements for reference products for abridged applications in the UK	06/03/2019
Initial THR	Update to guidance on traditional use requirements and list of herbal substances, preparations and combinations.	06/03/2019
Initial HR/NR	Update to guidance on homeopathic medicinal products.	06/03/2019
Initial MAs	Update guidance on PMFs	06/03/2019
Initial MAs	Update to guidance on ATMPs	06/03/2019
Initial MAs	Update to guidance on Biosimilars	06/03/2019
Initial MAs	Update to guidance on CEPs and ASMFs	06/03/2019
Initial MAs	To further define the outline for rolling review required for new MAs	29/03/2019
Centrally Authorised MAs	CAP conversion guidance and PL number allocation	Completed
Clinical Trial Authorisations	Guidance on registration of clinical trials of investigational medicinal products and publication of summary results	07/03/2019
NIBSC		
Batch Release testing	Guidance for manufacturers of biological medicines regarding independent batch testing requirements	22/02/2019
Provision of biological reference materials	Information for customers biological reference materials	28/02/2019
Research	Information for NIBSC collaborators	28/02/2019
New IT System		
User Reference Guide	Step by Step guide to submitting MAH submissions via the MHRA Portal	29/03/2019
Information	Q&As related to submitting MAH submissions via the MHRA Portal	29/03/2019
User Reference Guide	Step by Step guide to submitting Clinical Trial submissions via the MHRA Portal	29/03/2019
User Reference Guide	Navigation guide to the landing page of the portal including raising issues	29/03/2019
Information Pack for Brokers inc URG and information	Explains how companies register and submit via portal	29/03/2019

Information	Q&As for the range of stakeholders needing to gain access to the portal	04/03/2019
Information	Q&As on the Company Administrator role	04/03/2019
User Reference Guide	Step by step guide to gain access to the MHRA Portal	04/03/2019
User Reference Guide	Step by step guide on the Company Administrator role	04/03/2019
Information	Q&As related to testing and setting up via Gateway	11/03/2019
User Reference Guide	A step by step guide to the registration process in order to retrieve Gateway encryption	11/03/2019
User Reference Guide/ short slide deck	Step by Step guide to submitting Clinical Trial submissions via the MHRA Portal	11/03/2019
User Reference Guide	A step by step guide to the registration and test process for submitting via ICSR Submissions	11/03/2019
User Reference Guide	A step by step guide to the submission of ICSRs and PV Referrals using MISP	11/03/2019
Information	Q&As related to ICSR Submissions	11/03/2019
Registration form for eSUSAR	Information for registration on eSUSAR portal	11/03/2019
eSUSAR Online Reporting A quick guide	Registering users, managing trials, step by step submission of SUSAR	11/03/2019
Vigilance, Surveillance and Paediatrics		
Pharmacovigilance procedures (PSURs, RMPs, PASS, Safety referrals)	Further guidance on pharmacovigilance procedures	01/03/2019
Renewal: marketing authorisation for a human medicine	Guidance for submission including fee	08/03/2019
Paediatrics	Update to existing guidance on legal requirements for children's medicines on MHRA website	08/03/2019
Paediatrics	Guidance on procedures for UK PIPs	08/03/2019
Paediatrics	Guidance on completed paediatric studies	08/03/2019
Market Surveillance of Medicines	Processes for sending and receiving ICSRs	15/03/2019
Patient Information	Updated guidance on patient information	29/03/2019

Pharmacovigilance	List of medicinal products subject to additional monitoring under regulation 202A	29/03/2019
User Reference Guide	Process for manufacturers and producers to submit key product information	29/03/2019
Information	Questions for e-cigarette producers	29/03/2019
Information	E-cigarettes: regulations for consumer products	29/03/2019
Guideline on the format and content of applications for agreement or modification of a paediatric investigation plan and requests for waivers or deferrals and concerning the operation of the compliance check and on criteria for assessing significant studies(2014/C 338/01)	Explains the process for companies submitting paediatric investigation plans	29/03/2019
User Reference Guide for companies submitting PiP inc other sub processes	Give screenshots and step by step guidance	29/03/2019
Information for companies to deal with additional process queries	Q&As	29/03/2019
Information	Explains the process for companies submitting PSURS to the MHRA (webpage update)	29/03/2019
Information	Explains the process for companies submitting via the new portal	29/03/2019
Information	Addresses likely questions from PSUR submitters using the new process	29/03/2019