

# PREP Act – COVID-19



## Frequently Asked Questions for drug or biological product or devices

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the Department of Health and Human Services (Secretary) (HHS) to issue a PREP Act Declaration (“Declaration”) that provides immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency\*. Effective February 4, 2020 the HHS issued a Declaration in respect of COVID-19.



## Who has immunity under PREP Act?

**Immunity is granted at the Secretary’s discretion and its specific applicability to you and your company should be discussed with your legal advisors.** Broadly speaking, the liability immunity applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of medical countermeasures in respect of a situation in a Declaration. The only statutory exception to this immunity is for actions or failures to act that constitute willful misconduct.



## What is Immunity?

Courts must dismiss claims brought against any entity or individual covered by the PREP Act. Claims that courts must dismiss include claims for any loss that is related to any stage of design, development, testing, manufacture, labeling, distribution, formulation, labeling, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing or use of a countermeasure recommended in a Declaration.



## **Are we covered by our existing Insurance for Countermeasures to diseases, threats or conditions covered by a Declaration?**

**Advice on the applicability of your current Insurance coverage must be made on a case-by-case basis in consultation with your Insurance Broker and your legal counsel.** If the countermeasures in which you are involved are consistent with your regular activities, (e.g. manufacture of medical devices) it is likely that your Insurers would continue to cover such activities after a Declaration. If however, a company expands its operations to encompass countermeasures, Insurers may not include such activities in your existing program. In either event, we recommend that you ensure that all activities are covered under an Insurance Policy and that you do not rely solely on potential immunity as such immunity may be challenged in the courts.



## **How do we get coverage?**

Engage your Insurance Broker and your Insurance Carriers to seek affirmative coverage for any countermeasures that you are engaged in. In the event that your Insurers are unable or unwilling to insure such activities, Willis Towers Watson's Life Sciences team is engaged with a number of specialist Insurers who will write Liability Policies to insure qualified pandemic drug or biological products or devices.

### **Source**

<sup>1</sup><https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx>

## **What is a Qualified Product?**

You should seek advice from your legal counsel as to whether any Products in which you are involved are "qualified products".

A Qualified Product<sup>1</sup> is a drug or biological product or device that is:

Manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic, or limit the harm such a pandemic or epidemic might otherwise cause; manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product or device; or intended to enhance the use or effect of these drugs, biological products or devices **and**

- Approved, licensed or cleared FDA;
- Authorized for emergency use by FDA;
- Permitted to be used pursuant to Federal law in conditions inconsistent with its approval, clearance, or licensing;
- Shipped and held by a government agency or someone working on that agency's behalf for emergency use only when authorized, or
- Exempted by FDA for use as an investigational drug or device under research for possible use to diagnose, mitigate, prevent, treat, cure or limit harm of a pandemic or epidemic or life-threatening condition caused by such a drug or device.

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**Disclaimer:** Each applicable policy of insurance must be reviewed to determine the extent, if any, of coverage for COVID-19. Coverage may vary depending on the jurisdiction and circumstances. For global client programs it is critical to consider all local operations and how policies may or may not include COVID-19 coverage. The information contained herein is not intended to constitute legal or other professional advice and should not be relied upon in lieu of consultation with your own legal and/or other professional advisors. Some of the information in this publication may be compiled by third party sources we consider to be reliable, however we do not guarantee and are not responsible for the accuracy of such information. We assume no duty in contract, tort, or otherwise in connection with this publication and expressly disclaim, to the fullest extent permitted by law, any liability in connection with this publication. Willis Towers Watson offers insurance-related services through its appropriately licensed entities in each jurisdiction in which it operates. COVID-19 is a rapidly evolving situation and changes are occurring frequently. Willis Towers Watson does not undertake to update the information included herein after the date of publication. Accordingly, readers should be aware that certain content may have changed since the date of this publication. Please reach out to the author or your Willis Towers Watson contact for more information.

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