Comments on the EU Pharmacovigilance Strategy

European Cancer Patient Coalition (ECPC)
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Pharmacovigilence is an important public health issue which impacts greatly on patient safety. A successful pharmacovigilence system depends on the capacity to monitor and evaluate the safety of medicines effectively, communicate this safety information effectively and without delay to prevent undue harm to patients. So far, the pharmacovigilence systems in the EU and its Member States have been somewhat uncoordinated with long and complicated decision lines. A more robust truly European Pharmacovigilence system is needed.

ECPC calls on the EU and its member states to take responsibility for ensuring the safety of medicines available in the EU, the coordination of information and the involvement of patients in reporting adverse drug reactions.

A Legal Framework Focused on Patient Safety

ECPC welcomes a thorough revision of the current pharmacovigilance legal framework, so that it may be constructed in the interests of patient safety and public health. This will require changes to Directive 2001/83/EC and Regulation 726/2004 to create a robust pharmacovigilance system that harmonises requirements in all Member States and allows for EU decision-making on safety issues. Existing EU referral procedures should be rationalised and Committee structures strengthened. Better regulation is urgently needed to avert putting patients at risk and to guard against the possibility of contradictory messages circulating in national media, which could undermine patient safety. We further support the creation of a new Pharmacovigilance Committee within EMEA that would have clearly defined responsibilities and include two patient representatives. This Pharmacovigilance Committee must be independently funded. Patient representatives must be resourced and remunerated by official funds to allow them to assume this important role.

Improving Transparency

ECPC supports the codification of legal and guideline provisions on transparency and communication. Furthermore, we suggest increased collaboration between stakeholders, and in particular a meaningful engagement with patient groups. Any decision-making should involve patients, external experts and peer-review.

Non-interventional post-authorisation safety studies should be better regulated and harmonised across the EU. These studies should serve a true safety purpose and establish evidence, that would show how a medicine works effectively in a larger population group, rather than for any marketing purposes. This could be linked to a “new” product label for 2 years.

Reducing the Bureaucratic Burden

ECPC supports any measure that streamlines the current Pharmacovigilance system in order to make it more effective and thus reduce unnecessary bureaucracy and costs and improve patient safety. Greater collaboration with international partners should continue to be investigated as a means towards this end.

The Innovation-Pharmacovigilance Link: Live-saving for Cancer Patients

Many cancers are still life threatening and patients live in hope of new life extending treatment options. Cancer patients may have a different view on “risk” than patients suffering from chronic diseases who may already have several treatment options. We strongly urge a close link to be made between the market authorisation and the pharmacovigilance system, allowing products to be authorised earlier under strict and clearly defined rules for post-authorisation safety studies, thus offering hope to patients with currently unmet medical needs.

Eudravigilance should be strengthened

The role of "**Eudravigilance" is key to the rationalisation and simplification of the system.** Its programme of electronic exchange of suspected adverse reaction reports and continuous monitoring of safety issues should be expanded.

Patient Reporting: Clear Legal Basis required

It is essential that both healthcare professionals and patients are motivated to report adverse drug reactions. This requires that the public is educated about reporting. ECPC supports the intention that adverse reaction reporting forms be an integral part of patient information leaflets for centrally approved and intensively monitored medicines. Currently available evidence from Member States that allow patient reporting is positive. The quality of reporting is good and there is no “reporting flood”. We support the creation of a European list of intensively monitored products which together with centrally approved products should be in all EU languages and have a uniform patient reporting form. However, we recommend that patients report to the authorities and their doctors rather than the marketing authorisation holder.

We further suggest that hospitalised patients be given the package leaflet including the reporting form when they are given medicines. All too often, patients are currently given medicines in hospitals without knowing any details of what they are taking.

Drug Safety Communication – Identification of a New Product

ECPC supports the introduction of a new “key safety information“ section in the Summary of Product Characteristics and Patient Information Leaflet.

As a further important step towards improving drug safety communication to the public, we suggest that new products be clearly labeled as “new” for their first two-years on the market to enable patients can make informed choices. We also propose that a stakeholder forum on drug safety communication be created.

Crucially, the outcome of regulatory action must be routinely monitored to ensure that public health has been adequately protected in accordance with legal requirements. This quality management requires clear standards and routine auditing.

Nothing about us, without us!

The European Cancer Patient Coalition (ECPC) was founded in September 2003 with the aim of giving cancer patients a voice in shaping the European Union's policies that impact on cancer care. ECPC's objectives are:

- Promote the fundamental rights of European cancer patients
- Increase cancer patients' representation and influence at the highest level of decision making Europe-wide
- Help patients obtain timely access to appropriate and accurate information, prevention advice, medical diagnosis, treatment and care
- Empower patients to become true partners in the healthcare system
- Promote the advancement of cancer research

Currently, **ECPC** has over 250 members from 26 EU Member States and represents patients with cancers from the most common sites such as lung, breast, prostate and colorectal cancer to the more rare cancers such as multiple myeloma, chronic myeloid leukaemia as well as childhood cancers.