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Tackling Barriers To Standardized Electronic Formatting And Navigating The EU Clinical Trials Regulation: A Conference Preview

by Maureen Kenny

A two-day conference on European pharmaceutical regulatory affairs that is taking place in Brussels later this month will explore many of the main regulatory topics of concern to companies at the present time. Two of the speakers, Mickel Hedemand of the Danish Medicines Agency and Dr Surendra Gokhale of Roche, provide a taste of what they'll be covering at the event

Assessing the impact of current political changes in the EU on the pharmaceutical regulatory landscape, exploring the new EU Clinical Trials Regulation, and the timelines and milestones involved with the EU eSubmission roadmap are among the many topics that will be explored at an upcoming conference on EU regulatory affairs.

Also on the agenda are current practice and outlook for the future with regard to orphan drugs in the EU, lessons learned over 10 years of the EU Paediatric Regulation, how to knock down barriers between regulatory and legal departments within pharma companies, and managing regulatory oversight at a global level.

Senior regulators from the European Medicines Agency and the UK and Danish national agencies will be among the speakers at the EU Regulatory Affairs Forum, which will take place in Brussels, Belgium, on May 17-18. A senior European Commission official will give the keynote presentation. Other speakers and panellists include senior pharmaceutical regulatory affairs experts from companies such as GlaxoSmithKline, Meda Pharma, AstraZeneca, Biogen, Sanofi, Teva and B Braun Medical. Knect365, an Informa company, is organizing the conference.

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The speakers include Mickel Hedemand of the Danish Medicines Agency (DKMA) and Dr Surendra Gokhale of Roche.

EU eSubmission Roadmap

In one session, Hedemand, a special adviser at the DKMA, will cover the EU eSubmission Roadmap on the implementation of mandatory use of the electronic common technical document (eCTD) format for regulatory submissions. In another session, he will explore some of the problematic areas surrounding variations.

We have been moving forward by means of initiatives and tools such as the eCTD, the Common European Submission Platform (CESP), and the EMA's eSubmission Gateway, says Hedemand. "However, we are still being held back by legacy technology. I hope to encourage applicants to embrace the new opportunities so that both applicants and authorities can benefit from a smoother process," he told the *Pink Sheet*. "The eSubmission Roadmap is both setting the direction and ensuring we are moving forward."

The EU Heads of Medicines Agencies group endorsed the *final updated version* of the roadmap at the end of February. As the roadmap notes, electronic submission of applications within the EU pharmaceutical regulatory network has increased, but the uptake of a standard electronic format for dossiers and the use of electronic data have been slow. In the human sector, electronic submission of applications is widespread, but non-standard electronic submission formats, including NeeS (non eCTD electronic submissions), are still largely used as an alternative format.

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The technical requirements for submitting electronic submissions have generally speaking been harmonized but, Hedemand points out, the complexity of the European regulatory landscape makes it quite challenging to meet all demands. "Besides the basics of knowing eCTD and keeping track of your own submissions, I think the keyword here is communication. It may seem trivial, but for an employee who only has seconds to skim a submission it may not be so easy to see what is actually being submitted."

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Hedemand will elaborate on these points at the conference. In the session on filing variation submissions, the Danish expert will explore among other things the reasons behind dossier rejections in particular countries, and what industry can do to improve matters.

Clinical Trials Regulation

Gokhale, who is head of EU/International Clinical Trials Regulatory Management at Roche, will explore the implications for industry of the forthcoming EU Clinical Trials Regulation.

The CTR, which will replace the Clinical Trials Directive in October 2018 and introduce a new clinical trials submission portal and database, is a more stringent legislative approach to ensuring greater harmonization in the Clinical Trial Authorisation submission management and maintenance process, Gokhale notes. Its multiple objectives include reducing unnecessary administrative burden without compromising subject safety and quality.

"Readiness of the EU portal to be managed by the EMA but also preparedness of individual EU country health authorities and ethics committees will be key to success," Gokhale told the *Pink Sheet*. For innovative industry sponsors, aligning internal company procedures, implementing different systems and improving planning ability will be critical factors for the effective use of new CTR procedure, the Roche executive added.

> ***The objectives of the new EU Clinical Trials Regulation include reducing unnecessary administrative burden without compromising subject safety and quality.***

During the conference, Gokhale will present the approach Roche is taking and provide some specifics around the company's cross-functional approach to managing this important change in EU pharmaceutical legislation.

Keynote sessions

The two keynote sessions on May 17, the opening day of the regulatory affairs conference, will be shared with the Knect365 EU Pharma Law Forum 2017, which is taking place at the same venue in Brussels on May 16-18.

In the first session, Aude L'hirondel of the European Commission's health and food safety department, DG SANTE, will explore the regulatory landscape for pharmaceuticals. In the second

session, Rubén Pita of the EMA will provide feedback on framing emerging technologies/nanotechnologies.

For additional information on the two conferences, visit *https://lifesciences.knect365.com/eu-regulatory-affairs/agenda/1* and *https://lifesciences.knect365.com/pharmalaw/agenda/1*.

From the editors of Scrip Regulatory Affairs.