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REGULATORY NEWSLETTER N.23

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Introduction

CROMSOURCE is committed to sharing our expertise with our clients and future clients. This reflects the first part of our 'Advise Agree Deliver' motto! In this spirit we have pleasure in making available this issue of our Regulatory Newsletter.

This newsletter is put together by our expert regulatory team and tracks the changes occurring in European and US regulations relating to clinical research performed in both medicinal products and medical devices.

The Newsletter is a quarterly publication distributed via email and posted on the CROMSOURCE website. We hope you find this information useful, and welcome feedback, questions and suggestions.

Contact us on cromsource@cromsource.com at any time.

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Contents

Abbreviations

Acronym	Definition
ASCA	Accreditation Scheme for Conformity Assessment
ATMPs	Advanced Therapy Medicinal Products
BCS	Biopharmaceutics Classification System
eCTD	electronic Common Technical Document
CAPs	Centrally Authorised Products
CAR-T	chimeric antigen T cell receptor
CDER	Center for Drug Evaluation and Research
CDRH	Centre for Devices and Radiological Health
CE	Conformité Européene (European Conformity)
CESP	Common European Submission Portal
CGMP	Current Good Manufacturing Practice
CLIA	Clinical Laboratory Improvement Amendments
CTIS	Clinical Trial Information System
CTFG	Clinical Trials Facilitation Group
CTIMPs	Clinical Trials of Investigational Medical Products
CTR	Clinical Trials Regulation (EU): 536/2014
CUP	Compassionate Use Program
DSUR	Development Safety Update Report
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration (United States)
FD&C Act	Food Drug & Cosmetic Act
HDE	Humanitarian Device Exemption
HRA	Health Research Authority (UK)
ICF	Informed Consent Form
ICH	International Conference for Harmonization
IEC	International Electrotechnical Commission
IMDRF	International Medical Device Regulators Forum
IMP	Investigational Medicinal Product
IRIS	EMA online portal for orphan designation process
IT	information-technology
IVDR	In Vitro Diagnostics Regulation, EU 2017/746
IVDMDs	In Vitro Diagnostics Medical Devices
MAH	Marketing Authorisation Holder

Acronym	Definition
MAPP	Manual of Policies and Procedures
MD	Medical Device
MDR	Medical Device Regulation ,EU 2017/745
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
MNP	Medical Need Program
MRA	Mutual Recognition Agreement
MS	Member State
QP	Qualified Person
QPPV	Qualified Person for Pharmacovigilance
PMA	Premarket Approval
PSMF	Pharmacovigilance System Master File
SAE	Serious Adverse Events
SSIL	Site Surveillance Inspection List
SSM	Site Selection Model
UDI	Unique Drug Identifier
UK	United Kingdom
UMN	Unmet Medical Need
VHP-plus	Voluntary Harmonisation Procedure- plus

NEWS FROM EUROPE: MEDICINAL PRODUCTS

News from the European Commission

The European Commission draft guidelines on Good Clinical Practice for ATMP

The European Commission published draft guidelines on good clinical practice specific to advanced therapy medicinal products (ATMPs).

The European Commission underlines that ATMPs are very complex and innovative products. The short shelf-life of the product may require from manufacturers the implementation of tight controls on logistical arrangements to administer them and for sponsors specific arrangements for long-term follow up of the subjects. Conducting clinical trial with ATMPs and placebo could be also the challenge for sponsors. The guidelines provide advice how to proceed in such case. In addition, it has been also recognised that it may not always be feasible to generate relevant preclinical data before the product is tested in humans in case of clinical trials with ATMP.

The Guidelines will adapt good clinical practice requirements to ATMPs and also comply with the requirements in Clinical Trials Regulation (EU) No 536/2014. Stakeholders are invited to comment on this consultation by 31 October 2018 at the latest. The comments will be received by the European Commission in the finalisation of the guideline.

News from the European Medicines Agency

The source of each news item below is the EMA website.
https://www.ema.europa.eu/

EU Telematics strategy and implementation roadmap 2018-2019

The EMA publishes telematics strategy and implementation plan for European Union for 2018 and 2019.
EU Telematics aim is to put in place and maintain common information-technology (IT) services to implement European pharmaceutical policy and legislation. The European Commission, the EMA and national competent authorities together make a European medicines regulatory network.

Published roadmap 2018-2019 communicates stakeholders and companies that some activities is going to be on hold: like creating eCTD version 4.0 or some EudraVigilance activities. However, the EMA still maintains the plan of releasing Clinical Trial Information System (CTIS): (EU database and EU portal) to come into force on time and to make CTR fully applicable for the European Union member states (MSs) in 2020.

The main key factor which may affect the release of CTIS is the outcome of Brexit i.e. relocation the EMA and anticipated staff loss.

IRIS secure online portal for orphan drugs - guidance for sponsors submitting an application

In May, the EMA launched a new secure online portal "IRIS" for sponsors to submit applications for orphan designation. The new process of application for orphan designation became mandatory from **19 September 2018**. To instruct sponsors, the EMA has published in July the guidance for sponsors submitting an application via IRIS secure online portal. The document provides information how submit the study with orphan drug to the EMA, when and what kind of documents should be submitted. The guidance describes the whole process from submitting the application to the follow up results. The guideline also encourages to submit applications in parallel with regulatory agencies outside EU (US, Japan).

ICH guideline M9 on biopharmaceutics classification system based biowaivers

The EMA published for consultation the ICH M9 guideline on biopharmaceutics classification system (BCS) based biowaivers. The guideline reached step 2b of ICH process. The ICH M9 guideline categorizes drug substances into four BCS classes where the drug substance exhibits high solubility and, either high permeability (BCS Class I) or low permeability (BCS Class III).

A biowaiver is only applicable when the drug substance(s) in test and reference products are identical. The guidance explains that BCS-based biowaivers may be used to demonstrate bioequivalence for example between products used in early clinical development through commercialization, for line extensions of the same pharmaceutical form of innovator products, in applications for generic drug products, and post- approval changes that would otherwise require *in vivo* bioequivalence evaluation, in accordance with regional regulations. After worldwide consultation the document will provide recommendations to support the waiver of bioequivalence studies and result in harmonisation of current regional guidelines.

Other Initiatives

National pilot projects supporting the transition to the new CTR – list of MSs published by CTFG

The Clinical Trials Facilitation Group (CTFG) published the list of the European Union Member States (MSs) started pilots projects at national level to facilitate implementation to the CTR. In addition the CTFG added the countries participating in Voluntary Harmonisation Procedure-plus (VHP-plus). The VHP-plus gives permission to the Member States to involve Ethics Committees in the clinical trial assessment on a voluntary basis. The published list includes short description of the processes in each European country and links to the relevant guidance published by MSs relating to their national pilot project.

News from Individual Countries

- **Belgium**

Changes of submissions and notifications to the R&D (human) Division of the FAMHP.

From **1 October 2018**, the submission of applications or documents of clinical trials, clinical investigations, performance studies and Unmet Medical Need (UMNs) via Common European Submission portal (CESP) to the Research & Development (human) Division of the FAMHP will become mandatory.

The list of applications and notifications for which CESP must be used:

- Clinical trials (medicines) Initial application for a clinical trial
- Substantial amendment for a clinical trial
- ASR/DSUR submission
- Urgent safety measure
- Temporary halt notification
- End of trial declaration
- CTR Pilot – initial application for a clinical trial
- CTR Pilot – Substantial modification for a clinical trial
- Clinical investigations (medical devices) Initial application for a clinical investigation
- Serious Adverse Events Notification
- Notification of end of clinical investigation / performance study
- Unmet Medical Needs Initial application for a CUP/MNP
- Periodic Reevaluation for a CUP/MNP
- Substantial Amendment for a CUP/MNP
- Clinical trials, clinical investigations and Unmet Medical Needs
- Approval of the ethics committee

For 'deliberate release' clinical trial applications with a genetically modified organism the FAMHP will still request to perform the submission by post (CD-ROM/USB + signed cover letter).

- **The United Kingdom**

MHRA allows include a patient previously treated with an ATMP

The MHRA has published a guidance presenting a points to be considered when submitting a new clinical trial for authorization with IMP administered after previous ATMP use by patients. Previously using ATMP (CAR-T cell, gene therapy, tumour vaccines) was considered by the MHRA as a standard exclusion criterion for participation in a clinical trial. However, the MHRA observed that recent data shows that using IMP by patients previously administrated by ATMP could be amenable and justifiable. The MHRA explains their decision and advices sponsors how to mitigate the risk in case of new clinical trial with IMP after previous administration of ATMP and when uses IMP is going to be also ATMP.

MHRA and HRA joint statement regarding eConsent

The MHRA and the Health Research Authority (HRA) have published Joint statement on seeking consent by electronic methods (eConsent). The statement confirms that electronic methods may be used for seeking, confirming and documenting informed consent in every UK nations.

eConsent enables participants of clinical trial to make an informed consent decision via a tablet, smartphone, digital multimedia and make them possibility also to use electronic signatures under informed consent. The patient will still have a choice. eConsent may be only a supplement to the traditional paper version of ICF or where possible entirely replace it.

This approach is focusing on clinical trials of investigational medical products (CTIMPs) however the MHRA and HRA explain in statement that the basic principles can be applied to all research conducted in the UK.

The joint statement provides legal basis of using eConsent, how to manage the process of receiving e-signature from participants, advices how to record and save such eConsent to meet an audit and inspection expectations.

NEWS FROM EUROPE: MEDICAL DEVICES

News from the European Commission

European Commission published new documents refer to MDR and IVDR

In July and August 2018, the European Commission published the following documents addressed to the Manufacturers of Medical Devices referring to new Medical Device (EU) Regulations 745/2017 (MDR) and 746/2017 (IVDR):

- Factsheet for manufacturers of medical devices
- Step by step implementation model for medical devices Regulation
- Exhaustive list of requirements for manufacturers of medical devices
- Factsheet for manufacturers of in-vitro diagnostic medical devices
- Step by step implementation model for in-vitro diagnostic medical devices Regulation
- New rules to ensure safety of medical devices

The Commission presents and explains the Regulations in very user friendly format trying to underline the main requirements and steps for manufacturers. The publications are also good source of information for everyone who wants to be ready for the Regulations which should be implemented by 2020 (MDR) and by 2022 (IVDR).

News from Individual Countries

- **Switzerland**

Change in practice of authorisation procedure clinical trials with medical devices

From **6 September 2018**, the submissions for authorisation applications and the notifications relating to clinical trials with medical device have to be done to Swissmedic electronically via the Swissmedic eGov Portal.

The applicants should continue to submit the tabular summaries of SAE reports by e-mail to clinicaltrials.devices@swissmedic.ch.

All other submissions like:

- First submission of an authorisation application for Category C trials of medical devices (not CE marked)
- Amendments that are submitted to authorization
- Amendments requiring notification
- Safety (risks and safety measures)
- Serious adverse events (SAEs) and device deficiencies
- Annual safety reports
- Completion, discontinuation, interruption of the trial have to be switched to the new electronic submission route with new forms via the Swissmedic Portal.

Other initiatives

IMDRF opens three new consultations on labelling, unique device identifiers (UDIs) and adverse event reporting

The International Medical Device Regulators Forum (IMDRF) opened for consultation three new guidelines which are going to provide globally harmonised principles for medical devices.

Principles of Labeling for Medical Devices and IVD Medical Devices

The document features sections on general labelling principles for MDs (instructions for use), in vitro diagnostics medical devices (IVDMDs) and other than IVDMDs; labelling principles for software MDs, for MDs and IVDMDs intended only for layperson use and information intended for the patient.

Unique Device Identification system (UDI System)

The guidance specifies the fundamental elements of a harmonized UDI system and the guiding principles for designing and operating. The document also discusses the application of a UDI to packaging, UDI databases and establishing responsibility for creating and maintaining a UDI system. I addition, the document clarifies some of the requirements of special cases of medical devices based on learning experience in the course of the last few years.

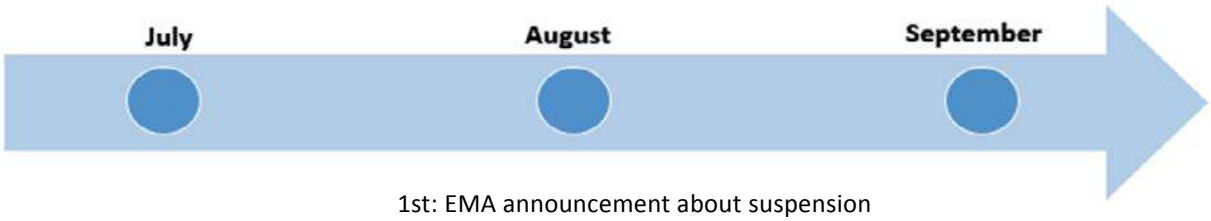
IMDRF Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology structure and codes

The guidance is prepared by the Adverse Event Working Group and presents consultation features a harmonized terminology for reporting adverse events related to medical devices and in vitro diagnostics medical devices.

OTHER "HOT" TOPICS IN THE EU
Key Brexit updates

10th: Gaps in industry preparedness for Brexit identified by EMA
19th: Published the EC Communication outlining on preparing for the UK's withdrawal from the EU EMA guidance
26th: EMA guidance for MAHs affected by Brexit

6th: European Commission notice to sponsors- rules in the field of clinical trials



1st: EMA announcement about suspension of some activities
6th: MHRA published outlines what to expect during the implementation period
23rd: No deal Brexit scenario: MHRA recommendations and plan

EMA identifies gaps in industry preparedness for Brexit

On 10 July 2018, the EMA published the results of survey sent to companies in January 2018. The document shows that some marketing authorisation holders (MAHs) are on track with their regulatory planning once the UK leaves the EU but also identifies gaps informing that some companies need to step up efforts to ensure medicine supply in the EU. The survey was sent to MAHs of the 694 centrally authorised products (CAPs) (661 human and 33 veterinary products) who are located in the UK or who have quality control, batch release and/or import or manufacturing sites, or a QPPV or PSMF in the UK. EMA informs that for 10% of the products included in the survey EMA still has not received feedback. "EMA urges those companies who have not yet informed EMA of their Brexit preparedness plans to do so as soon as possible to mitigate any risks to the continuous supply of medicines for human and veterinary use within the EU."

EMA published also Report from EMA industry survey on Brexit preparedness

European Commission publishes Communication on preparing for the UK's withdrawal from the EU

The European Commission published adapted communication outlining the ongoing work on the preparation for all outcomes for Brexit. They present two main scenarios for stakeholders UK and EU authorities to be prepared when UK leaves the EU:

- "If the Withdrawal Agreement is ratified before 30 March 2019, EU law will cease to apply to and in the UK on 1 January 2021, i.e. after a transition period of 21 months.
- If the Withdrawal Agreement is not ratified before 30 March 2019, there will be no transition period and EU law will cease to apply to and in the UK as of 30 March 2019. This is referred to as the "no deal" or "cliff-edge" scenario."

Simplified transfer process for some MAHs affected by Brexit – EMA guidance

On 26July 2018, the EMA updated the guidance Electronic submission of Article 57(2) data Questions & answers (Q&As) for MAHs to simplify them the transfer process before the UK's withdrawal from the EU. The updated or new Q&As have been highlighted in red.

EMA to further temporarily scale back and suspend activities

On 1 August 2018, the EMA informed about launching the third phase of its business continuity plan on 1 October 2018 at the latest. The EMA will temporarily scale back some activities or suspend additional activities through to 2019 due to EMA physical move to Amsterdam and reduction of staff. They will only take a reactive role related to collaboration at international level, development and revision on guidelines will be limited, working parties activities will be on hold, projects and programs activities will be suspended, organisation and attendance at stakeholder meetings will be limited and the launch of new procedures of Clinical data publication will be temporarily suspended.

MHRA outlines what to expect during the implementation period

In August, the MHRA published the guidance "What the implementation period means for the life science sector." The guidance intention is to present the scenario when the Withdrawal Agreement is ratified before 30 March 2019.The MHRA presents its activities before, during and beyond the implementation period. It explains how the implementation will affect upcoming Regulations: Clinical Trials Regulation fully applicable in 2020, MDR in 2020 and IVDR in 2022.

No- deal Brexit scenario for pharmaceutical industry and suppliers of medical devices

On 23 August 2018, the MHRA published also the guidance in case when the Withdrawal Agreement is not ratified before 30 March 2019. The MHRA underlines that if no-deal scenario the UK will still align where possible with the CTR without delay and will comply with all key elements of MDR and IVDR. The guidance says also that where needed the UK law will be changed and the MHRA will give adequate time for business to implement any new requirements.

European Commission notice to sponsors - rules in the field of clinical trials

On 6 September 2018, the European Commission published notice to stakeholders providing the rules in the fields of clinical trials when the UK leaves the EU. From 30 March 2019 the UK will become 'third country' and European Union laws, regulations and administrative provisions in the conduct of clinical trials or clinical investigations will no longer apply to the UK.

The sponsors of clinical trials should be aware and to be prepared for the following consequences of the Brexit:

- The import of investigational medicinal products from the UK to the EU

Investigational medicinal products and comparator investigational medicinal products intended to be used in a clinical trial and taken from the UK will need to be authorised and checked in accordance with the standards of good manufacturing practices by qualified person (QP) based in one of the EU MS. The QP authorisation is also required if only part of the manufacturing (e.g. packaging or repacking) is performed in the third country. The stakeholders will need to be well prepared and have permanently and continuously at their disposal the services of at least one qualified person located in the EU not in the UK.

- Establishment requirements for the sponsor of a clinical trial or a legal representative in the EU

When the UK become 'third country', the sponsors outside the EU and from UK will need to establish EU sponsor or a legal representative in one of 27th EU countries. If the legal representative is still located in the UK, the sponsor will need to submit substantial amendment to the concerned EU MS changing appropriate documents.

- Submission of clinical trial information to the EU clinical trials database EudraCT

Protocol related information will no longer have to be submitted to EudraCT, except when the trial is part of an agreed Paediatric Investigation Plan and the UK is the only country in which the protocol has been submitted.

Results of clinical trials conducted in the UK and completed before 30 March 2019, results of multi-country trials where the United Kingdom was the only EU/EEA Member state, results also after the withdrawal date, if this is required for non-EU/EEA studies (i.e. if the trial is part of an agreed Paediatric Investigation Plan) have to be submitted to EU clinical trials database EudraCT.

NEWS FROM THE UNITED STATES OF AMERICA – "HOT" TOPICS

US FDA's Medical Device Division Confirms Regulatory Guidance Plans for 2019

Updated cybersecurity requirements for medical device premarket submissions, Abbreviated and Special 510(k) program refinements, and medical software policy changes stemming from the 21st Century Cures Act rank highly among topics for a new list of guidance documents the US Food and Drug Administration's Center for Devices and Radiological Health (CDRH) plans to publish during the agency's 2019 fiscal year.

CDRH's new list of final and draft guidance documents under development for 2019 reflects the division's priorities in terms of public health and increasing regulatory process efficiencies based on available resources. Proposed guidance documents have been grouped into higher-priority (A List) and lower priority (B List) groups.

Broad topics such as updates to CDRH's cybersecurity regulatory approach, Least Burdensome Provisions and benefit-risk determination factors as well as program-specific guidelines covering 510(k), Unique Device Identification (UDI) and other policies topped the Center's list for the coming fiscal year.

Top-priority CDRH guidance topics for 2019

A-list final guidance documents CDRH plans to publish in 2019 cover topics such as:

- Special 510(k), Breakthrough Devices and Humanitarian Device Exemption (HDE) programs, as well as on criteria for expansion of FDA's Abbreviated 510(k) program;
- UDI compliance deadlines for Class I and unclassified devices, as well as for direct marking of inventory;
- FDA's Q-Submission (Q-Sub) program policies;
- Policies covering multiple-function devices;
- Clinical and patient decision support software, as well as changes to current medical software policies mandated by the 21st Century Cures Act;
- Least Burdensome Provisions, as well as uncertainty considerations for benefit-risk determinations in Premarket Approval (PMA) reviews, De Novo device classifications and HDEs.

Among draft-guidance A List subjects identified by CDRH for 2019 publication, industry and stakeholder anticipation runs high for new cybersecurity requirements and recommendations under development for devices presenting moderate to high levels of concern in terms of public safety risks and vulnerabilities.

Additional high-priority draft guidance planned for the 2019 fiscal year address issues including:

- An Accreditation Scheme for Conformity Assessment (ASCA) of medical devices to FDA-recognized consensus standards;
- Clinically focused guidance including updated recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) waiver applications for IVD manufacturers; policies for patient engagement in clinical trials; and recommendations for dual 510(k) and CLIA waivers;
- A computer software assurance program for manufacturing, operations and quality system software;
- Guidance for what to include in premarket submissions for software contained in devices;
- Lifecycle regulatory requirements for medical device servicing.

Lower-priority guidance on CDRH's 2019 radar

CDRH's plans to publish B List guidance documents is contingent upon availability of development and publication resources, and cover more niche and targeted topics.

Proposed B List final guidance for 2019 pertain to topics including UDI requirements for convenience kits; form and content requirements for Unique Device Identifiers; and conformance of medical X-ray imaging devices to IEC standards.

Finally, B List draft CDRH guidance tentatively slated for 2019 publication address non-clinical testing and clinical considerations for implanted brain-computer interface devices, and 510(k) submission requirements for continuous ventilators.

FDA Voices > CDRH FY 2019 Proposed Guidance Development and Retrospective Review

CROMSOURCE will monitor CDRH's progress over the course of 2019 and provide additional reporting and analysis of individual guidance as they are published.

FDA Reveals How Manufacturing Facilities are Prioritized for Inspections

The US FDA announced on September 5, 2018 and released an internal Manual of Policies and Procedures (MAPP) on how pharmaceutical manufacturing sites are prioritized and selected for surveillance inspections.

The release of the 7-page MAPP comes as FDA's inspections program in Fiscal Year 2017 had to decide what sites to inspect from about 5,063 human pharmaceutical sites worldwide, 3,025 of which are outside the US. In 2017, FDA conducted 1,453 inspections, including 762 on foreign soil, to ensure manufacturers were following Current Good Manufacturing Practice (CGMP) requirements.

"FDA prioritizes inspections of sites regardless of their location. For manufacturing facilities in other countries, inspections may be conducted by staff in foreign offices, those on temporary duty assignments, or staff that travel internationally to conduct the inspection," FDA Commissioner Scott Gottlieb explained.

According to the MAPP, the Office of Surveillance, within the Office of Pharmaceutical Quality, is responsible for producing CDER's Site Surveillance Inspection List (SSIL) that prioritizes sites for surveillance inspections.

The Site Selection Model (SSM), used by CDER staff to prioritize manufacturing sites for routine quality-related inspections, considers risk related to drug (drug substance and finished product) quality as may arise from violations of the CGMP requirements in the Food Drug & Cosmetic Act (FD&C Act).

The SSM will use risk factors consistent with section 510 of the FD&C Act, which identifies specific risk factors and allows FDA to determine additional ones, including: "a) The compliance history of the establishment; b) The record, history, and nature of recalls linked to the establishment; and c) The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at the establishment."

The agency also uses its Mutual Recognition Agreement to coordinate with the EU on which drug inspections need to be conducted. "In doing so, we're able to dedicate more of our investigators' time to those sites that pose the greatest risk," Gottlieb noted.

Press Announcements > Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's global efforts to help assure product quality and transparency at foreign drug manufacturing facilities

International Arrangements > Mutual Recognition Agreement (MRA)

The Mutual Recognition Agreement (MRA) between FDA and European Union allows drug inspectors to rely upon information from drug inspections conducted within each other's borders. Under the Food and Drug Administration Safety and Innovation Act, enacted in 2012, FDA has the authority to enter into agreements to recognize drug inspections conducted by foreign regulatory authorities if the FDA determined those authorities are capable of conducting inspections that met U.S. requirements. FDA and the EU have collaborated since May 2014 to evaluate the way they each inspect drug manufacturers and assess the risk and benefits of mutual recognition of drug inspections.

MRA:

- Yields greater efficiencies for U.S. and E.U. regulatory systems by avoiding duplication of inspections
- Enables reallocation of resources towards inspection of drug manufacturing facilities with potentially higher public health risks across the globe

FDA will continue to perform some inspections in EU countries with capable inspectorates, such as product manufacturing assessment inspections to support marketing approval decisions. However, FDA expects to perform fewer routine surveillance inspections in EU countries with a capable inspectorate.

FDA is collaborating with the following inspectorates it has assessed as capable and is reviewing their recent inspection reports and related information in determining each manufacturer's suitability for the U.S. market in lieu of an FDA site inspection. FDA expects to complete its capability assessment of all EU inspectorates by July 2019.

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