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Clinical Safety & Pharmacovigilance Regulatory Intelligence Review

Cumulative COVID-19 Extract

VERSION HISTORY

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TABLE OF CONTENTS

1. COVID-19 GUIDANCE & PHARMACOVIGILANCE

1.1 Guidance for Clinical Trials

1.1.1 EU Webinar on COVID-19 Guidance for the management of Clinical Trials (15-May-2020)

The European Commission held a webinar on 15-May-2020 to provide an overview of the most important elements of the Guidance on the management of clinical trials during the COVID-19 pandemic. The slides from the webinar and the corresponding video recording are now available as part of EudraLex Volume 10.

→ Link to EudraLex Volume 10

1.1.2 FDA issues Guidance for statistical analysis of trials impacted by COVID-19 (16-Jun-2020)

The FDA has published a new guidance document entitled "Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency".

Considering the disruption caused by the pandemic, this guidance provides recommendations on statistical considerations to address the impact of COVID-19 on meeting objectives of clinical trials.

The guidance outlines considerations for the statistical analysis of the primary and key secondary endpoints in a trial affected by COVID-19 to help ensure that the trial will provide interpretable findings with correct statistical quantification of uncertainty.

→ Link to FDA Guidance Page

1.1.3 FDA issues Guidance to promote timely availability of COVID-19 vaccines (30-Jun-2020)

The FDA has published a new guidance document entitled "Development and Licensure of Vaccines to Prevent COVID-19", which includes recommendations regarding the data needed to facilitate the manufacturing, clinical development, and approval of a COVID-19 vaccine. Amongst all topics covered, the guidance includes sections describing safety considerations for Clinical Trials and post-licensure safety evaluation.

→ Link to FDA News Release
→ Link to FDA Guidance Page

1.1.4 ANSM updates guidance on managing Clinical Trials during COVID-19 (10-Aug-2020)

The French Agency first published on 20-Mar-2020 some guidance to deal with the COVID-19 situation. Unlike the EU Guidance, the ANSM clearly provides some flexibility regarding safety reporting compliance. Although SUSARs should be submitted in line with requirements, the French Agency allows a 2-month delay for the submission of DSURs.

Regarding the vigilance section, the latest update only concerns the naming conventions for the submission of the Annual Safety Report.

→ Link to ANSM Guidance Page

1.1.5 FDA issues guidance to assess COVID-19-Related Symptoms in Clinical Trials (14-Sep-2020)

The FDA has published a new guidance document entitled "Assessing COVID-19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment".

This guidance is intended to help sponsors assess the benefits of potential treatments through a set of common COVID-19-related symptoms and an approach to their measurement during clinical trials.

→ Link to FDA Guidance
→ Link to Federal Register Notice

1.1.6 New FDA Guidance on Emergency Use Authorization for COVID-19 Vaccines (06-Oct-2020)

The FDA has issued a new Guidance Document on requirements for the issuance of an Emergency Use Authorization (EUA) for vaccines intended to prevent COVID-19. This document is intended to remain in effect only for the duration of the Public Health Emergency related to COVID-19, and includes recommendations regarding the data and information needed to support the issuance of an EUA, including Safety and Effectiveness Information.

The FDA has also launched a new webpage to highlight new information that becomes available specifically on COVID-19 Vaccines. This includes a section on regulatory information for Vaccine Developers, as well as relevant Publications such as a recent article published in the NEJM on Safety and Efficacy Follow-up Considerations associated to an EUA.

- → Link to "FDA in Brief" Statement
- → Link to FDA Guidance Page
- → Link to FDA Page on COVID-19 Vaccines

1.1.7 MHRA issues guidance on minimizing impact of COVID-19 on Clinical Trials (11-Nov-2020)

The MHRA has published new guidance, which complements the guidance released earlier on managing clinical trials during COVID-19. This new guidance is intended to help avoid disruptions to the conduct and integrity of clinical trials during the continuing pandemic. This new information does not include provisions with a direct relevance to Pharmacovigilance activities.

- → Link to MHRA Page: MHRA guidance on COVID-19
- → Direct link to MHRA Guidance on minimising disruptions

1.1.8 Members of ACCESS Consortium agree to fast-track variant vaccines (04-Mar-2021)

The ACCESS Consortium represents a coalition of regulatory authorities from the UK, Australia, Canada, Singapore and Switzerland and participating authorities have announced their agreement to expedite the regulatory approval process for modified COVID-19 vaccines. The consortium has produced a guidance, which describes the information that would be required for approval of variant vaccines.

- → Link to MHRA Press Release
- → Link to Health Canada's Guidance Page
- → Link to TGA News Release

1.1.9 FDA issues revised Guidance to address emergence of virus variants (17-May-2021)

The FDA has issued a series of revised Guidance Documents for medical product developers to address the emergence and potential future emergence of variants of SARS-CoV-2.

This includes an update to the Guidance Document from October 2020, which describes the requirements for the issuance of an Emergency Use Authorization (EUA) for vaccines intended to prevent COVID-19. This document includes recommendations regarding the data and information needed to support the issuance of an EUA, including Safety and Effectiveness Information. The revised guidance incudes recommendations for modifications to authorized vaccines and their assessment of safety to support an EUA for a modified vaccine.

In a similar manner, the FDA has also revised the guidance from May 2020 and entitled "COVID-19: Developing Drugs and Biological Products for Treatment or Prevention". In addition, a new document has been published on "Development of Monoclonal Antibody Products Targeting SARS-CoV-2, including Addressing the Impact of Emerging Variants, During the COVID-19 Public Health Emergency".

Furthermore, the FDA has issued an additional guidance document entitled "COVID-19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention Guidance for Industry", which complements the above-mentioned guidance.

- → Link to FDA News Release
- → Link to FDA Guidance Page on EUA for COVID-19 Vaccines
- → Link to FDA Guidance Page on COVID-19: Developing Drugs and Biological Products
- → Link to FDA Guidance Page on Development of Monoclonal Antibody Products
- → Link to FDA Guidance Page: COVID-19 - Master Protocols

1.1.10 FDA updates COVID-19 Guidance for Conducting Clinical Trials (30-Aug-2021)

The FDA issued an updated version of its guidance, which was initially published on 18-Mar-2020.

The document recommends sponsors to evaluate whether alternative methods for safety assessments (e.g., phone contact, virtual visit, etc.) could be sufficient to assure the safety of trial participants in the context of the COVID-19 Public Health Emergency. In some cases, additional safety monitoring may be necessary, e.g. if study subjects no longer have access to investigational products.

Changes to Protocols and Informed Consents intended to eliminate immediate hazards for trial participants should be discussed with the IRBs/IEC as early as possible but the FDA is accepting that these are implemented prior to IRB and FDA approval, where required.

The guidance includes content with considerations for using alternate laboratories or imaging centers, holding trial participant visits via video conference, and conducting required postmarketing clinical trials (Questions Q18 to Q20).

A couple of questions relate to safety reporting in specific circumstances, such as the occurrence of COVID-19 infections in trials that are not investigating treatments for COVID-19 (Questions Q22 to Q23). Question Q24 clarifies that Investigators are required to review all IND safety reports transmitted by the Sponsor and submit them to the IRB.

The latest revision includes a new question (Q28), which covers the need to perform on-site monitoring for the data that have already been monitored remotely once the pandemic restrictions are lifted.

As a side note, the CDER Small Business & Industry Assistance (SBIA) held a short webinar on 30-Apr-2020 to present the guidance and the corresponding material is now available on the FDA website, including slides and video recording.

- → Link to FDA News Release
- → Link to FDA Law Blog article
- → Link to FDA Guidance
- → Link to FDA SBIA Webinar Page

1.1.11 Access Consortium joins consensus on new COVID-19 vaccines approval (15-Sep-2021)

As reported in previous issues, a number of regulatory workshops were organised over the past year under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA) and the EMA has provided updates on an on-going basis about the outcome of the discusisons.

A virtual workshop took place on 24-Jun-2021 on COVID-19 vaccine development and virus variants, where participants discussed key regulatory considerations related to the development of second-generation COVID-19 vaccines and booster doses.

The ACCESS Consortium represents a coalition of regulatory authorities from the UK, Australia, Canada, Singapore and Switzerland and its members have subsequently issued statements to confirm their agreement that well-justified and appropriately designed immunobridging studies are an acceptable approach for authorising new COVID-19 vaccines.

- → Link to EMA News Release
- → Link to MHRA Decision
- → Link to Health Canada Statement
- → Link to Swissmedic News Release

1.1.12 MHRA updates Guidance on managing Clinical Trials during COVID-19 (16-Nov-2021)

Although the overarching EU Guidance does not include any flexibility, the MHRA have expressed their understanding that safety reporting timelines will not always be met. The guidance further specifies that every effort should be made to submit SUSARs on time, thus setting a priority for this type of reports. Changes have been made on this page to provide more information on applicable Regulatory Flexibilities, including for SUSAR and DSUR reporting as well as Urgent Safety Measures (USM).

In the latest revision, the section on Urgent Safety Measures (USM) was updated to reflect that the notification to the MHRA should now be performed following the standard procedure defined for other Clinical Trials.

- → Link to MHRA Page: Managing Clinical Trials during COVID-19

1.1.13 EMA updates Guidance to expedite approval of variant vaccines (21-Dec-2021)

In February 2021, the EMA issued a Reflection Paper outlining the requirements for manufacturers planning to modify their COVID-19 vaccines in order to address variants of SARS-CoV-2, recognising the need to define an expedited regulatory process for the adaptation of approved vaccines.

The CHMP Reflection Paper defines the data needed to support the approval of such 'variant' vaccines. With regards to Clinical data, large-scale safety and efficacy studies are not deemed necessary and the efficacy of variant vaccines should be demonstrated in immunogenicity studies. Post-authorisation studies will be required to monitor the long-term safety and effectiveness of variant COVID-19 vaccines.

In June 2021, the EMA published additional Procedural Guidance for variant strain(s) update to COVID-19 vaccines, which describes the procedural aspects for the submission of a variation to change the composition of vaccines approved via the centralised procedure. This Guidance has just been updated.

- → Link to EMA Reflection Paper on requirements for variant vaccines
- → Link to EMA COVID-19 Guidance Page
- → Direct link to EMA Procedural guidance for variant strain(s) update to vaccines

1.1.14 EMA COVID-19 Guidance for the management of Clinical Trials (10-Feb-2022)

The EMA first published this document on 20-Mar-2020 and the latest revision (V.5 dated 10-Feb-2022) includes updated references to the new EU Clinical Trials Regulation (EU) No 536/2014.

The document provides guidance for sponsors on how they should adjust the management of clinical trials and participants during the COVID-19 pandemic to protect subject safety and data validity.

Regarding Safety Reporting, the guidance only states that Sponsors are expected to remain compliant with applicable requirements and investigators should continue collecting adverse events from the study subjects, which may be done through alternative means e.g. by phone when physical visits are not possible.

Immediate actions may be required to protect the subjects against immediate hazard, in which case the dispositions for Urgent Safety Measures (USM) can be used. These allow actions to be taken without prior notification to Competent Authorities and Ethics Committees.

As reported at the time, the EMA also published a document entitled: "Points to consider on implications of Coronavirus disease (COVID-19) on methodological aspects of ongoing clinical trials", which was produced by the Biostatistics Working Party (BSWP). This guidance is intended to help ensure study integrity and interpretation of study results while safeguarding the safety of trial participants.

- → Link to EMA Press Release
- → Link to EMA GCP Page: COVID-19 Pandemic
- → Link to EMA COVID-19 Page
- → Direct link to EU Guidance Document
- → Direct link to BSWP Points to Consider Page

1.1.15 FDA updates guidance on Emergency Use Authorization for Vaccines (31-Mar-2022)

The FDA has issued a revised version of its Guidance Document describing the requirements for the issuance of an Emergency Use Authorization (EUA) for vaccines intended to prevent COVID-19.

This document was initially published in October 2020 and includes recommendations regarding the data and information needed to support the issuance of an EUA, including Safety and Effectiveness Information.

The latest revision includes updated recommendations for the clinical data to support effectiveness of a vaccine modified to target variants. The FDA also removed the expectation that sponsors should continue to collect placebo-controlled data after issuance of an EUA.

- → Link to FDA Guidance Page

1.1.16 Additional Resources

The European Heads of Medicines Agencies (HMA) has published a document that provides links to the guidance published by EU Member States on the management of Clinical Trials during the COVID-19 pandemic.

- → Link to HMA Document

The EFGCP (European Forum for Good Clinical Practice) has established a complete repository of guidance publications for Clinical Trials in relation to COVID-19.

- → Link to EFGCP Repository

The Sidley law firm and Sunnikan Consulting have also published useful information providing links to the guidance published by various Medicine Agencies to assist Sponsors manage the challenges brought by the pandemic in the conduct of Clinical Trials.

- → Link to Sidley Update (Part 1 and Part 2)
- → Link to Sunnikan Consulting Page

1.2 Guidance for Post-Marketing

1.2.1 Health Canada issues Notice on Mandatory Reporting Requirement (23-Mar-2020)

Health Canada has published a Notice for Industry on Mandatory Reporting Requirements during the COVID-19 Pandemic, which follows the same spirit as the FDA guidance.

Health Canada acknowledges that compliance with safety reporting timeframes may not be feasible due to the disruption caused by COVID-19 on business operations. The existing requirements should be met for high priority products whereas Health Canada will accept that other reports may be delayed. The guidance defines which products and types of reports must be submitted in compliance with applicable requirements. Please note that the prioritization criteria are not identical to those defined by the US FDA.

→ Link to Health Canada's Notice

1.2.2 FDA issues Policy to adjust REMS requirements (23-Mar-2020)

The FDA has issued a new guidance to address the possible difficulties that patients may experience to complete laboratory testing or imaging studies, as required under existing Risk Evaluation and Mitigation Strategy (REMS) for some products.

For drugs subject to such REMS requirements, healthcare professionals should evaluate carefully the benefits and risks of continuing treatment in the absence of laboratory testing and imaging studies. The FDA does not intend to take action against companies for such REMS violations during the Public Health Emergency.

→ Link to FDA News Release
→ Direct link to FDA Guidance Page

1.2.3 EMA issues COVID-19 update of the IME List (20-Apr-2020)

The Important Medical Event (IME) Terms list includes a list of MedDRA Preferred Terms that are considered Serious by the EudraVigilance Expert Working Group (EV-EWG). Since 2009, the IME list is available for guidance purposes only and a new update is released with each new version of the MedDRA dictionary.

Further to the release of a new version based on MedDRA version 23.0 on 16-Mar-2020, the EMA has published a revised version to consider the new COVID-19 terms added by the MSSO to the new release of version 23.0.

→ Link to EMA EudraVigilance Overview Page
→ Direct link to IME list

1.2.4 FDA updates Guidance on AE Reporting during a Pandemic (11-May-2020)

The FDA has published a new version of its Guidance Document entitled "Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic".

As reported when this document was first published on 19-Mar-2020, the guidance brings flexibility and defines priorities for Safety Reporting to the FDA when resources become insufficient for companies to meet the requirements for all Safety Reports.

The updated version brings few but significant changes compared to the original version. Most importantly, the definitions of the priority categories presented in Table 1 have been revised. For approved drug and biological products (NDA, ANDA, or BLA), 15-day Alert reports should be submitted to the FDA for all products targeting the pathogen or the disease, whether or not this use is included in the approved labeling. The requirements have also been harmonized and death outcome reports should always be prioritized for both drug and biologicals products. Furthermore, where the guidance stated that all delayed reports should be submitted to the FDA within 6 months of returning to the pre-pandemic state, it now specifies that a different timeframe may be set by the FDA (see Section D of the Guidance Document).

The summary of the guidance presented on the Safety Observer blog has been updated accordingly.

→ Link to Safety Observer blogpost
→ Direct link to FDA Guidance Document

1.2.5 MHRA COVID-19 Guidance on regulatory flexibility (20-May-2020)

The MHRA has updated its page describing regulatory flexibilities resulting from the COVID-19 pandemic.

The section on Pharmacovigilance covers several topics including Safety Variations, dissemination of educational materials and DHPCs. Regarding ICSRs, it describes that follow-up activities should be prioritised in order to minimise the burden on Health Care Professionals.

Full compliance remains expected regarding safety reporting requirements to the MHRA, with one exception: The PSUR submission can be delayed or waved for products approved in the UK only, i.e. those products that are not included in the EURD List.

The page now includes a section on "Relaxation of Risk Minimisation Measures", which describes the new urgent procedure for the MHRA to review proposals to adjust requirements. The section includes the example of Pregnancy Prevention Plans for which it may be appropriate to perform pregnancy testing remotely.

The section "Flexibility in reporting requirement for ICSRs" describes that in addition to the priorities defined at the European level, a category should be added to include all serious ICSRs which reference an impact of the pandemic.

The information was updated on 04-Aug-2020 in order to highlight areas of flexibility that differ from the EU, which concerns the ICSR reporting requirements, amongst others. In a similar manner, the presentation also identifies that some flexibilities apply to essential products other than COVID-19 treatments.

→ Link to MHRA Page: COVID-19 regulatory flexibilities

1.2.6 EU issues updated COVID-19 Guidance on regulatory flexibility (01-Jul-2020)

The European Commission has revised the question-and-answer (Q&A) document explaining the regulatory flexibilities that can be applied to help companies cope with the consequences of the pandemic.

The Pharmacovigilance section (Section 4) describes that the pandemic may force companies to activate Business Continuity Plans and prioritise Safety Reporting activities. The document defines priorities for the submission of ICSRs to EudraVigilance, and the top priority is assigned to Serious ICSRs associated with products used for the treatment or prevention of COVID-19. When MAHs use such prioritisation, this should be reflected in their PSMF but there is no requirement to notify the EMA.

The revisions brought by the latest revision are marked in the document, which all relate to the Pharmacovigilance section. In addition to the question regarding ICSR submission and prioritization included on 20-Apr-2020, the document now contains 3 new questions to cover Pharmacovigilance Quality Management aspects including CAPAs, Audits and Inspections (Questions 4.2 to 4.4).

→ Link to EMA COVID-19 Guidance Page
→ Direct link to EU Q&A Document

1.2.7 ENCePP Guidance for Pharmacoepidemiology Studies adjusts to COVID-19 (10-Jul-2020)

The latest revision of the ENCePP guide on Methodological Standards in Pharmacoepidemiology includes a new foreword to guide the reader to those chapters of relevance for studies carried-out in the context of the COVID-19 pandemic.

→ Link to ENCePP Guide Page
→ Link to EMA Page: Guidance on COVID-19

1.2.8 EMA guidance on ICSRs in the context of COVID-19 (30-Oct-2020)

The EMA has issued a new detailed guidance to provide recommendations for the processing and submission of ICSRs associated with products used for the treatment or prevention of COVID-19.

More specifically, the document describes how these ICSRs should be processed, depending on the use of the product, e.g. off-label or compassionate use, and depending on the source of the report including literature and digital media.

The document also includes MedDRA coding guidance to be used until the new COVID-19 terms are included in the official MedDRA release, which is planned to be implemented in EudraVigilance on 04-May -2020.

The latest revision reflects the availability of COVID-19-related terms from the updated MedDRA version 23.0 onwards, together with the release of a COVID-19 SMQ with MedDRA version 23.1.

→ Link to EMA COVID-19 Guidance Page
→ Direct link to EMA Detailed Guidance

1.2.9 EMA extends MLM service to include potential COVID-19 treatments (04-Nov-2020)

The EMA has added nine active substances investigated as potential treatments for COVID-19 to the list of products monitored by the Agency through the Medical Literature Monitoring (MLM) service. The EMA has also added COVID-19-related search terms to its regular literature searches for six active substance groups that were already included in the service.

These additional literature searches started on 01-Jun-2020 in EMBASE, and on 01-Jul-2020 in EBSCO. Revisions to the Search Strategies in both databases were subsequently published on 14-Jul-2020. Corrected versions of the Search Strategies in both databases were published on 04-Nov-2020.

→ Link to EMA MLM Page

1.2.10 EMA issues new requirements on PSURs for COVID-19 vaccines (09-Jul-2021)

The EMA has published new guidance to address specific considerations for Periodic Safety Update Reports (PSURs), highlighting that the “Summary Monthly Safety Reports” required in EMA’s Core RMP Guidance document are not meant to replace the PSURs.

This new guidance is intended to complement existing GVP Guidelines, as well as relevant COVID-19 Guidance issued by the EMA. The document specifies additional requirements, as applicable to the standard PSUR sections including but not limited to Exposure Data, Signals and Risks.

→ Link to EMA COVID-19 Guidance Page
→ Direct link to Core PSUR guidance for COVID-19 vaccines

1.2.11 EMA updates Risk Management guidance for COVID-19 vaccines (10-Feb-2022)

The EMA has published a revised version of the guidance first issued in November 2020 to complement GVP Guidelines and provide specific considerations on Risk Management Plans (RMPs) for COVID-19 vaccines.

Following discussion at the PRAC, the guidance has been updated in light of the experience accrued during the pandemic to include specific considerations on:

- Content requirements for summary safety reports to be submitted by MAHs of COVID-19 vaccines, and details on safety topics for which monitoring with the usual PSURs is more appropriate.
- Considerations for the frequency of summary safety reports (monthly or bi-monthly), and for the possible removal of the requirement to submit such safety reports.

A separate document describes the Pharmacovigilance Plan of the EU Regulatory Network for COVID-19 vaccines.

→ Core RMP guidance for COVID-19 vaccines
→ Pharmacovigilance Plan of the EU Regulatory Network

1.3 Additional Guidance

1.3.1 NCI issues convention to capture COVID-19 Events (25-Mar-2020)

The American NCI (National Cancer Institute) has published a short document to provide guidance for site staff on the collection of Adverse Events related to COVID-19 Infection. This document describes the convention to be used while completing the CRF in concerned Clinical Trials, which may be used as a guide for other trials.

→ Link to NCI Convention

1.3.2 CDISC issues Data Management Guidance (21-Apr-2020)

The Clinical Data Interchange Standards Consortium (CDISC) has published a set of resources to assist Study Sponsors with Data Management activities for Clinical Trials impacted by the COVID-19 pandemic.

→ Link to CenterWatch article
→ Link to CDICS Page

1.3.3 MSSO issues COVID-19 update of MedDRA 23.0 release (29-Apr-2020)

As announced previously, the MSSO has now made available the updated English and Japanese versions of MedDRA 23.0, which includes new COVID-19 related terms and revisions. As a reminder, users are urged to implement this new version by 04-May-2020.

The MSSO has created a new webpage that presents all information relevant to this COVID-19 update, which includes a recording and the presentation material from the webinar held on 17-Apr-2020.

The MSSO has announced on 29-Apr-2020 that the update is available in all languages supported. SMQs have not been updated yet and it is planned that concerned SMQs will be updated in MedDRA Version 23.1 in September 2020, which should also include a new dedicated SMQ for COVID-19.

→ Link to MedDRA News Release (18-Apr-2020)
→ Link to MedDRA News Release (29-Apr-2020)
→ Link to MedDRA COVID-19 Information Page

1.3.4 EMA issues new document on considerations for COVID-19 vaccine approval (19-Nov-2020)

The EMA has published a new document, which describes the aspects that should be considered by vaccine developers in their strategy for Marketing Application. This short document includes recommendations related to Clinical Efficacy and Clinical Safety, and the associated post-approval follow-up.

For information, the EMA announced concomitantly that a public meeting will be held on 11-Dec-2020 to explain the role of the Agency and the EU regulatory processes for the approval of COVID-19 vaccines. This public meeting will be broadcast live and open to all citizens.

→ Link to EMA Page: Guidance for COVID-19 medicine developers
→ Direct link to EMA considerations on COVID-19 vaccine approval
→ Link to EMA News Release (Public Meeting)

1.3.5 EFPIA issues guidance for Crisis Planning in Pharmacovigilance (??-???-2020)

It came to our attention that the EFPIA (European Federation of Pharmaceutical Industries and Associations) has published a document entitled “Crisis Planning for pharmacovigilance compliance management due to COVID-19 pandemic”. The document provides some guidance for the prioritization of Pharmacovigilance activities to mitigate the possible significant and sudden impact of COVID-19 on resources, which should be described in the Business Continuity Plan of each company.

This document has apparently been produced jointly with other European Industry organisations, and complements the Q&A published by the European Commission to explain the regulatory flexibilities that can be applied to help companies cope with the consequences of the pandemic.

→ Link to EFPIA Regulatory Affairs Page
→ Direct link to Guidance Document on Crisis Planning

1.3.6 WHO updates COVID-19 vaccine safety surveillance manual (12-Jul-2021)

The WHO published its COVID-19 vaccine safety surveillance manual on 22-Dec-2020, which builds upon the principles described in the Global Vaccine Safety Blueprint, the WHO global manual on surveillance of adverse events following immunization, and the CIOMS guide to active vaccine safety surveillance. Amongst other objectives, the manual includes guidance for enhancing and harmonizing vaccine safety surveillance systems, and for vaccine safety communication during the COVID-19 pandemic.

An additional module has now been published, which covers the safety surveillance of COVID-19 vaccines in pregnant and breastfeeding women. It provides specific considerations and limitations of available methods as well as tools for implementation

- → Link to WHO COVID-19 vaccines safety surveillance manual
- → Link to WHO Page: Module on surveillance in pregnant and breastfeeding women

2. PRODUCT SAFETY ANNOUNCEMENTS

2.1 COVID-19 Vaccines – Periodic Updates

EMA issues new safety updates for COVID-19 Vaccines (17-Mar-2022)

In line with the Pharmacovigilance Plan of the EU Regulatory Network for COVID-19 vaccines, the EMA has published a new Safety Update report for the COVID-19 Vaccines approved in the European Union.

The March update indicates that the PI for the COVID-19 Vaccine Janssen will be updated to include cutaneous small vessel vasculitis as a new side effect. The PRAC also recommends updating the product information with a warning to reflect the potential of flare-ups of capillary leak syndrome following vaccination with Spikevax.

→ Link to EMA Page: Safety of COVID-19 vaccines

ANSM issues updates on safety of COVID-19 Vaccines (04-Apr-2022)

The French Agency has published new weekly updates on the safety of approved COVID-19 Vaccines, which currently include the vaccines produced by Pfizer/BioNTech, Moderna, AstraZeneca and Janssen. In addition to the weekly updates and key figures, a complete Pharmacovigilance Report is made available on the ANSM website.

→ Link to ANSM Webpage on COVID-19 vaccines weekly monitoring (in French)
→ Direct link to ANSM latest update – 04-Apr-2022 (in French)

MHRA provides updated information on safety of COVID-19 Vaccines (07-Apr-2022)

The MHRA updates the information on COVID-19 Vaccines on a weekly basis with summaries of Yellow Card reports for the vaccines used in the UK, which include those produced by Pfizer/BioNTech, Oxford University/AstraZeneca, and Moderna. As of 30-Mar-2022, the benefits continue to outweigh the risks.

→ Link to MHRA Page: Weekly Safety Summaries