Falsified Medicines Directive news: EDQM announce collaboration with the European Medicines Verification Organisation

Richard Price

The European Directorate for the Quality of Medicines & HealthCare (EDQM), an agency of the Council of Europe, has announced a new relationship with the European Medicines Verification Organisation (EMVO). EDQM will in future conduct periodic conformity assessments of the European Medicines Verification System (EMVS) and its governance.

The European Medicines Verification System is the product of the EMVO, a designed solution by five European medicines supply chain organisations to meet the verification and authentication requirements of the 2011 Falsified Medicines Directive. It provides a centralised 'blueprint' model that each country can adopt under the governance of 'national medicines verification organisations' (NMVOs), which are currently in the process of construction.

EDQM's new role with the system provides a form of external audit for the overall EMVO system 'to determine whether the EMVO European Hub and blueprint systems are designed, managed and operated in accordance with the standards described in the Delegated Act on the Unique Identifier.'

The announcement appears to bring to an end the previous concept of a second European medicines verification system to be operated under EDQM's governance called E-tact, that would have competed with EMVO's system. This leaves the EMVS as the only well developed system for implementation of the Falsified

Medicines Directive's verification and authentication requirements.

REGULATORY NEWS: EUROPEAN MEDICINES AGENCY OUTLINES PLANS FOR FASTER AUTHORISATION PROCEDURES FOR PRIORITY MEDICINES

The European Medicines Agency (EMA) has set out for public consultation plans to offer early and enhanced scientific and regulatory support to medicine developers where a potential medicine has been deemed 'of major public health interest'. This would include medicines that 'have the potential to benefit patients who presently have no treatment options, or that may offer a major therapeutic advantage over existing treatments.'

The additional support from the agency would include:

- ▶ The early appointment of a rapporteur from EMA's Committee for Medicinal Products for Human Use (CHMP) to facilitate continuity in support and building of knowledge in view of the submission of a marketing authorisation application;
- ▶ A kick-off meeting with a multidisciplinary group of experts from relevant EMA scientific committees and working parties to give preliminary guidance on the overall development plan and recommended regulatory pathway; and,
- ▶ Scientific advice at key development milestones with potential involvement of multiple stakeholders (eg, health technology assessment bodies and patients), when relevant.

Following a public consultation on matters such as the eligibility criteria, the Agency intend to launch the new scheme in the first quarter of 2016.

EUROPEAN COMMISSION LAUNCHES CONSULTATION ON WORK LIFE BALANCE FOR WORKING PARENTS AND CAREGIVERS

The European Commission has launched a public consultation to take views on how best to address the challenges of work-life balance faced by working parents and caregivers. The consultation takes the form of a reasonably straightforward online survey to which any member of the public and organisation may respond. The deadline for response is the 17 February 2016.

The initiative for the consultation comes from a publicly expressed desire by the Commission to 'increase the participation of women in the labour market by improving the current EU legal and policy framework and adapting it to today's labour market to allow for working parents and people with dependent relatives to better balance family and work life, allow for a greater sharing of care responsibilities between women and men, and to strengthen gender equality.'

The percentage of women in employment in 2014 was 63.5%, which is 11.5 percentage points off the Europe 2020 target agreed by EU Member States. Eurofound figures estimate the gender employment gap costs 325 billion euros to the EU, or 2.5% of the EU gross domestic product. The Commission view the primary factors in lower female labour market participation as a lack of possibilities to balance work and family responsibilities, including lack of affordable childcare, rigid working arrangements or absence of incentives for men to take more care responsibilities in their families.

The Commission's survey seeks views on the potentially available measures to improve the labour market environment for working parents and caregivers, including issues such as family-related leave arrangements and flexible working arrangements.

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