



Rx RESPONSE

Medicines to patients in times of emergency



Rx Response is an information-sharing forum comprised of pharmaceutical manufacturers, distributors, pharmacies, hospitals, disaster relief agencies and state/federal government agencies.

The program engages during a severe natural disaster, large-scale terrorist attack or a pandemic that disrupts the normal supply of medicines.

BACKGROUND

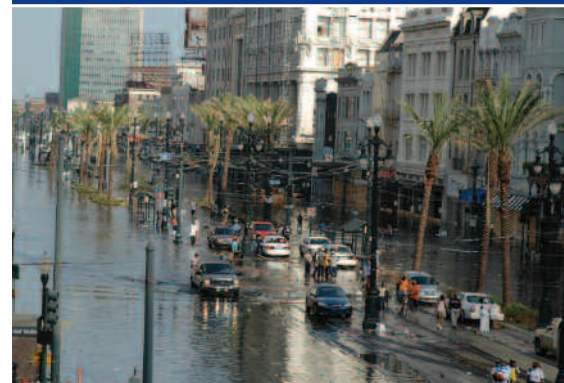
In the event of a severe public health emergency, one of the many critical factors in preserving and protecting public health will be continued access to essential medicines—for treatment of injury or illness caused by the event, as well as continued supply of essential day-to-day medicines to patients for the duration of the emergency. Members of America’s pharmaceutical supply system are committed to working in partnership to help deliver medicines to people who need them in the event of such an emergency—whether caused by a natural disaster, act of terrorism or pandemic.

Addressing such severe public health emergencies will require more than the individual efforts of companies or industry groups alone. It will take communication among a broad cross-section of private and public sector parties to identify issues and challenges to maintaining the integrity of the pharmaceutical product supply system and facilitating resolution for each issue or challenge.

An association of pharmaceutical manufacturing companies (PhRMA, BIO and GPhA), distributors (HDMA), pharmacies (NACDS and NCPA) and hospitals (AHA), in partnership with the American Red Cross, developed a program to help support the continuing provision of medicines to patients whose health is threatened by a severe public health emergency. The program, called **Rx Response**, is designed to address disruptions to the normal pharmaceutical supply system in the event of a severe public health emergency. This document summarizes the key elements of **Rx Response**.

Rx Response represents a unique effort in today’s business environment. The parties responsible for an entire industry sector are seeking a way to ensure supply system resilience through times of crisis. This effort is unique in that it provides a collaborative setting for members of the private sector pharmaceutical supply system to speak clearly and directly with key government agencies about disaster-related needs and concerns.

“Support the continued provision of critical medicines to patients whose health is threatened by a severe public health emergency”



GUIDING PRINCIPLES

The **Rx Response** program's core principles are grounded in the recognition that access to medicines during times of severe public health emergency requires a broad effort and close communication among the many public and private sector stakeholders that will be called upon to respond. This includes government agencies, as well as private relief groups such as the American Red Cross.

These principles are/include:

- **Collaboration**—Information-sharing and problem-solving must be fostered between key private and public sector partners.
- **Continuation of Normal Business Functions to the Maximum Extent Possible**—To the greatest extent possible, the existing supply system must be preserved during disasters by working to maintain normal business relationships.
- **Utilization of Individual Partner Expertise**—By assisting individual organizations and first-line responders to employ their respective individual emergency response plans, the respective strengths and skills of these organizations can fully be leveraged to address problems that single entities cannot solve alone.
- **Simplicity**—Plans, toolsets and supporting processes should be kept as simple and understandable as possible.
- **Focus**—Efforts should center on the most important issues affecting the normal flow of pharmaceutical products.



WHAT IS A SEVERE PUBLIC HEALTH EMERGENCY?

Because existing relief plans and emergency medical service programs are sufficient to address local or smaller regional public health emergencies, the **Rx Response** program will focus on addressing major domestic public health emergencies of national significance rather than those emergencies that affect a limited population or geographic area. While public health emergencies will be determined on a case-by-case basis, there are a number of existing mechanisms that will be used by **Rx Response** to help guide decision-making:

- Disaster declaration by a U.S. Governor or the U.S. President
- American Red Cross *Level V+ Event*
- Department of Homeland Security (DHS) *Severe Classification*
- World Health Organization (WHO) *Phase IV+ Event*
- Health and Human Services (HHS) *Stage 2+ Event*
- Other situations warranting a response as determined by the respective decision-making bodies within the represented industry groups



Event Description	Effect on Pharmaceutical Product	Rx Response Strategy
<p>Localized Events (e.g., tornado, localized bombing, flu outbreak)</p>	<p>Minimal; normal supply system expected to address limited barriers (if any)</p>	<p>Monitor and report event-specific information, as appropriate</p>
<p>Regional Natural Disasters (e.g., earthquakes, fires, floods and hurricanes)</p>	<p>Potentially significant; pharmaceutical product may not be able to reach disaster area or cannot be prescribed or dispensed</p>	<ul style="list-style-type: none"> • Activate the program • Monitor the situation • Share information with partners • Identify and resolve barriers, where possible and appropriate
<p>Large-Scale Acts of Terrorism</p>	<p>Potentially significant; pharmaceutical product may not be able to reach disaster area or cannot be prescribed or dispensed</p>	<ul style="list-style-type: none"> • Activate the program • Monitor the situation • Share information with partners • Identify and resolve barriers, where possible and appropriate
<p>Pandemic Events</p>	<p>Collective forum to work with government agencies to address barriers to critical product delivery; voice to HHS response leadership and DHS Critical Infrastructure</p>	<ul style="list-style-type: none"> • Activate the program • Monitor the situation • Share information with partners • Identify and resolve barriers, where possible and appropriate



RX RESPONSE STRATEGY PLANNING

The **Rx Response** program's strategy helps to ensure readiness and response in the event of a severe public emergency through:

- Promptly identifying and addressing pharmaceutical supply system barriers and issues arising during a disaster, such as disruption in transportation systems; and
- Engaging with federal, state and local government agencies—working through other organizations if appropriate—to address risks to the delivery of pharmaceuticals to patients that the private sector cannot address on its own, such as facilitation of credentialing and authorizing transportation permits, or working with authorities to approve appropriate health professionals to administer and dispense medications.

The **Rx Response** Coordinating Body and Support Team works to coordinate communications and interactions, as appropriate, through the development of informational, communications and operational plans and tools. The following is a brief description of each of these vehicles.



“The Rx Response program’s strategy helps to ensure readiness and response in the event of a severe public emergency”

PLANS:

- **Crisis Management Plans**—A process by which interactive communications among a variety of private and public sector stakeholders will proactively help to identify and address risks and issues affecting the supply of critical medicines during a severe public health emergency.
- **Communications Plans**—A defined process with tools for coordinated internal and external communications.



TOOLS:

- **Information Center (InfoCenter)**—The hub by which information will be captured and shared. InfoCenter has an external dimension for informing the public, paired with an internal (private/secured) portal for collecting and sharing information, as appropriate, among **Rx Response** partners. InfoCenter features a database housing designated emergency planning and response contacts for key planning and response stakeholders.
- **Operations Center**—The physical and virtual locations from which the industry and its partners will assess, identify and resolve supply system issues and challenges.



RX RESPONSE COORDINATION

While each association and organization involved in this initiative is responsible for its own individual planning and response efforts, information-sharing and problem-solving, as appropriate, will be managed by the following:

- 1. Coordinating Body**—representing **Rx Response** partners, including pharmaceutical supply system trade associations, volunteer organizations and public entities performing a first responder role. This body will convene in the event of a severe public health emergency to exchange information, as appropriate, related to identifying and helping to address supply system challenges. It will also coordinate any external communications.





Members of the Coordinating Body will be determined by the particular health emergency at hand and may include a representative from some or all of the following:

Pharmaceutical Supply System Parties

- Manufacturers
 - Pharmaceutical Research and Manufacturers of America (PhRMA)
 - Biotechnology Industry Organization (BIO)
 - Generic Pharmaceutical Association (GPhA)
- Distributors
 - Healthcare Distribution Management Association (HDMA)
- Pharmacies
 - National Community Pharmacists Association (NCPA)
 - National Association of Chain Drug Stores (NACDS)
- Hospitals
 - American Hospital Association (AHA)

Disaster/Relief Organizations

- American Red Cross (ARC)

Government

- State Emergency Management and Public Health Departments
- County/Parish Emergency Management and Public Health Departments
- U.S. Department of Homeland Security
- U.S. Department of Health and Human Services

2. Support Teams—industry and individual enterprise teams will be responsible for planning, overseeing and coordinating emergency response on behalf of the companies they represent. Each industry Support Team may also provide support to the representative participating on the Coordinating Body.

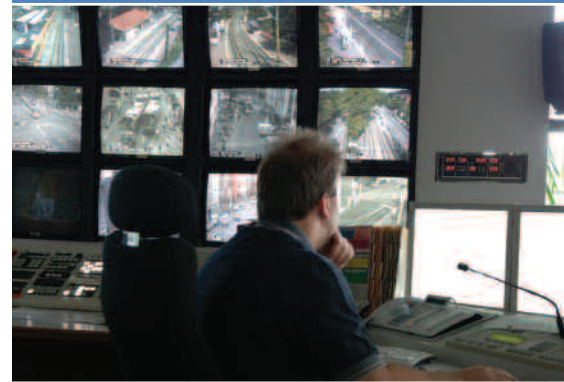
Natural Disaster Response

Rx Response is...

- A multi-party, private-sector driven, closed-system (non-public) coalition to share information and address pharmaceutical supply system risks in a disaster, as appropriate
 - A means to monitor the disaster situation and identify risks to the pharmaceutical supply system
 - A forum to facilitate problem solving of supply system issues
- A means to support first-line emergency response parties
- Applicable to medicines only

Rx Response is not...

- A public call-in center
- A source of medical advice or prescriptions
- An order entry or coordinating capability among various parties to order medicines or provide for their distribution and dispensing
- A decision-making body for individual sectors



Pandemic Response

Rx Response is...

- A collective forum to work with government agencies to address barriers to critical product delivery
- A voice to DHS Critical Infrastructure
- A purveyor of organized intelligence
- A means by which to share pharmaceutical supply best practices, as appropriate

Rx Response is not...

- A government clearing-house on vaccine and anti-viral availability
- A one stop shop for pandemic information



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