Are you compliant?

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The term "compliance" theoretically indicates the act of conforming, acquiescing, or yielding; conformity; cooperation or obedience. However, within regulatory affairs we use *compliance* on many daily operational levels. Depending on our speciality this could relate to GMP for manufacturing activities, GCP compliance within clinical settings, regulatory labelling, training or strategy. More recently, company ethical compliance has also come to the forefront as an important area for consideration. Often as regulatory professionals we are required to challenge some of the definitions of conformance – in many ways, scientific advice can sometimes be perceived as challenging cooperation with current regulatory guidance.

In this edition of *Regulatory Rapporteur* we delve into this very broad area of regulatory compliance, with our focus articles spanning pharmacovigilance (PV), xEVMPD and medical devices. The articles all highlight that this is a challenging, and sometimes daunting, subject which has faced escalating pressures within the increasingly global pharmaceutical environment.

Our first article is on PV compliance and specifically that of risk management plans (RMPs). The RMP is currently a hot topic and the focus of much discussion in industry due to the recent overhaul of the RMP guidance template. The complexity of the new RMP has introduced many challenges in preparing a high-quality document compliant with all requirements. This article discusses those challenges from an industry perspective of applying the new legislation and template, through to the importance of, and difficulties posed by, writing for the general public, and a comparison of the EU RMP with its US equivalent, the risk evaluation and mitigation strategy or "REMS".

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The second article looks to the recent requirement updates for the extended EudraVigilance Medicinal Product Dictionary (xEVMPD) data. The author discusses the requirements and the challenges, which for many companies is to establish and operate processes that remain compliant with maintenance requirements.

Compliance with regard to medical devices is the next topic, and specifically the overall changes to directives and regulations which impact on all of those involved in the supply of devices, from manufacturers to notified bodies and competent authorities. As with medicinal products, devices compliance has been impacted by the desire for globalisation and the need for harmonisation and consistency.

Robust pharmacovigilance systems are of critical importance to both sponsors of clinical trials and marketing authorisation holders (MAHs) alike. Our authors outline some of the key requirements, both in clinical and post-authorisation pharmacovigilance settings, and explore options available. Despite the volume of regulatory requirements and guidance relating to pharmacovigilance, these systems do not need to be particularly complex and there are situations where a "small-scale" system may be appropriate.

Our final compliance article examines the patient information leaflet (PIL) which supplements the advice given by healthcare professionals. The importance of PIL content is discussed, as well as label harmonisation initiatives that include the company core data sheet (CCDS) and the concept and creation of a "CorePIL".

On a separate note, we look at the increasing use of herbal medicines in the UK. This includes attitudes towards these products, UK legislation governing the production and sale of herbals and the registration scheme recently established by the MHRA.

We also feature Part 1 of a two-part paper which outlines regulatory procedures and requirements in Ukraine and Russia. The regulatory framework for initial registrations and post-approval variations is well defined; however, experience suggests that good knowledge of the regulatory environment is essential when working with this market. Despite the current political uncertainty, at the time of going to press feedback was that the Ministry of Health in Ukraine remained stable.

We hope that you enjoy the diversity of the varying aspects of the compliance focus articles mixed with our usual variety of standalone articles.