

EU Whistleblowing Directive: What Life Sciences Companies Need to Know

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On December 16, 2019, the much-anticipated [European Union Whistleblowing Directive](#) (the “Directive”), providing minimum EU-wide standards to protect whistle-blowers, entered into force.

Does the Directive matter for life sciences companies? It definitely does. Once the Directive is fully implemented, companies with 50 or more employees will be required to establish internal reporting channels to allow whistle-blowers (that is, persons who report or disclose information relating to potential breaches of EU law) to report information in a confidential manner, and to enjoy protection from retaliation. In some instances, whistle-blowers will also be able to make subsequent disclosures to competent authorities and to the media while retaining protection against retaliation.

When will the Directive impact life sciences companies? At the latest, in December 2021. Unless companies operate in countries in which whistle-blower protection is already in place, they will need to monitor national legislation, to better understand when and how each EU Member State will implement the Directive into national legislation.

How will the Directive impact life sciences companies? In principle, national legislation adopted to implement the Directive will require companies to assess their current internal reporting systems and ensure that resources are properly allocated to them. Legislation will protect whistle-blowers who report their concerns based on a reasonable belief that a potential breach of certain EU law provisions has occurred. Based on the Directive, whistle-blowers will be awarded protection when reporting suspected breaches of provisions relevant to the life sciences sector, including standards of quality and safety for medicinal products and medical devices listed in the Directive. Further, EU Member States may and likely will decide to expand such protection to include suspected breaches of any law. The implementation of the Directive will expectedly result in increased whistleblowing activity considering that, once harmonized whistleblowing protection is awarded and advertised across the EU, individuals will feel more confident that their concerns will be assessed and addressed. In Switzerland, employees of the private sector are not protected by any whistleblowing legislation and, in all probability, will not be protected by standards comparable to the Directive in the near future. On March 5, 2020, the Swiss Parliament’s National Council rejected a legislative draft awarding protection to whistle-blowers. Recent statements made by the Swiss Minister of Justice suggest that a new draft bill is unlikely to be presented in the near future.

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Despite the Swiss Parliament's decision not to enact whistleblowing legislation, the Directive will soon impact life sciences companies (including Swiss companies with affiliates in the EU) in a variety of ways. That said, it is worth noting that, regardless of the legal obligations introduced by the Directive, companies can already benefit from implementing an effective internal reporting system. For example, enforcement data shows that companies that encourage internal reporting are typically subject to lesser fines than companies that do not.

For life sciences companies which on a daily basis choose to foster a speak-up and effective compliance culture, the Directive and its implementing laws may just be the latest litmus test. For the others, any legislative developments will hopefully be an opportunity to strengthen a necessary commitment to compliance and transparency.