Irish Pharmaceutical Healthcare Association

What is Self-Regulation?

In the pharmaceutical industry, self-regulation is where an industry-level organisation such as a trade association, as distinct from a government organisation, sets and upholds the rules and standards, which complement and often go beyond those of the law. This type of self-regulation aims to ensure compliance and comprises a combination of proactive and reactive measures. In practice, this means a combination of setting high standards which include detailed guidance on interpreting and applying the rules, comprehensive training and governance over activities through a robust complaints system.

These high standards help to ensure the appropriate use of medicines and support high-quality patient care. Self-regulation also demonstrates the industry's commitment to setting, developing and upholding high standards with a view to earning public trust.

Why do we have Self-Regulation?

IPHA members are well established companies that have the relevant expertise and willingness to adhere to voluntary codes of practice that set standards for ethical marketing activities and interactions with healthcare professionals, healthcare organisations and patient organisations. In general, self-regulatory bodies can levy sanctions against companies that are found to be in violation of their self-regulatory code. Compliance with the IPHA Code of Practice for the Pharmaceutical Industry is a requirement of IPHA membership. A number of non-IPHA members also voluntarily comply with the code (see www.transferofvalue.ie for members and non-members that comply with the IPHA Code of Practice for the Pharmaceutical Industry). The adoption of a code which sets standards of conduct at a national level also serves to create a level playing field where companies of all sizes and maturity operate under one set of agreed standards.

Self-regulatory bodies in the pharmaceutical industry internationally have a deep knowledge of how the industry works and use these insights to ensure codes and standards of governance stay current and evolve to reflect the ever-changing ways in which the pharmaceutical industry interacts with the healthcare system in each country.

The Covid pandemic provided a clear illustration of the agility with which self-regulatory bodies can respond to a rapidly changing environment. As the world moved to virtual interactions during the Covid-19 pandemic, there remained a need to ensure that doctors continued to receive scientific information about disease areas and potential treatments. We produced clear guidance on virtual interactions between pharmaceutical companies and healthcare professionals that helped ensure interactions were conducted with high standards. As this above example illustrates, more than ever doctors receive information from pharmaceutical companies from outside of their home country and so the alignment of self-regulatory bodies is critical to ensure there are consistent high standards rules in place wherever interactions take place.

The Future of Self-Regulation

Self-regulation of the pharmaceutical industry is structured to ensure the self-regulatory bodies maintain their independence in their enforcement activities alongside the provision of support to the industry to embed the ethical codes. While arrangements differ by country, the principle of independence is fiercely protected in the way self-regulation is organised.

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As with any system, self-regulation needs to be open to scrutiny and oversight to ensure it operates effectively. The interactions with the regulatory authorities in each country are critical to ensuring self-regulation remains fit for purpose.

Self-regulation must continue to understand and respond to new challenges and to continue to improve standards so as to maintain and increase public and healthcare professionals' confidence in the pharmaceutical industry. During the last decade, there have been several examples of how ethical standards have been improved. These include the prohibition of branded promotional aids that used to be provided to healthcare professionals, stricter controls over the provision of samples of medicines and the improvement in transparency through disclosure (see www.transferofvalue.ie). As an industry, we are never complacent and will continue to drive improvements.

Finally, we know that self-regulation is both a privilege and a responsibility, and through our proactive approach to continually improving standards, to embedding these standards throughout the sector, and enforcing compliance where necessary, we are committed to delivering on this mission.