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THE PHARMACEUTICAL INDUSTRY IN 2020 – RAPID RESPONSE AND REGULAR CHALLENGES

Over the last 15 months, we have seen unprecedented efforts by the pharmaceutical industry in supporting the global response to the coronavirus pandemic. This rapid response has posed – and will continue to pose – challenges to the pharmaceutical industry, which has also had to get on with its usual "day job" of bringing non-Covid products to market and responding to safety and compliance concerns.

Primary causes of pharmaceutical recall actions in 2020

When we think about recall of pharmaceutical products, we immediately consider that it is the safety or the efficacy of the active ingredient in the pharmaceutical product that is in issue. This is rarely the case. Although a few such examples can be noted in 2020, the majority of recalls in 2020 related to other types of issues. Indeed, notwithstanding the pressures of the Covid-19 pandemic, 2020 saw pharmaceutical companies reacting to familiar, pre-Covid, product safety and compliance issues:

1. **Deficiencies in Patient Information Leaflets (PIL's).** There are numerous examples of incorrect PIL's in 2020, most concerning the omission or inaccuracy of important safety information. Such deficiencies covered issues such as the omission of warnings about side effects, instructions as to how to take the product, and storage information. Notwithstanding the safety implications, shortcomings in patient information are problematic from the perspective of potential product liability claims, as the accuracy (or otherwise) of patient information will be closely scrutinized by Claimant lawyers and the Courts should there be an allegation of injury arising out of the use of the product.

2. **Labeling issues.** Labelling issues continue to be seen in various guises, including discrepancies between prescribed dosage on the product packaging and that stated on the vial, syringe or bottle. Labeling-related recalls also concern missing batch numbers (which impact traceability), expiry dates and language issues.

3. **Contamination.** Pharmaceutical companies consistently have robust quality control procedures. Even still, as with every year, 2020 saw a number of adulteration cases, both in terms of foreign bodies in finished products and cross contamination during the production process.

4. **Production and manufacturing errors.** These are the result of issues arising on the production floor, and are often picked up in routine testing and sampling. The results of such issues can be seen in the production of out-of-specification products, packaging issues such as blister packs not containing the correct number of tablets and bottles that do not have child-resistant caps.

All potential safety and compliance issues require investigation by the license holder to determine what, if any, action needs to be taken. Being aware of potential issues is crucial and pre and post-market vigilance is key. Of course, pharmaceutical products undergo an extremely vigorous pre-market evaluation before market authorization is granted and the production process is subject to strict quality assurance controls. However, in addition to this, it is important to have rehearsed internal processes to respond to a recall situation.

Recall planning as part of risk mitigation

Most companies have strong controls in place for pre-market risk mitigation, but ensuring that those in the business are ready if a recall situation arises is something that is often overlooked. A recall dry run – or recall drill – can be invaluable in preparing for such an eventuality. It can greatly assist in validating the recall plan, by helping the internal recall management team understand their roles and responsibilities, appreciate the speed at which a recall happens, better evaluate their insurance position, and prepare to execute on their recall notification, logistics, storage and disposal obligations. Identifying shortcomings in processes or the knowledge of key personnel will be possible outside of the high-pressured environment of a real-time recall event.

That said, even when companies conduct these drills, they are too often completed with one jurisdiction in mind (typically the home nation), and limited consideration is given to the interconnectedness of regulatory bodies across the globe. Forethought must be given to the entire global marketplace and what steps each regulatory body will expect a company to take, and when.

Similarly, all too often, a company quickly becomes engrossed in the details of the recall process in one jurisdiction, and fails to consider triggers related to obligations in other countries. Supplying a product to a global marketplace requires a coordinated response at a global level. Failure to do so, puts the company at risk of civil and criminal sanctions.

The Covid-19 context

It is not possible to comment on 2020, without examining the impact of Covid-19. Inevitably, both the pharmaceutical industry and global regulators were keen to ensure that Covid-19 vaccines were made available as soon as possible as the virus continued to spread around the world. The usual timescales for researching, testing, manufacturing and obtaining regulatory approvals for vaccines were significantly condensed. Unsurprisingly, questions as to the legal liability for the safety of vaccines was an issue that was raised in many jurisdictions and which has been handled differently around the world. In the UK, those allegedly injured by Covid vaccines are likely to have to turn to the Vaccine Damage Act for compensation. In terms of drugs, concerns have been raised about products that have been used off-label for Covid-19 prevention or treatment.

While claims have been limited in number so far, it is naïve to consider that claims will not be pursued in respect of vaccines or drug therapies and companies should prepare for potential Claimant action in the future.

Of course, regulators continue to monitor vaccines and drugs placed on the market to treat Covid-19 and take the action they consider necessary to address any potential safety concerns.

What does the future hold?

2020 has taught us that it really is not possible to predict what might happen in the future and how individuals, businesses and the legal community will need to pivot quickly respond. What is certain, however, is that the pharmaceutical industry will continue to evolve and technology will present ever more complex and ground-breaking ways in which to address health issues. With these new innovations will come new legal challenges and inherent risks. Being informed as to what these risks may be, and how to respond to them quickly if they arise, is the most effective form of risk mitigation that a company can undertake.