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FDA Releases Guidance on Postmarketing Adverse Event Reporting During a Pandemic

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Food, Drugs, and Devices

The U.S. Food and Drug Administration (FDA) released guidance on March 19, 2020 entitled "Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic" (Guidance).[1] The Guidance revises FDA's February 2012 final guidance for industry on adverse event reporting during an influenza pandemic[2] to clarify that the guidance applies to any pandemic, including COVID-19.

FDA's recommendations remain largely the same, and include information about pandemic preparedness and the Agency's expectations for adverse event reporting during and after a pandemic. In particular, although FDA expects that normal adverse event reporting processes should be maintained to the maximum extent possible during a pandemic, **FDA does not intend to object if submission of certain required adverse event reports is delayed due to pandemic-related high employee absenteeism**.

FDA recognizes that a pandemic may result in high employee absenteeism—both for industry and FDA—and the Guidance's enforcement approach is intended to allow companies to "focus their limited resources" on the timely submission of certain types of reports.[3] These include, among others, reports related to medical products indicated for the treatment or prevention of the pathogen causing the pandemic and reports on products presenting special concerns as specified by FDA. The Guidance includes a table outlining FDA's approach to reporting during a pandemic if normal processes are not feasible, explaining which reports firms may generally store if necessary.[4] If it is possible to submit more than the minimum reporting described in the table, reports should be submitted in order of priority (e.g., 15-day and 30-day reports before periodic safety reports). These recommendations do not apply to adverse event reporting

[1] The Guidance is available at https://www.fda.gov/media/72498/download. It applies to postmarketing adverse event reporting for drugs, biologics, medical devices, combination products, and dietary supplements. It does not apply to monitoring and reporting of adverse events for medical products under Emergency Use Authorizations, or for investigational use of drugs, biologics, and devices.

[2] FDA, Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic (Feb. 2012).

[3] Guidance, at 1.

[4] *Id.,* Table 1. An appendix also lists the current requirements for postmarket safety reports for specified types of products or applications.

during a pandemic by firms that are able to continue reporting operations,[5] and FDA strongly encourages firms to submit as many required reports as possible.

If a company is unable to perform normal adverse event reporting during a pandemic, then adverse event reports should be stored consistent with the company's continuity of operations plan (COOP), which is discussed further below. Such stored reports generally should be submitted within six months of adverse event reporting processes being restored to their pre-pandemic state. Stored reports should be submitted in order of priority, for example 15-day reports first, then 30-day reports, followed by periodic safety reports. Companies are expected to resume on-time adverse event reporting once the pandemic ends.

If a company is delayed in adverse event reporting during a pandemic it should retain documentation of two conditions:

1. Declaration of the pandemic (e.g., by the World Health Organization), including date of declaration of the pandemic and ending date of the pandemic, and
2. High absenteeism and/or other factors (e.g., an increase in adverse event reporting) that is/are preventing the firm from meeting normal adverse event reporting requirements.[6]

The company should notify the appropriate FDA unit of these conditions "as soon as practicable, recognizing that notifications may be delayed due to the need to address more urgent safety issues."[7] If a company cannot meet the minimum levels of reporting in the Guidance, it should consult with FDA.

As in its previous iteration, the Guidance encourages companies to prepare for pandemics, including by developing a COOP. A COOP "should include instructions for reporting adverse events and provide a plan for the submission of any stored reports not submitted in the regulatory timeframes."[8] FDA refers companies to Department of Health and Human Services Pandemic Preparedness Resources, as well as the HealthCare Emergency Preparedness Information Gateway, for general information about pandemic preparedness planning and developing a COOP.

The Guidance is effective immediately, but comments may still be submitted to the Agency for consideration.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices practice:

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[5] *Id.* at 4.

[6] *Id.* at 3-4.

[7] *Id.* at 4.

[8] *Id.* at 3.

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To best advise our clients on the rapidly evolving public health situation in the U.S., our COVID-19 task force is staying abreast of daily developments and tracking the latest federal, state and local policies related to COVID-19. We have also developed a COVID-19 Legal and Business Toolkit to help our clients navigate the wide range of issues presented by this public health emergency.