



European pharmaceutical recalls increase by 19%

Sedgwick brand protection releases latest European product recall index report for Q2 2022

LONDON, 19 September 2022– Sedgwick brand protection published their latest European product recall index report for Q2. Recalls for the pharmaceutical sector increased to 80 in this year’s second quarter, up 19% compared to Q1. However, recall rates are still well below the 106 events in Q2 2021.

The focus for both the EU and UK in the pharmaceutical sector has been on making health data more accessible, whilst also maintaining high levels of privacy and security, with regulators in both jurisdictions recently issuing recommendations for accomplishing these goals.

The EU is working to move ahead with the creation of a European Health Data Space (EHDS) and the UK has proposed its own ambitious strategy for NHS data usage and protection. The proposed changes will affect virtually everyone in the healthcare space, including pharmaceutical companies, medical professionals, medical device makers, suppliers and retailers.

Data security becomes a key priority for the EU as it adapts to the new clinical trial system. The European Medicines Agency (EMA) has issued a guidance around keeping data confidential in the new Clinical Trials Information System.

In the UK, there has been an increased focus on addressing anti-competitive conduct in the sector, with the Competition and Markets Authority (CMA) releasing its annual plan for 2022 - 2023 at the end of last quarter. It outlines how the agency will protect consumers, foster competition and support low carbon growth across the UK.

To download the latest report, visit [European product recall index report](#).

Q2 2022 pharmaceutical recall highlights:

While the number of pharmaceutical recalls increased to 80 in Q2 2022 (up 19% from last quarter), recall rates remain well below the 106 events in Q2 2021.

Safety continued to be the most common reason for pharmaceutical recalls. There were 25 safety recalls, accounting for nearly one third (31%) of all events.

Failed specifications were the second most common cause and was cited in 19 recalls, with mislabelling linked to eight events in Q2.

As they have for the past four quarters, France and the UK were the leading countries of notification. France recorded 23 notifications, stable with the 24 from the last quarter. The

UK also recorded similar numbers with 16 recall notifications in Q2, compared to 18 in Q1 2022.

“Given the issues of data security across the pharmaceutical sector, evident in the number of Q2 recalls, businesses should be focusing on assessing any vulnerabilities and areas where security may need to be adapted for the proposed rules. Companies should be reviewing all the places where health data is used across their organization and the NHS’ proposed commitments, so they can assess any risks or opportunities the new strategy could create,” said Mark Buckingham, international product recall consultant at Sedgwick.

Buckingham added: “pharmaceutical companies and suppliers should review regulations in both the EU and the UK around limiting anti-competitive behaviour and block exemption laws to reduce their risk of being investigated. Even if they are not fined, simply being the target of an investigation frequently damages a company’s reputation and brings attendant costs and resource burdens.”

The recall index is the industry’s leading research and analysis produced quarterly by Sedgwick’s experts in best practice product recall and remediation solutions. It is an essential reference for manufacturers and retailers seeking impartial and reliable perspective on past, present and future recall data and product safety trends.

For more information on Sedgwick brand protection, visit <https://www.sedgwick.com/brandprotection>.

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