eHealthlaw&policy

The monthly journal for the connected health industry

VOLUME 02 ISSUE 01 JANUARY 2015 WWW.E-COMLAW.COM

FDA proposes electronic labels rule for drugs

The US Food and Drug Administration (FDA) proposed a rule on 18 December requiring pharmaceutical firms to electronically distribute prescribing information (PI) for drugs intended for healthcare providers, where the PI appears on or inside the package from where the product is dispensed. Manufacturers would send PI updates to the FDA to post to its labels.fda.gov website.

"I think the biggest benefit arises from having a central database housing full prescribing information for all drugs," said David Hoffmeister, Partner at Wilson Sonsini Goodrich & Rosati. "This will likely replace hard copy books, which become outdated fast." The proposal does not apply to patient labelling or to PI accompanying promotional materials.

A concern is possible confusion between electronically updated PI and paper labels. "A physician could experience uncertainty if he/she consults electronic PI, then finds different information in an older, paper version that a sales representative left behind," said Susan Lee, Associate at Hogan Lovells. The proposal's comment period ends on 18 March 2015.

IN THIS ISSUE

Commission publishes Report on its mHealth consultation

The European Commission published its Summary Report on the public consultation on the Green Paper on mobile health ('mHealth') on 12 January, which provides an overview of the responses from stakeholders to issues related to the uptake of mHealth in Europe.

According to the Summary Report a 'strong majority' of respondents stressed the need for 'strong privacy and security principles' for mHealth to build trust, a 'majority of respondents' thought that safety and performance requirements of lifestyle and wellbeing apps are not adequately covered by the current EU legal framework, whilst 'some respondents' warned against the risk of over regulation in regards to the certification of mHealth apps.

"Many of the responses reflect the reality that if used properly mHealth can help Europe's public healthcare providers achieve desperately needed cost savings while ensuring quality of care - but there needs to be smart approaches to procuring mHealth solutions if such efficiencies are to be delivered," said Dr. Alexander Csaki, Partner at Bird & Bird.

Many respondents also highlighted the need for app developers to have complete clarity on their liability when designing mHealth solutions, and that European and national actions should ensure interoperability of mHealth solutions with electronic health records.

The Commission's consultation on mHealth, which launched on 10 April 2014, received 211 responses from a range of stakeholders including public authorities, healthcare providers, patients' organisations and web entrepreneurs, from inside and outside the EU. The Summary Report provides analysis of the number and type, and geographical distribution of the respondents.

"It was a shame that medical providers and patients were under-represented," comments Charlotte Davies, Lead Analyst, Healthcare at Ovum, "only a fifth of respondents were from the former and only 3% were from patient organisations - and over a quarter were from Belgium with only a few responses from smaller EU countries such as Denmark, which is one of the EU's leading eHealth markets."

The Commission will now assess the actions proposed and produce a set of policy responses based on the consultation in the course of 2015. In addition to this a series of follow-up actions to support mHealth development forseen under Horizon 2020 will also be taken into account in future working programmes.

Latest draft of Europe's GDPR defines pseudonymous data

The EU Council of Ministers latest draft of the General Data Protection Regulation dated 19 December contains proposals significant for healthcare, which include an emphasis on enabling health data exchanges and the introduction of a definition of pseudonymous data.

"There are indeed some interesting points for the healthcare sector in the latest draft," said Tanguy Van Overstraeten, Partner at Linklaters. "Notable points include a greater emphasis on enabling exchanges of health data, for example to help contain cross-border health threats, as well as the recognition of a more lenient regime for persons subject to professional secrecy."

Article 9 of the draft allows the processing of health data where 'processing is necessary for reasons of public interest' such as protecting against cross-border threats or ensuring high quality and safety standards of healthcare and medicinal products or devices. Explains Pierre Desmarais, Lawyer at Desmarais Avocats, "Article 9 clearly seems to recognise the value of health data for medicine. This is a great step, since it suggests good prospects for big data in healthcare."

Article 4 sets out the definition of pseudonymisation, however footnote 13 states that the use of pseudonymised data will need to be debated in the context of a further debate on pseudonymising personal data. "The debate is not closed and the addition of a definition has the merit of officialising a 'hybrid' type of data, halfway between anonymous and personal data," adds Overstraeten.