The new PV legislation: **the end of the beginning**

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On 14 May 2013, the actor Angelina Jolie went public with her decision to undergo a prophylactic mastectomy. In her courageous article titled, "My Medical Choice", (a *New York Times* opinion piece), she explained that she carries the "faulty" $BRCA_1$ gene which would increase her risk of developing breast cancer and ovarian cancer by 87%. Her going public sparked headlines about the ill-fate of $BRCA_1$ carriers. For the medical community, her decision intensified the discussions on how best to evaluate and communicate risks to allow patients to make informed decisions. While the 87% risk increase is an abstract figure which is difficult to relate to on a personal level, the figure alone may not even have been the sole basis on which her decision was made. Her personal experiences with close family falling ill with cancer may have influenced her assessment of personal benefit and risk with respect to the intervention.

One of the centrepieces of the new "Pharma Package" that came into force more than a year ago addresses this dilemma with respect to pharmacotherapy and public health. For the first time, a regulatory framework places pharmacotherapy risks into the context of, for instance, the natural progression of the underlying (untreated) disease, available therapeutic alternatives, medical manageability of the risks and the effectiveness of the treatment. This allows for structured, evidence-based regulatory decision-making to ensure the benefits outweigh the risks within the framework of public health.

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For this issue of *Regulatory Rapporteur*, we asked contributors from regulatory authorities and industry to provide their experiences one year on from the introduction of the new pharmacovigilance legislation in July 2012. Although we are now some months past the one-year mark, the articles were written on the premise of a year in the life of the new legislation. Thus in our first article, Doris Stenver of the Danish Medicines Agency describes one year's experience as a member of the newly created Pharmacovigilance Risk Assessment Committee (PRAC). This Committee is tasked to assess benefit and risk in a number of regulatory scenarios, for instance, approval and emerging safety issues. Her article gives valuable insight into the regulatory EU decision-making process that is "*in statu nascendi*", ie, it continues to evolve as more experience is gained.

Next, Bettina Schade discusses the experience of the Austrian Medicines Agency with the national implementation of the new European pharmacovigilance legislation. Her article gives valuable insight into a regulator's perspective of introducing the changes required.

In last year's editorial (Volume 9, Issue 3), we mentioned the difficulty of finding, at that point in time, expert authors who had the time to contribute articles on the new legislation, because they were deeply involved in the enormous task of putting this new legislation into place. In contrast, this year the authors were in a far better position to give their perspectives and valuable insights on what is outstanding and what is to come.

The MHRA's Mick Foy provides a UK regulatory perspective, demonstrating that the new legislation is also the starting point for continual change and improvement of the European pharmacovigilance system. His article also summarises elements of implementation that are still to come. In addition, we have a cross-company contribution offering an industry viewpoint on the upgrade of the EudraVigilance medicinal product dictionary (XEVMPD), as well as an article which looks in detail at the "old" versus the "new" PSUR format.

The implementation status of the new pharmacovigilance legislation, a year after coming into force, may well be described by a quotation from Winston Churchill: "Now this is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning". To this end, we are convinced that the new legislation is a large stepping stone on the path to making medicines safer and to further implementing the "first, do no harm" credo in pharmacotherapy.