EU needs guidelines on off-label use of medicines

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Since the European Parliament requested better guidance on the widespread off-label use of medicine, very little has been done, writes Piernicola Pedicini.

Almost exactly two years ago, MEPs, representing different countries and political groups across Europe, came together to adopt the report on ‘safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance’, which I was responsible for drafting.

Two years later, protecting patients against unnecessary or potential harm associated with healthcare, remains crucial to ensuring patient safety and a high standard of care throughout Europe.

In this regard, my report called on the European Medicines Agency to develop guidelines on the off-label and unlicensed use of medicines based on medical need, as well as to compile a list of off-label
medicines in use despite licensed alternatives. Before being placed on the European market, medicines obtain an authorisation and a label for their indication.

This process follows rigorous regulatory standards and procedures to demonstrate that the medicine is scientifically robust, efficient and of high quality. This process was put in place to ensure a high level of patient safety to avoid a repeat of tragedies, like what happened with Thalidomide in the 50s.

By taking an off-label medicine, patients receive a medicine for a purpose other than its authorised indication, for instance to treat a different disease and/or in another dosage or modality of administration.

Using a medicine off-label can be of real benefit to patients when no other treatment option is available, which is often the case with rare diseases or child and adolescent care, but entails higher risks for patients. Since Parliament called for increased guidance on the off-label use of medicines, little has been done in this area.

However, the recently published study on off-label use of medicinal products in the EU, gives hope that the European Commission will now have sufficient elements to take action in this area and fulfil MEPs' long standing request.

The report presents important evidence on the need for a harmonised approach across Europe. Among the valuable policy options presented, the report includes the development of guidelines on off-label use at EU level, thus recognising the value of the call made by the European Parliament in 2015.

Most importantly, this option seems to find the widest support among the stakeholders that contributed to the study and those attending the event, 'Safeguarding patient safety and quality of care in Europe: Good practice for off-label use of medicines', which I hosted in the European Parliament in September 2016.

In my opinion, the aim of such guidelines should be to provide physicians with guidance on when and how off-label prescribing should occur, while maximising patient safety and respecting the EU regulatory framework for medicines. This will ensure that patients have access to off-label products when in high need and when no authorised alternative is available.

In the 50+ years of common EU pharmaceutical legislation, European citizens have significantly benefited from the high-standards set when it comes to market authorisation, good-manufacturing practices and post-market surveillance procedures.

However, EU effort in this area should not now start to recede, as the use of medicines off-label for reasons other than the medical need of patients, continues to increase. As a medical physicist, I know how the use of an unlicensed medicine can be a double edged sword, with both favourable and unfavourable consequences.

Despite the prominence of off-label drug use, patients are typically unaware that they are being prescribed a product off-label. Currently doctors in Europe are not required to tell a patient that a drug they are being prescribed entails an off-label use.

I believe it is essential that patients are informed and understand the risks and potential adverse consequences of this choice. If a patient is not fully aware that they are being prescribed an off-label product, they may not be able to correctly report any unintended side effects and the physician may be exposed to liability claims.
Following the publication of the Commission study on off-label use of medicinal products in the EU, it is now time for both the Commission and the European Medicines Agency to take concrete steps in search of greater clarity in this area by defining European guidelines on the use of off-label medicine, for the benefit of both physicians and patients alike.

About the author

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