# COVID-19: The Importance of Digital Additional Risk Minimization for Life Sciences Organizations

The COVID-19 pandemic is compelling pharmaceutical organizations to rapidly adjust their day-to-day operations in myriad ways. Under normal circumstances, traditional — often manual — methods of additional risk minimization can be cumbersome to manage. Today, with many hospitals under strict visitor policies and postal systems under significant strain, pharmaceutical leaders have an imperative to deliver additional risk minimization messages in innovative ways.

## What is additional risk minimization?

All medicinal products have risks and benefits associated with their use, and marketing authorization holders (MAHs) must ensure that information on risks reaches healthcare providers, patients and caregivers clearly and efficiently. For many products, risk information is communicated through:

- The package leaflet/label that comes with the product.
- The summary of product characteristics (SmPC) or prescribing information aimed at providers.
- Labeling (e.g., inside and on the product packaging).

When the risks associated with a product are more serious or are more likely to occur, MAHs have a regulatory obligation to carry out additional risk minimization activities, on top of communicating the risks through the label, patient information leaflet (PIL) and SmPC. These can include:

- Pregnancy prevention programs.
- Educational materials, traditionally delivered as patient and provider paper brochures.
- Letters to providers.

## How is COVID-19 affecting risk minimization operations?

The pharmaceutical industry has historically relied on paper-based methods of communicating risk minimization messages, which are given to providers by local market representatives during in-person meetings or sent in the mail. Providers can then share patient-facing versions of these educational materials.

Global lockdowns due to the COVID-19 pandemic highlight the unsustainability of manually delivering risk minimization materials to ensure they reach the intended audiences. Relying on postal systems that are becoming strained due to high levels of demand, coupled with widespread staffing issues due to prevailing sickness or isolation, can result in delays to materials being received. When we then factor in the need to coordinate across geographies (ensuring that materials are adapted to local needs and translated in a timely fashion), tasks that were previously considered complex, but routine, become problematic or impossible.

Even where hard copy materials can be delivered, a combination of extreme pressure on providers and their redeployment from some specialist departments to emergency and respiratory services means that creating meaningful engagement on additional risk minimization topics is likely to be a challenge.

Despite these issues, MAHs must still abide by the regulations and ensure that additional risk minimization messages are delivered and effective.

## How can digital methods of communication help my organization deliver additional risk minimization messages?

Digital methods of communication provide a “no contact” option for communicating information and are already widely used for

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a variety of healthcare and life sciences purposes. Due to the COVID-19 pandemic, many people have needed to rapidly increase their proficiency and comfort level with digital technologies for everything from holding work meetings to shopping. Even after the COVID-19 pandemic abates, it's likely that these behaviors will continue as consumers and businesses recognize the convenience and flexibility digital tools allow.

Digital delivery offers many benefits for additional risk minimization, providing the potential for greater effectiveness due to:

- Interactive features, such as dynamic checklists, and the ability to accommodate multiple formats such as video, animation or audio.
- Simpler, less costly content updates (compared with adjusting, reprinting and redistributing brochures), ensuring providers and patients can always readily access the most up-to-date information.
- Allowing overburdened providers to access information on their terms and in formats that best suit them. There are also possibilities for setting electronic reminders to ensure that additional risk minimization topics are not neglected.
- The ability to better measure the effectiveness of these tools using standard digital analytics and/or simple questionnaires, helping MAHs continually improve their messages and better prepare for inspections.

## What should pharmaceutical leaders do next?

Organizations that already have programs in place for delivering additional risk minimization initiatives digitally are at an advantage during times of volatility. Tools that were once considered a unique innovation will quickly become core to pharmaceutical organizations' day-to-day work.

- If you are not already involved in an existing digital initiative, get to know the project — if it is currently running for one or two products, it could be quickly tailored for others.
- To ensure your digital product meets the needs of stakeholders, pursue some degree of product testing. Identify quick ways of gathering feedback, even from objective colleagues in other parts of your organization.
- Do not neglect the need for organizational engagement. Employees across global headquarters and affiliate offices may need to be educated on how new digital delivery systems work and their associated benefits.
- Review processes and mechanisms for tracking compliance around translating, adapting and approving materials that may also need to be established or enhanced.

For more information on how to set up a digital program for additional risk minimization, contact us or visit our COVID-19 resource page.

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