



**GLOBAL LIFE SCIENCES: EU UPDATE**

**New EU Data Protection Regulation to have Significant Impact on Life Sciences**

A draft EU Regulation on Data Protection was released un-officially last week. The Regulation, which is unlikely to become law until 2014 at the earliest, will replace the existing EU data protection regime and will have significant implications for the life sciences industry. The main implications are summarised below.

- **Greater Enforcement** – fines can be imposed of up to **5% of the annual worldwide turnover** of a business for failure to comply with data protection requirements. In addition, supervisory authorities will be able to impose a ban on processing personal data, suspend international data transfers and enter premises.
- **Class Actions** – any organisation which aims to protect the data protection rights of individuals, such as consumer organisations, can make complaints to supervisory authorities and bring class actions on behalf of individuals for non compliance.
- **Application to Non European Businesses** – the data protection requirements will apply widely both to businesses in the EU and to businesses outside the EU that “direct” their data processing activities to the EU. This could mean US based life sciences businesses becoming subject to EU data protection requirements. Where a business (i.e. a data controller) is established in more than one EU Member State then the “lead authority” will be where the business has its “main establishment”.
- **Accountability** – businesses will be required to adopt policies and implement appropriate measures to be able to demonstrate compliance with the requirements in the Regulation. This will include keeping a detailed record of forms of data processing, carrying out data protection impact assessments and training of staff. This could add significant compliance costs to life sciences companies. Privacy by design measures must also be implemented to ensure, for example, that data is not collected or retained beyond the minimum necessary. This will be relevant for clinical trials and pharmacovigilance.
- **Data Protection Notifications** – while the requirement in some EU Member States to notify the Data Protection Authority will largely be abolished businesses will be required to consult a supervisory authority where a data protection impact assessment shows that processing is likely to present a high degree of risk, for example processing of health data. This could be particularly important for life sciences companies as the authority can on review of the assessment prohibit the processing of personal data.
- **Information Security** – the draft Regulation requires implementation of appropriate technical and organisational security measures. An evaluation of the risks must be carried out before implementing the security measures. Importantly, in the event of a security breach, the supervisory authority and individuals adversely affected must be informed. The notification must, as a rule, be made within 24 hours.
- **Health Data and Consent** – the Regulation places the legal burden on the data controller to prove that the individual has given consent and gives an individual a right to withdraw their consent at any time. These new consent requirements could have important implications for clinical trials and other studies. Health data may also

This **Sidley update** has been prepared by Sidley Austin LLP for informational purposes only and does not constitute legal advice. This information is not intended to create, and receipt of it does not constitute, a lawyer-client relationship. Readers should not act upon this without seeking advice from professional advisers.

Attorney Advertising - For purposes of compliance with New York State Bar rules, our headquarters are Sidley Austin LLP, 787 Seventh Avenue, New York, NY 10019, 212.839.5300 and One South Dearborn, Chicago, IL 60603, 312.853.7000.

Prior results do not guarantee a similar outcome.

be processed for the purposes of preventative medicine, medical diagnosis and for other reasons of public health interest. How these grounds apply to life sciences companies, for example in pharmacovigilance, still needs to be determined.

- **Data Protection Officers** – businesses with over 250 employees are required to appoint a data protection officer who must have expert knowledge of data protection law and practices. The appointment which must be for a term of at least two years should be notified to the supervisory authority and the public.
- **Increased Rights of Individuals** – businesses must have transparent and easily accessible data protection policies and provide information using clear and plain language. An individual also has a right to correct his or her personal data and, importantly for social media, will have a right to be forgotten (i.e., to have his or her personal data erased) and a right to data portability (i.e., to transfer personal data to another provider). While the focus on transparency may require data protection policies and consent forms to be reviewed it is unclear how the right to be forgotten will impact on the life sciences industry that needs to retain personal data for research and other purposes.
- **Transfer of Personal Data from the EU** – the Regulation maintains the current restriction on transferring personal data to countries outside the EU that are not considered to provide an adequate level of protection e.g. the US. The Regulation provides that one of the main solutions to permit such international transfers is the adoption of Binding Corporate Rules, which are a set of data protection rules adopted by an international corporate group that meet EU requirements and must be approved by a lead supervisory authority. Significantly, the draft Regulation contemplates that specific sectors of a country could be deemed adequate – perhaps paving the way for recognition of the healthcare industry in US as having adequate data protection laws, such as with HIPAA.

The draft Regulation may be revised before it is officially published as a draft proposal by the European Commission at the end of January 2012 and will certainly be subject to lengthy discussion and revision before it is finally adopted and becomes law. However, it is clear that whatever the final form of the Regulation it will have a significant impact on the life sciences industry and will require a new approach to the collection, use and transfer of health data.

If you have any questions regarding this update, please contact the Sidley lawyer with whom you usually work.

### The EU Life Sciences Practice of Sidley Austin LLP

Sidley's EU Life Sciences practice assists multinational companies and trade associations with food, pharmaceutical, biotechnology, medical device, cosmetics and dietary supplement issues in the European Union and its 27 Member States. Our lawyers offer strategic advice for gaining and maintaining market access. We anticipate government actions, advise on approval and submission strategies, and interface with trade associations, consultants and governmental officials. Clients turn to our group for assistance with compliance issues relating to Good Manufacturing Practice, EU Drug Safety/Pharmacovigilance, and Quality System regulations, as well as EU competition and trade law issues.

For further information on the EU Life Sciences Practice, please contact:

William Long  
+44.20.7360.2061  
[wlong@sidley.com](mailto:wlong@sidley.com)

Maurits J.F. Lugard  
+32.2.504.6417  
[mlugard@sidley.com](mailto:mlugard@sidley.com)

Maarten Meulenbelt  
+32.2.504.6467  
[mmeulenbelt@sidley.com](mailto:mmeulenbelt@sidley.com)

Kristina Nordlander  
+32.2.504.6449  
[knordlander@sidley.com](mailto:knordlander@sidley.com)

To receive future copies of this and other Sidley updates via email, please sign up at [www.sidley.com/subscribe](http://www.sidley.com/subscribe)

BEIJING BRUSSELS CHICAGO DALLAS FRANKFURT GENEVA HONG KONG LONDON LOS ANGELES NEW YORK  
PALO ALTO SAN FRANCISCO SHANGHAI SINGAPORE SYDNEY TOKYO WASHINGTON, D.C.

[www.sidley.com](http://www.sidley.com)

Sidley Austin LLP, a Delaware limited liability partnership which operates at the firm's offices other than Chicago, London, Hong Kong, Singapore and Sydney, is affiliated with other partnerships, including Sidley Austin LLP, an Illinois limited liability partnership (Chicago); Sidley Austin LLP, a separate Delaware limited liability partnership (London); Sidley Austin LLP, a separate Delaware limited liability partnership (Singapore); Sidley Austin, a New York general partnership (Hong Kong); Sidley Austin, a Delaware general partnership of registered foreign lawyers restricted to practicing foreign law (Sydney); and Sidley Austin Nishikawa Foreign Law Joint Enterprise (Tokyo). The affiliated partnerships are referred to herein collectively as Sidley Austin, Sidley or the firm.

SIDLEY AUSTIN LLP  
**SIDLEY**