Security and big data on CDRH priorities list

The Center for Devices and Radiological Health ('CDRH'), part of the US Food and Drug Administration, published on 20 October its 'Regulatory Science Priorities for FY 2016,' which highlights ten areas to be prioritised in order to improve the safety of medical devices and innovation; a number of these areas involve eHealth.

On the list is the leveraging of 'big data' for regulatory decision making. The CDRH comments that there is a need to further utilise so-called 'big data warehouses' such as the clinical trials database, which contain huge amounts of information for example on the safety of medical devices, to inform and enhance decision making. Another area identified as a priority is that of cyber security, in relation to both digital health and medical devices. The CDRH calls for further research around the security of medical devices that are networked together, and on how software modifications affect device performance.

The CDRH hopes that stakeholders can make use of their list of priorities to 'better target their regulatory science resources as well [as] complement these activities.'

ICO fines online pharmacy for selling patient personal data

The UK's Information Commissioner's Office ('ICO') has fined online pharmacy Pharmacy2U Ltd £130,000 for selling the names and addresses of 21,500 patients without their consent, in what is described in the ICO's monetary penalty notice published on 20 October as 'a serious contravention' of UK data protection legislation.

ICO Deputy Commissioner David Smith stated that, "It is inconceivable that a business in this sector could believe these actions were acceptable." Smith describes Pharmacy2U - the UK's largest NHS-approved online pharmacy - as 'a reputable company' that has made a 'serious error of judgement.' According to the ICO's report, Pharmacy2U's database lists were advertised on the Alchemy website, and 21,500 Pharmacy2U customer names and addresses were supplied to Griffin Media Solutions, an Australian lottery company and Camphill Village Trust Ltd.

One of the companies to purchase data from Pharmacy2U, the Australian lottery company, requested data relating to males aged over 70. Pharmacy2U was provided with the proposed mailer to be sent to these recipients that informed them that they had been selected to 'win millions of dollars.' According to the ICO, a senior executive at Pharmacy2U approved the order stating that the proposed mailer was "OK but let's use the less spammy creative please, and if we get any complaints I would like to stop this immediately."

"More regulation is not the answer," said Richard Parker, Associate at Hill Dickinson LLP. "There are well over 10,000 NHS community pharmacies within England alone and the services they provide are already regulated via NHS England, the Care Quality Commission and the General Pharmaceutical Council. This regulatory regime requires NHS pharmacies to comply with standards including data protection and confidentiality laws."

Matthew Godfrey-Faussett, Partner at Pinsent Masons LLP, thinks that the NHS should be ensuring that its approved suppliers are complying with relevant laws. "In my view, where the source of the data is the NHS, a ban should apply, save where a strict set of criteria are being complied with," said Godfrey-Faussett. "One way of balancing the impact of that constraint would be for the NHS to establish a quality standard which could be used by authorised entities to distinguish themselves in the market. The NHS would need the discipline to remove the standard from any entity that commits a breach of the criteria."

EU net neutrality regulation could provide boon for eHealth services

The European Parliament's adoption on 27 October of a regulation on net neutrality, which also ends EU-wide roaming charges, will impact eHealth operators. The rules allow for 'specialised services,' permitting optimised internet access services at higher prices as long as the services require both higher quality and reliability and could not be provided otherwise. The regulation specifies telemedicine as among these 'specialised services.'

"Innovative health services shall not be possible without such optimisation, and such optimisation shall not be possible at standard prices," said Raquel Ballesteros, Partner at Bird & Bird. "If we want to have innovative health services we have to exempt the access services supporting them from the net neutrality principle."

"A lot will hinge on how the new law is implemented and ultimately interpreted," adds Philippe Bradley-Schmieg, Associate at Covington & Burling. "The provisions are only triggered when relying on them is 'not to the detriment of the availability or general quality of internet access services for end-users.' As a practical matter, specialised services may have to make way for other services in high traffic or congested periods."

Services that do not require optimised access could also benefit; for example, according to Ballesteros, remote consultations and remote monitoring will be more easily and equally available across the EU, as they will not be subject to discriminatory conditions such as roaming charges.