



Dr Lincoln Tsang Partner
Arnold & Porter Kaye Scholer LLP, London
lincoln.tsang@apks.com

Safety of online primary care in the UK: the CQC brings forward its inspection programme

On 3 March 2017, a joint statement was made by the four UK regulators: the Care Quality Commission ('CQC'), the General Medical Council ('GMC'), the General Pharmaceutical Council ('GPhC') and the Medicines and Healthcare products Regulatory Agency ('MHRA'), which are respectively responsible for regulating healthcare, the medical and pharmaceutical professions, and medicines and medical devices. The joint statement reminds providers and healthcare professionals that they should follow professional guidelines to ensure online clinical and pharmaceutical services are provided safely and effectively to the general public. Dr Lincoln Tsang, a Partner at Arnold & Porter Kaye Scholer LLP, specialising in regulatory, compliance and enforcement matters concerning the life sciences sector, assesses the latest developments relating to the safety of online primary care in the UK and the CQC's move to bring forward a programme of inspections prioritising those services it considers as potentially presenting a significant risk to patients.

The statement was made following the CQC's inspection of two providers of digital primary care, MD Direct (which had traded through the website assetchemist.co.uk) and HR Healthcare Ltd (through the website treated.com) that identified significant concerns about patient safety. The CQC's inspection of HR Healthcare Ltd was influenced by an investigation by Dr Faye Kirkland for BBC Radio 5 Live in October 2016, which looked into the online sale of antibiotics by this provider. Immediately after the inspections, the CQC suspended the registration of HR Healthcare Ltd. MD Direct responded to the CQC's concerns by voluntarily cancelling its registration. Both providers have stopped providing services to patients in England (assetchemist.co.uk now uses an alternative online GP provider for its prescription service).

Inspectors found that the two providers demonstrated significant clinical safety and organisational risk to patients, with widespread failings to provide safe care. Amongst the concerns which were identified, the CQC found:

- No (or minimal) identity


checks for patients;

- No way of identifying whether or not patients lacked capacity to consent or understand their prescribed treatment or medical advice, or if there were any safeguarding concerns (and if they were identified, minimal structures in place to handle them);
- No systems or processes to contact the patient's regular GP, including when medication was prescribed that required monitoring or follow-up;
- Prescribing practices that did not take account of the patient's clinical condition or consider differential diagnoses;
- Inadequate medical history taking to inform appropriate prescribing; and
- No assurances that clinicians had relevant skills or qualifications for the role they were performing.

Whilst acknowledging that well-run services can offer a convenient and effective form of treatment, the CQC has found that services too readily sell prescription-only medicines without undertaking proper checks or verification of the patient's individual circumstances.

Such a practice, in the CQC's view - supported by other professional and medicines regulators - will likely expose patients to unjustifiable risk of harm. The joint statement recognises that technological advances in eHealth and mHealth have brought opportunities to deliver healthcare in new ways, including online primary medical services. Potentially, this innovation facilitates patients' access to care and treatment when they need it. However, the concern expressed by the UK regulators is focused on appropriate clinical assessment and management of individual patients in providing the online primary care service and for patients to buy prescription-only medicines online.

Consistent with the prevailing UK and EU medicines regulations, the MHRA indicates that prescription-only medicines are prescription only for a reason and should only be taken under the supervision of a healthcare professional. Therefore, they should only be prescribed following a full assessment as to their suitability for the patient. A proper consultation with a qualified



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healthcare professional is essential to ensure (a) appropriate diagnosis of the patient's condition, (b) proper review of the medical history, and (c) monitoring of patient recovery from the condition following treatment with the prescribed medicine as well as management of the potential side effects that may arise. The view is taken collectively by the UK regulators that the same safeguards should be put in place for patients whether they attend a physical consultation with their general practitioner or seek medical advice and treatment online. As with conventional GP surgeries, these online companies and pharmacies are required to provide safe, high-quality and compassionate care and must adhere to exactly the same standards.

Following an internal review of all 43 online services that are registered, the CQC has brought forward a programme of inspections prioritising those services it considers as potentially presenting a significant risk to patients. Health Minister, Lord O'Shaughnessy said in the joint statement: "We have empowered the CQC to run a tough and

comprehensive inspection regime and commend their work to uncover failings in digital care provision. Online providers can be a convenient option, but patient safety must always be the priority and we urge the public to follow CQC's advice when buying medicines online."

The CQC's enforcement powers

The CQC has statutory powers to regulate online primary care and to enforce the Health and Social Care Act 2008, the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, and the Care Quality Commission (Registration) Regulations 2009.

Regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 requires providers to provide care and treatment in a safe way. A registered person is required under Regulation 12(2) to fulfil certain specific statutory obligations for the purpose of regulatory compliance. The intention of this regulation is, amongst others, to prevent people from receiving unsafe care and treatment and prevent avoidable risk of harm or

harm. In this regard, providers must assess the risks to people's health and safety during any care or treatment and make sure that staff have the qualifications, competence, skills and experience to keep people safe.

Breach of Regulation 12 is a criminal offence as it relates specifically to harm or the risk of harm, and constitutes requirements imposed by the CQC. The CQC can prosecute for a breach of this regulation or for a breach of part of the regulation if a failure to meet the regulation results in avoidable harm to a person using the service or if a person using the service is exposed to significant risk of harm. Distinguishing from other enforcement regimes, the CQC does not have to serve a Warning Notice before prosecution. The CQC has powers to pursue criminal sanctions when there has been a breach of the fundamental standards of quality and safety or some other criminal offence. Where breaches of regulations do not constitute a criminal offence, the CQC can enforce the standards by using civil powers to impose conditions, suspend a registration or

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cancel a registration. Failure to comply with the steps required when the CQC uses its civil powers is a criminal offence and may result in prosecution.

The CQC's guidance on digital healthcare

Going forward, the CQC published in March 2017 a guidance document clarifying the CQC's existing primary care guidance by setting out how the CQC proposes to regulate digital healthcare providers in primary care. The CQC has now developed a broad definition for 'digital healthcare providers' to mean: 'healthcare services that provide a regulated activity by an online means. This involves transmitting information by text, sound, images or other digital forms for the prevention, diagnosis, or treatment of disease and to follow up patients' treatment.'

The new guidance acknowledges that the use of technology to deliver regulated activities remotely is increasing significantly. Digital health encompassing telehealth, telecare, tele-monitoring, e-medicine, eHealth, and mobile health, is a rapidly growing sector which aims to improve access to healthcare advice, diagnosis and treatment. However, as indicated in the joint statement provided by the professional regulatory bodies for medical doctors and pharmacists, there is professional and public concern that some of these services may not be clinically safe and may put patients at risk. The CQC's approach to regulating digital healthcare providers in primary care is based on an operating model that is underpinned by regulations in the Health and Social Act 2008 and Registration Regulations made under it.

Fundamentally, the CQC will evaluate whether the services are safe, effective, caring, responsive to people's needs

and well-led. These key-lines of inquiry ('KLOEs') underlie the assessment framework to guide inspection to be carried out by the CQC. Each of these KLOEs is accompanied by a number of questions that inspectors will consider as part of the assessment, which are characterised by the CQC as 'prompts.' The CQC has developed a set of prompts specifically tailored for digital healthcare providers in primary care. The table at Figure 1 illustrates how these KLOEs are addressed in the guidance.

Currently, the CQC does not have powers to rate digital healthcare providers although it expects to be granted these powers in the future so that users can make an informed judgment on whether to use a service or not.

Conclusion

In a broader context, the UK Accelerated Access Review published by the UK Government in October 2016 sets out an ambitious framework for how the UK can transform its NHS, pulling innovation - medical technologies, diagnostics, digital and biopharma products alike - through the system for the benefit of patients and improving the international competitiveness of the UK. Recommendations were made on how to accelerate access for NHS patients to innovative medicines, medical technologies, diagnostics and digital products, making the UK the best place in the world to design, develop and deploy these innovations. Digital health appears to be a key to the NHS Transformational Agenda as now contemplated by the UK Government. The transformational innovation provided by digital health brings about multifaceted regulatory challenges to ensure that the diffusion of technology in the healthcare system can be safely and effectively delivered, as evidenced in the latest CQC position.

KLOEs	Prompts suggested by the CQC Guidance
Assessment of safety	There is a need to ascertain (a) whether protocols exist to identify and verify the patient at the start of the first and subsequent consultations and (b) whether there is a process in place for the provider to protect against patients using multiple identities to obtain online prescriptions for high-risk medicines and antibiotics.
Assessment of effectiveness	It is necessary to ascertain patients' individual needs and preferences by reference to: an up-to-date medical history, explanation of the presenting complaint or purpose of the appointment, a clinical assessment including diagnosis, referral and ongoing management, treatment already received, and medication that is being taken or prescribed including over the counter.
Assessment of caring	There is a need to establish whether: (a) a patient is able to see referral letters and receive all test results; (b) patients are able to have test results interpreted; (c) the clinician with whom a patient had the interaction is available to review the results; (d) patients are properly informed and consent to interactions is recorded; and (e) patient confidentiality is assured for remote consultation.
Assessment of responsiveness of the services	It is important (a) to manage the patients' expectation in respect of the limitations of the service, and (b) to engage the wider National Health Service and the local NHS to ensure its actions are in line with both national and local priorities. The latter is particularly important in the case of suspected notifiable infectious diseases.
Assessment of a well-led organisation	Account should be taken of parameters such as management oversight, competence and expertise.

Figure 1